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PRESIDEN LOS SEÑORES REPRESENTANTES

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(Presidente)

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ACTÚAN EN SECRETARÍA LOS TITULARES DOCTORA VIRGINIA ORTIZ
Y LOS PROSECRETARIOS SEÑORA MARIANA ARIAS Y SEÑOR MEDARDO MANINI RÍOS

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Informe

Vacunas contra SARS-CoV-2 COVID 19. Aportes para la consideración de su uso en Uruguay

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1.Introducción y justificación

La pandemia de SARS-CoV-2 COVID 19 requirió en forma rápida de la implementación de distintas medidas de control. Desde que se conoció la secuencia genética completa del SARS-CoV-2 se inició el desarrollo de vacunas basadas en distintas plataformas, que vienen mostrando buenos perfiles de eficacia y seguridad , lo que motivó la aprobación de emergencia por parte de organismos internacionales y nacionales, y desde diciembre de 2020 su aplicación en varios países. Este proceso viene siendo seguido de cerca por los científicos en Uruguay.

1.1 El grupo *ad hoc*

Con el objetivo de analizar las vacunas contra SARS Cov 2 en desarrollo de forma interdisciplinaria, y a instancias de la Unidad de Inmunizaciones del MSP, se constituyó en agosto de 2020 un grupo *ad hoc* a la Comisión Nacional Asesora de Vacunas, integrado por científicos de la Universidad de la

República, del Grupo Asesor Científico Honorario y de distintas áreas del MSP. Desde entonces este grupo ha venido analizando en forma permanente e ininterrumpida, toda la información disponible sobre el desarrollo de las distintas vacunas contra la infección por SARS CoV 2. Esto comprende el estudio de las características, las ventajas y desventajas de cada una de las vacunas con especial énfasis en los aspectos de seguridad, inmunogenicidad y eficacia, así como la vigilancia y monitoreo que deberá llevarse a cabo una vez implementadas.

1.2 Metodología de trabajo

Para el análisis de las distintas vacunas en desarrollo se han jerarquizado los datos provenientes de publicaciones científicas que han sido sometidas a procesos de revisión independiente realizada por expertos en el tema, los preprint y cuando esta información no está disponible, se ha complementado con la información en medios de prensa confiables o aportado por la propia industria, en forma confidencial o no (se hace constar donde corresponde). Dado que la calidad de la información muchas veces es parcial o no es de la mejor calidad, el análisis de los datos puede verse limitado en profundidad y calidad. Al análisis crítico de toda esta evidencia, con las limitaciones que puede tener por lo ya expuesto, se complementa con la opinión experta de los integrantes del grupo.

El grupo ha destacado permanentemente que para que el análisis tenga la mayor utilidad posible, es fundamental disponer de la mayor cantidad de evidencia, sobre todo datos completos de los estudios de fase III (intermedios o datos finales) y así optimizar el análisis y el asesoramiento a brindar.

Este proceso ha estado guiado por la necesidad de ofrecer a la población vacunas con un perfil de eficacia y seguridad adecuado, acorde a las necesidades epidemiológicas del país, procurando generar confianza en la población sobre la vacunación, teniendo en cuenta su rol para el control de las otras infecciones inmunoprevenibles incluidas en el esquema regular de vacunación desde larguísimo tiempo y de impacto probado.

Dado que este proceso es altamente dinámico, la revisión de la información, evidencia, experiencias y comunicaciones que van surgiendo es constante, se realizan reuniones periódicas desde agosto. Como producto de este proceso se

elabora un documento marco y resúmenes ejecutivos que se actualizan periódicamente y se elevan a las autoridades sanitarias.

2. Vacunas contra SARS-CoV-2 COVID 19

2.1 Conceptos generales

Pese al escaso tiempo transcurrido desde que se conociera la secuencia genética del virus SARS-CoV-2 actualmente se han desarrollado distintas vacunas que vienen demostrando perfiles de seguridad y eficacia suficientes como para que algunas hayan sido aprobadas de emergencia por FDA, EMA, y por distintos Ministerios de Salud y organismos reguladores nacionales (UK, ANMAT, ANVISA por ejemplo).

Dadas las características únicas de la pandemia de SARS-CoV-2, el objetivo de las vacunas contra COVID19 es reducir la mortalidad, morbilidad y el impacto social negativo debido a la transmisión de SARS-CoV2.

Esto implica considerar criterios de asignación de riesgo que son:

- Riesgo de adquirir la infección
- Riesgo de presentar enfermedad más severa y mayor mortalidad
- Riesgo de transmitir la infección a otros
- Impacto social negativo

En Uruguay dada la situación epidemiológica actual, con crecimiento sostenido de los casos, transmisión comunitaria del virus y las perspectivas que esto condiciona, la medida de la vacunación es una urgencia de salud pública y es necesario extremar los esfuerzos para iniciar una campaña de vacunación lo antes posible.

La recomendación acerca de qué vacunas utilizar, requiere del continuo y permanente análisis de todos los aspectos a considerar de las vacunas.

Dada la prioridad de lograr la mayor cobertura de los grupos objetivos, y considerando que probablemente dado el acceso se deba a recurrir a más de un tipo de vacunas, deberá considerarse muy especialmente la provisión de las diferentes condiciones de las distintas vacunas para minimizar el riesgo de errores programáticos.

Debe asegurarse la provisión de las dos dosis de la misma vacuna a cada persona.

Asimismo se deberá tener en cuenta estos aspectos a la hora de la comunicación a la población.

Al considerar más de una plataforma de vacuna, la selección entre población objetivo y tipo de vacuna a ofrecer podría estar condicionada por los mejores resultados de eficacia y seguridad en cada una de estas poblaciones

Por ejemplo: personas de 65 años y más, personas con factores de riesgo para infección grave, personas adultas jóvenes previamente sanas que pertenezcan al personal de salud.

No es posible determinar aún si con la vacunación se podrán modificar las medidas no farmacológicas de mitigación aplicadas hasta el momento, ni qué cobertura vacunal debería alcanzarse para ello.

En el mejor escenario de todos modos, la campaña llevará muchos meses, por lo que es importante que la población comprenda que para lograr el control de la epidemia se deberán mantener las medidas no farmacológicas.

Al 11 de febrero OMS reportaba 178 vacunas candidatas en fase preclínica, y 69 en fase clínica. Todas las vacunas para la prevención de la infección por SARS-CoV-2 analizadas son de desarrollo acelerado. Esto ha permitido lograr diseños de vacunas que han avanzado en las fases de desarrollo clínico (I, II y III) en tan solo 11 meses, después de que la secuencia genética completa del SARS-CoV-2 se hiciera pública. Esto ha sido posible, como se refieren los expertos a nivel internacional, “debido a que la vacunología actual está científicamente mucho más avanzada, a que el desarrollo no ha partido de cero (las plataformas tecnológicas fueron culminadas previamente exploradas para los coronavirus del SARS-CoV-1 y MERS), a que grupos de expertos independientes han evaluado los datos que se generan en tiempo real para progresar rápidamente en las fases, a que muchas empresas han sido subsidiadas por gobiernos de países industrializados, organismos científicos (CEPI, GAVI) y fundaciones filantrópicas”. A esto se suma que, a pesar del corto tiempo de desarrollo, las vacunas más avanzadas han recogido importante información sobre su seguridad en los estudios de fase III. Esto se relaciona con el hecho de que para evaluar la eficacia (protección) de la vacuna en un corto período, fue necesario contar con un enorme número de voluntarios de modo de acumular un número representativo de casos positivos confirmados por RT-PCR. Esto tuvo como efecto adicional el generar una copiosa información sobre la seguridad de la aplicación de la vacuna en un alto número de individuos.

No obstante lo anterior, no todos los grupos de riesgo han estado representados igualmente en los estudios de fase II y III. Uno de los principales grupos de riesgo son los adultos mayores. Los estudios de fase III, con los que

se determina la eficacia en condiciones ideales de investigación, no tuvieron como principales variables de estudio la eficacia en la infección grave, que es la que más afecta a esta población. El porcentaje de adultos mayores incluidos en estos estudios es escaso, por lo que los datos que surgen de ellos también deben interpretarse con precaución y comunicarse adecuadamente a la población.

La información aún es parcial para otros grupos, que han sido parcialmente representadas o excluidas en los ensayos clínicos (menores de 18 años, embarazadas, alérgicos, inmunosuprimidos, etc.) y la recomendación de vacunación depende del balance riesgo beneficio individual.

2.2 Características de las vacunas

Las vacunas que están en proceso de desarrollo y evaluación pertenecen a cuatro plataformas: vacunas basadas en ácidos nucleicos (ARN o ADN), vacunas basadas en vectores virales, vacunas de subunidades proteicas (y VLP *virus like protein*), y vacunas de virus inactivados.

2.2.1 Vacunas basadas en ácidos nucleicos (ARN o ADN)

Son un nuevo tipo de vacunas elaboradas a partir de ácidos nucleicos.

Vacunas de ARN

Son elaboradas con nanopartículas de ARN que tienen información para producir proteína S de SARS-CoV-2; una vez que ingresan a la célula se comienza a producir la proteína para estimular el sistema inmune. Dado que se trata de una plataforma nueva para vacunas, se carece de información previa acerca de aplicación masiva y eventuales efectos inesperados en personas con condiciones especiales.

Han mostrado muy buena inmunogenicidad, son de más fácil producción. En algunos casos requieren mayores exigencias respecto a la cadena de frío (-70°C en el caso de una de ellas) y sin experiencia de uso en el mercado hasta diciembre de 2020 que se comenzó a aplicar por primera vez en el Reino Unido y luego se extendió a otros países, con pocos datos de seguridad en grandes poblaciones.

Las vacunas analizadas elaboradas con esta plataforma son las vacunas de Pfizer, Moderna y CureVac.

Pfizer: el análisis de inmunogenicidad de esta vacuna se basa en la determinación de anticuerpos con la proteína S del virus, particularmente contra la región de unión al receptor (RBD, del inglés *Receptor Binding Domain*), los cuales alcanzan títulos superiores a los desarrollados en el curso de la infección con el virus. Estos anticuerpos además tienen alto potencial neutralizante. Es una de las vacunas que tiene un estudio de fase III finalizado, mostrando efectividad vacunal alta (95%, IC 95%: 90.3 – 97.6), y que cuenta con aprobación de uso de emergencia en varios países y por la OMS. Para mayores de 65 años la eficacia fue de 94.7% (1 vs 19 casos, IC 95%: 66.7 – 99.1), y para mayores de 75 años corresponden a un bajo número de casos, con una eficacia vacunal de 100% (0 vs 5 casos; IC 95%: –13.1 – 100.0). La eficacia en infección severa fue 66.3% (IC 95%: –125.5 – 96.3). Los datos de eficacia con o sin infección previa a los 7 días de la 2ª dosis son de 94.6% (98.9–97.3).

Los eventos adversos (EA) tras las dos dosis, en general, ocurrieron en 27% del grupo vacunado y 12% del grupo control, de los cuales 1.2% y 0.6% respectivamente fueron graves (grado 3) y 0.1% en cada grupo amenazó la vida (grado 4). Los efectos adversos locales, a 2 meses de seguimiento, fueron más frecuentes en adultos jóvenes que en mayores de 55 años. Los efectos adversos locales severos luego de la primera y segunda dosis fueron $\leq 0.6\%$ y no hubo reacciones grado 4 (potencial riesgo vital). Los EA vinculados a la reactogenicidad más frecuentes fueron: dolor sitio inyección ($> 80\%$), fatiga ($> 60\%$), cefalea ($> 50\%$), mialgias y escalofríos ($> 30\%$), artralgia ($> 20\%$), pirexia y endurecimiento sitio inyección ($> 10\%$).

Dada la frecuencia de este tipo de EA, en España se ha decidido no vacunar a los integrantes de un mismo servicio de salud el mismo día para evitar EA al mismo tiempo en varias personas. El grupo considera que esta estrategia es muy oportuna y evita riesgos innecesarios de sobrecarga del sistema de salud. A esto se suman los riesgos de alergias graves ocurridos en los individuos vacunados en condiciones reales a los pocos días de comenzada la vacunación en el Reino Unido y Estados Unidos. Dado que son datos de postcomercialización, no es posible determinar la magnitud en frecuencia y comparar con la frecuencia de este evento adverso para otras vacunas. Según datos recientes en Estados Unidos, la tasa es de 11 cada millón de dosis administradas.

La OMS considera como contraindicación su uso en caso de historia de reacción alérgica severa a cualquier componente de la vacuna, y no debe ser utilizada en personas con historia de alergia severa a polietilenglicol (PEG) o moléculas relacionadas a éste. Y considera una precaución el antecedente de una reacción alérgica grave a otra vacuna o inyectable.

El grupo de trabajo entiende que es una de las vacunas que tiene mayor información disponible, con datos promisorios de corto plazo, sobre todo para eficacia en infección sintomática. Ha sido aprobada para su uso de emergencia en Estados Unidos, Canadá, México, Europa, Chile y Argentina, entre otros. Es la primera vacuna avalada por la OMS. Ésta recomienda la aplicación de las dos dosis en un intervalo entre 21 y 28 días, con un máximo de 42 días, e insta a los países a asegurar recibir la segunda dosis. El grupo considera que este aspecto es fundamental, que se deben respetar las pautas posológicas con las que fueron aprobadas las vacunas para asegurar el beneficio reportado, y además este aspecto es un componente importante para minimizar los riesgos de surgimiento de variantes resistentes.

La OMS considera que el uso en algunos grupos de personas donde aún la información sobre la eficacia y/o seguridad es escasa, requiere de algunas precauciones y consideraciones, y que la vacunación debe considerarse según riesgo de infección. Estos grupos son: mayores de 85 años, menores de 16 años, embarazadas, mujeres en lactancia, portadores de VIH, inmunocomprometidos, enfermedades autoinmunes, infección SARS CoV 2 previa, personas que recibieron tratamiento para COVID19, personas cursando la COVID 19, personas portadoras de parálisis de Bell.

Presenta como desventaja la alta exigencia de la cadena de frío (-70°C).

Su aplicación requiere la implementación de infraestructura para la cadena de frío necesaria a nivel nacional para su arribo, almacenamiento y distribución, así como la capacitación del personal de salud a cargo de la administración de la vacuna. Además, será necesario contar con lugares seguros para la vacunación, por el riesgo de reacciones alérgicas graves y el mantenerse en el lugar de vacunación entre 15 y 30 minutos.

Moderna: induce una fuerte respuesta humoral, definida por altos títulos de anticuerpos con la proteína S del virus, particularmente contra la RBD, tanto en adultos jóvenes como mayores de 70 años, los cuales son superiores a los desarrollados en el curso de la infección con el virus. Estos anticuerpos además tienen alto potencial neutralizante, determinado por diferentes técnicas. Los niveles de anticuerpos inducidos por la vacunación se mantienen altos al menos por 119 días. Además, la formulación vacunal es capaz de inducir respuesta celular polarizada hacia un perfil Th1, caracterizada por la producción de IFN- γ . Ambos componentes inducidos, humoral y celular, están fuertemente asociados a una respuesta efectiva contra infecciones virales. El estudio de fase III mostró adecuada eficacia vacunal, 94,1% (89.3a96.8), con datos promisorios también en mayores de 65 años (4 vs 129 casos, 86.4%, IC 95%: 61.4 – 95.5) y en los casos severos (indica una eficacia de 100% pero no

muestra IC). Presentan datos de eficacia en individuos con factores de riesgo de infección grave con buena eficacia pero son datos de fase III intermedios. Los datos en población ya expuesta a la infección aún son limitados.

El perfil de seguridad a 9 semanas muestra una frecuencia de efectos adversos locales alta (primera dosis: 87.4%, segunda dosis: 90.5%) y sistémicos (primera dosis: 57%, segunda dosis: 81.9%) alta, con una severidad para los locales de 4% y 7% (primera dosis y segunda dosis respectivamente) y para los sistémicos de 3.2 y 17.4% respectivamente, más frecuentes que con la vacuna de Pfizer. La frecuencia de eventos que amenazan la vida es <0.1% y similar entre vacuna y placebo.

Presenta como desventaja las exigencias de la cadena de frío, si bien son menores que para la vacuna de Pfizer (-20°C).

Es una vacuna aprobada para su uso de emergencia en Estados Unidos, Canadá y Europa.

Tras el inicio de la vacunación en Estados Unidos se conoció por prensa el primer caso de alergia grave tras la vacunación.

La contraindicación para recibir la vacuna es la anafilaxia a cualquier componente de la vacuna.

CureVac: los reportes de estudios de inmunogenicidad con esta vacuna muestran Para dosis de 12 µg (n=11): 90% seroconversión de Ac contra prot S (día 43), 100% seroconversión de Ac neutralizantes (día 43) a los 15 días de la segunda dosis. El perfil de seguridad muestra una frecuencia de efectos adversos locales (mayor a 80 %) y sistémicos (100%) muy alta, con una severidad para los sistémicos de aproximadamente 13 y 35 % para la primera y segunda dosis, más frecuentes que con las vacunas de Pfizer y Moderna. Se conoce el diseño del estudio de fase III. Fue recientemente presentado ante la Agencia Europea del Medicamento para su consideración.

Vacunas de ADN

Al igual que las vacunas a ARN, las vacunas a ADN son plataformas nuevas que nunca se han aplicado masivamente en humanos. La trayectoria de este tipo de vacunas es más extensa que para las vacunas a ARN, ya que existen vacunas a ADN aprobadas para uso animal. En lo que refiere a humanos, las mismas han alcanzado evaluaciones clínicas de fase I.

Inovio: esta vacuna se administra intradermicamente a través de un dispositivo de electroporación (CELLECTRA 2000), que facilita la entrada del ADN en las células. Los reportes de estudios de inmunogenicidad con esta vacuna son completos pero se basan en un número de muestras bajo. Con la dosis más alta (2 mg) se induce un alto porcentaje de seroconversión de anticuerpos contra la proteína S (95 %) y de anticuerpos neutralizantes (84%), a las dos semanas después de la segunda dosis. Además, en todos los individuos vacunados se indujo una respuesta celular polarizada hacia un perfil Th1, con producción de IFN- γ y TNF- α (y ausencia de inducción de producción de IL-4).

El perfil de seguridad a corto plazo (al igual que las restantes vacunas) muestra escasos efectos adversos locales (10%) y sistémicos (10%), los cuales fueron en su totalidad leves (grado 1).

2.2.2. Vacunas basadas en vectores virales

Son plataformas con alguna experiencia de uso no masivo a nivel mundial. Como por ejemplo las usadas para las vacunas del Ébola. Las de vector viral humano tienen como riesgo potencial el desarrollo de anticuerpos contra el vector. En este grupo quedan comprendidas las vacunas de Astra Zeneca, Janssen, Cansino, Sputnik V.

AstraZeneca: el esquema de dos dosis de la vacuna induce niveles de anticuerpos contra la proteína S, tanto en adultos jóvenes como mayores de 70 años, similares a los desarrollados durante la infección, los cuales se mantienen al día 56. Estos anticuerpos presentan capacidad neutralizante determinada por varias técnicas. Además, se ha determinado que la preparación vacunal induce respuesta celular polarizada hacia un perfil Th1, con producción de IFN- γ . Sin embargo, a diferencia de la respuesta humoral, la respuesta celular no se potencia con una segunda dosis de la vacuna.

Los datos de fase II y del intermedio de fase III muestran efectos adversos sistémicos sobre todo fiebre en un porcentaje alto de individuos. El perfil de seguridad muestra una frecuencia de efectos adversos locales (88 %) y sistémicos (86%) alta para cohorte de 18–55 años con la primera dosis, con grado de severidad para los sistémicos de aproximadamente 5 %. A diferencia de las vacunas a ARN, los efectos adversos son menos frecuentes y severos

con la segunda dosis. Además, la frecuencia de los efectos adversos y su severidad disminuye a medida que aumenta la edad de los vacunados.

Para la vacuna de AstraZeneca, los datos actuales han determinado su aprobación en Reino Unido, Argentina y EMA. A pesar de utilizar mismos estudios clínicos para la aprobación, ambas agencias europeas obtienen valores sutilmente diferentes debido a la población que incluyen para los cálculos: la EMA los basa en la población que recibe las dosis en el intervalo finalmente aprobado entre 4 y 12 semanas (n 10468) y UK en los que la reciben entre 4 y 26 semanas (n 11636). Estas diferencias determinan variaciones en los valores de eficacia: 70.42% (58.84–80.63) vs 59.5% (45.8–69.7) respectivamente. El grupo considera que el valor de EMA es más acorde con la forma de uso que tendrá la vacuna según sus características de aprobación.

De los resultados de un estudio que está en pre impresión se concluyó que una dosis de la vacuna tiene adecuada eficacia y que los intervalos interdosis más largos tienen más beneficio que los más cortos. Este estudio recoge resultados de los protocolos que ya habían mostrado los datos intermedios (con 131 casos) y muestra la eficacia vacunal de la combinación de las dos pautas posológicas con un número de casos que llega a 332. La eficacia promedio de ambas pautas fue de 66.7% (57.4–74), levemente por debajo del hallado en el estudio intermedio anterior. Sin embargo, con ambas dosis estándar en los que recibieron 2 dosis con un intervalo de 12 semanas la eficacia fue de 82.4% (62.7–91.7), muy superior a la hallada para intervalos de 6 o menos semanas (54.9%)

Con una dosis estándar única la eficacia vacunal a los 90 días fue 76% (59–86). Los autores creen necesaria una segunda dosis para prolongar la protección dado el correlato de esta con el aumento de los anticuerpos neutralizantes. Los datos considerando sólo los asintomáticos aún no muestran eficacia estadísticamente significativa ni con 2 dosis estándar con intervalo 12 semanas ni con una dosis estándar, sin embargo cuando se combinan pacientes asintomáticos y sintomáticos los valores de eficacia mejoran, lo que sugiere que podrían tener efecto en la transmisión viral, pero esto aún no es concluyente. El estudio no muestra datos de eficacia según severidad ni por grupo de edad.

Es importante señalar que a partir de los 14 días de la primera dosis se observó una eficacia de 76% (59–86) que se mantuvo por 90 días, por lo que la protección vacunal comenzaría desde la primera dosis. El grupo SAGE de la OMS reunido el 8/2/21 mantuvo como recomendación no usar límite superior

de edad basados en datos de inmunogenicidad y seguridad, a pesar de la falta de evidencia por variables clínicas, y respaldó el intervalo entre 4 y 12 semanas, con preferencia por el intervalo más largo de 12 semanas.

El grupo considera que se debe utilizar la pauta de dosis estándar y el intervalo interdosis de 12 semanas. Con los datos de inmunogenicidad y seguridad actuales, las recomendaciones internacionales y el contexto de disponibilidad actual de vacunas, el grupo apoya el uso en mayores de 18 años sin límite superior de edad.

El perfil de seguridad que se evaluó con una cohorte más grande, que por lo menos recibió una dosis y es de aproximadamente 12000 individuos presenta el perfil de riesgo analizado en la tabla de resultados. Se destaca la importancia de la adecuada monitorización de los eventos neurológicos.

Janssen: la administración de una única dosis de vacuna logra 99% de seroconversión, medida como desarrollo de anticuerpos contra la proteína S al día 29. Dichos anticuerpos tienen capacidad de neutralizar al virus, aunque inferior a los desarrollados durante la infección natural. Además, se ha determinado que la vacuna induce una respuesta celular polarizada hacia un perfil Th1, con aumento de células T CD4+ y CD8+ productoras de IFN- γ . La inmunogenicidad de la vacuna no se ve comprometida en personas mayores a 65 años, induciendo respuestas humoral y celular comparables.

El perfil de seguridad muestra una frecuencia de efectos adversos locales (59%) y sistémicos (64%) alta para cohorte de 18–55 años, con una severidad para los sistémicos de aproximadamente 11 %. La frecuencia de los efectos adversos y su severidad disminuyen drásticamente en personas mayores de 65 años (27 y 36% efectos adversos locales y sistémicos, respectivamente, con solo 1% de efectos adversos severos).

La principal ventaja de esta vacuna sería su esquema de una sola dosis en tanto los datos de eficacia que se están generando en el estudio de fase III la avalen. En este estudio también se está ensayando el esquema de dos dosis. El vector viral que utilizan es adenovirus humano (Ad26). Los estudios fase I/II no incluyen análisis de inmunidad preexistente contra el vector, por lo que se desconoce el efecto que esto pueda tener sobre el desarrollo de la respuesta inmune protectora. No hay resultados de fase III. Se esperan datos intermedios de fase III para enero. Aún no se encuentra en uso.

CanSino: la respuesta inmune inducida por esta vacuna está caracterizada por una inducción de anticuerpos contra el RBD de la proteína S, con capacidad de neutralizar al virus. El porcentaje de seroconversión, determinado por anticuerpos contra el RBD (Receptor Binding Domaine) de la proteína S, es de 96%. Asimismo, la vacuna induce una respuesta celular polarizada hacia un perfil Th1, con aumento de células T CD4+ y CD8+ productoras de IFN- γ . Es la única vacuna para la cual se ha analizado cómo influye la preexistencia de inmunidad frente al vector en la inmunogenicidad de la vacuna, observándose una disminución de la misma. La edad de la persona vacunada también influye sobre la inmunogenicidad de la vacuna, siendo ésta menor (principalmente en lo que refiere a anticuerpos neutralizantes) en adultos mayores a 55 años.

El perfil de seguridad muestra una alta incidencia de efectos adversos (77%), habiendo una frecuencia de 9% de efectos adversos severos, principalmente fiebre grado 3 (8%). La tolerabilidad a la vacuna aumenta en adultos mayores a 55 años.

Al igual que la vacuna de Janssen, la principal ventaja de esta vacuna es su esquema de una sola dosis. A diferencia de ésta, la vacuna de Cansino utiliza el adenovirus humano Ad5 como vector viral (uno de los más prevalentes a nivel mundial). No se cuenta con estudios de fase III, pero está aprobada en China para uso local.

Sputnik V: esta vacuna combina dos vectores virales (Ad26 y Ad5) en la primera y segunda dosis, respectivamente, y está formulada de forma líquida (pronta para usar) o liofilizada (que facilita su transporte). Ambas formulaciones inducen niveles de anticuerpos contra el RBD de la proteína S superiores a los desarrollados durante la infección natural. La capacidad neutralizante de los anticuerpos inducidos es comparable con los presentes en suero de pacientes convalecientes. Los resultados intermedios de fase III demuestran además que la vacuna es capaz de inducir respuesta de anticuerpos en voluntarios mayores de 60 años, con las mismas características anteriormente mencionadas. Además, las preparaciones vacunales generan células T CD4+ y CD8+ específicas contra el virus, que son capaces de producir IFN- γ . Es de mencionar, que como todas las vacunas a vectores virales, la vacunación genera inmunidad frente al vector, poniendo en duda el potencial de futuras inmunizaciones basadas en el mismo. La diferencia de

esta vacuna es que utiliza dos subtipos (Ad26 y Ad5), lo que disminuiría el riesgo de desarrollo de anticuerpo con la segunda dosis.

El perfil de seguridad de la vacuna en su formulación pronta para usar (líquida) muestra una alta incidencia de efectos adversos (40% locales, y 95% sistémicos), fundamentalmente cuando se aplica el componente Ad26 de la vacuna (77% sistémicos). A diferencia de las vacunas previamente mencionadas, los efectos adversos son principalmente grado 1, y escasos grado 2, no reportándose efectos adversos severos. Los efectos adversos son más severos con la segunda dosis. En comparación con la formulación líquida, la preparación liofilizada es mucho menos reactogénica (60% locales, y 30% sistémicos).

Los datos del estudio de fase III analizados corresponden al análisis intermedio de 19866 individuos de 18 años o más (randomizados 3:1 vacunados con la preparación líquida : placebo), de los 40000 que tienen pensado incluir en el estudio final. La variable primaria de eficacia es prevención de enfermedad COVID19 PCR+ dentro de los 6 meses de la segunda dosis, pero los resultados presentados corresponden a esta variable medida a partir de los 21 días de la randomización. Se incluyeron 11% de individuos de 60 años o más y 25% con por lo menos una comorbilidad. Se analizaron los datos de 78 casos, 16 de 14964 en el grupo vacunal y 62 de 4902 en el grupo control. Estos datos demuestran una eficacia de 91,6% (IC 95%: 85,6 – 95,2). La eficacia de la vacuna es homogénea en los distintos estratos etarios analizados. En los mayores de 60 años, se observaron 2 casos de infección (en 1611) en el grupo vacunados, y 8 casos (en 533) en el grupo placebo (eficacia 91,3 IC 95: 67,1 – 98,3). No hay datos de eficacia en mayores de 75 años. Hubo 20 casos severos (de los cuales 19 fueron moderados y 1 extremadamente severo), y pertenecían todos al grupo placebo (Eficacia 100%, IC 95 94,9 – 100).

40% de los vacunados tuvieron algún EA, entre los más frecuentes: síndrome tipo influenza, reacción local, fiebre, astenia, la mayoría leves; hubo 0.3% de EA grado 3: (igual que en rama placebo), sin diferencias entre los adultos jóvenes y los mayores de 60 años. Ninguno de los EA serios se vinculó a la vacunación. No reportaron eventos de alergia severa. El análisis de la información proporcionada muestra un perfil de eficacia muy bueno y de seguridad muy aceptable. El grupo considera que los datos comunicados son

bastantes completos y positivos, aunque resta obtener resultados concretos con adultos mayores de 75 años. A pesar de los datos promisorios con una dosis, el grupo considera necesario inmunizar con dos dosis hasta tanto no se obtenga evidencia sólida que sustente esta recomendación. Aprobada para uso de emergencia en Rusia, Argentina, Argelia, Paraguay, Bolivia, Bielorrusia, Venezuela, Serbia, y otros países. La forma líquida requiere conservación a -18°C .

2.2.3 Vacunas inactivadas y de subunidades proteicas: se destacan por su mayor experiencia de uso y buen perfil seguridad. La inmunogenicidad de los estudios de fase II muestran resultados menores que los obtenidos con otras plataformas, y los datos en adultos mayores pueden ser menores que en adultos jóvenes.

Coronavac: induce el desarrollo de anticuerpos contra el RBD de la proteína S, que tienen potencial neutralizante. Se alcanzan muy altos porcentajes de seroconversión, cercanos al 100%, que dependen de la dosis y del esquema de inmunización utilizado. El análisis de la respuesta celular inducida es preliminar (solo en fase I) y no permite concluir la inducción de respuesta tipo Th1. Este dato es de suma importancia ya que esta vacuna está formulada con hidróxido de aluminio como adyuvante. Está ampliamente reportado que las vacunas adyuvantizadas con aluminio, en cualquiera de sus presentaciones, polarizan la respuesta inmune hacia un perfil Th2. Si bien este tipo de respuesta permite el desarrollo de anticuerpos capaces de neutralizar el virus e inhibir su entrada a las células, la inducción de células T CD8+ con potencial de eliminar células ya infectadas por el virus (efectores de respuesta Th1) se ve comprometida. Por los estudios de fase II, la respuesta inmunogénica es menor que para otras plataformas, y no incluyen sueros de pacientes convalecientes para su comparación.

El perfil de seguridad muestra escasos efectos adversos locales (10–20%) y sistémicos (aprox. 10%), los cuales fueron en su totalidad grado 1.

Los datos de fase III para evaluar su eficacia son parciales, y aún no se cuentan con los datos definitivos. El dato de eficacia de enfermedad sintomática global es de 50,3% (IC 95: 35,26 – 61,98), para Brasil, levemente por encima del 50%, mínimo estipulado por la OMS. En Turquía informan eficacia de 91 %.

Tiene aprobación para uso en China, Brasil, Indonesia, Turquía y Chile. En estos países, su aprobación de emergencia está sujeta al seguimiento continuo de la información que va brindando el laboratorio.

Sinopharm: ambas vacunas, Beijing y Wuhan, presentan similares características que Coronovac. Inducen el desarrollo de anticuerpos contra la proteína S, con potencial neutralizante, después de la segunda dosis (aproximadamente 100% de seroconversión). Además, la vacuna de Beijing demostró ser inmunogénica en adultos mayores de 60 años, aunque la respuesta inducida presentaba una cinética de desarrollo más lenta. Ningún ensayo incluyó sueros de pacientes convalecientes para su comparación con los inducidos por la vacunación. Tampoco se analizó la respuesta celular inducida por estas vacunas formuladas con hidróxido de aluminio como adyuvante.

Con respecto al perfil de seguridad, ambas vacunas muestran una baja frecuencia de efectos adversos locales (16 y 38% para Wuhan y Beijing, respectivamente) y sistémicos (5 y 8%) para cohorte de 18–55 años, sin efectos adversos severos. La frecuencia de los efectos adversos es aún menor en personas mayores de 65 años (38 vs 17% y 8 vs 4% efectos adversos locales y sistémicos, respectivamente).

El estudio de fase III en Perú estuvo momentáneamente detenido evaluando dos casos de Síndrome de Guillain Barré pero ya se retomó. No hay resultados de estudios de fase III. Tiene aprobación para uso en China.

Barath: la vacuna induce altos niveles de anticuerpos contra la proteína S, su RBD, así como contra otras proteínas del virus, superior a los desarrollados en el curso de la infección natural por el virus, los cuales se mantienen elevados al menos por 104 días. Estos anticuerpos tienen capacidad neutralizante tanto contra la cepa de virus vacunal, como contra otras no relacionadas. Asimismo, la inmunización induce una respuesta celular polarizada hacia un perfil netamente Th1, con inducción de células de memoria.

Esta vacuna presenta escasos efectos adversos (menor a 5% en frecuencia y sin efectos adversos severos).

No hay resultados aún de los estudios de fase III. No está en uso.

Si se consideran los datos de los análisis intermedios no publicados, informados por prensa, y considerando además la información previa sobre similares mecanismos de acción y experiencia previa de uso, las vacunas

inactivadas son las que ofrecen, empíricamente, más confianza sobre todo en su perfil de seguridad. Pero no es información que surja de los estudios de fase III finalizados ni por datos de eficacia. Ninguna de estas vacunas cuenta con aprobación por agencias reguladoras de medicamentos a nivel internacional de las más reconocidas en nuestro país como FDA o EMA.

Novavax: esta preparación a subunidades proteica (proteína S) formulada con adyuvante Matrix-M1 (basado en saponinas) induce el desarrollo de alto títulos de anticuerpos contra la proteína S, con capacidad neutralizante, superiores a los desarrollados durante la infección natural por el virus. Además, la vacuna induce una respuesta celular polarizada hacia un perfil Th1, con aumento de células T CD4+ productoras de IFN- γ .

El perfil de seguridad muestra efectos adversos locales (70%) y sistémicos (45%) altos, principalmente grado 1, con escasos grado 2. Estos se incrementan en frecuencia (89% y 73%, respectivamente) y severidad (8% grado 3) con la segunda dosis.

No hay aún estudios de fase III, y la vacuna no está en uso.

3. Lo que no se sabe sobre las vacunas en fases avanzadas de investigación disponibles y de las ya aprobadas:

- Seguridad a mediano y largo plazo
- Eficacia en subgrupos de personas por edad (sobre todo 65 y 75 años y más), comorbilidades, infección SARS Cov 2 previa
- Eficacia en asintomáticos (prevención de transmisión)
- Eficacia en casos severos, hospitalizaciones, ingreso a CTI, muertes (no hay estudios aún que muestren datos al respecto como variables primarias de análisis)
- Duración de la inmunidad
- Pauta final de administración
- Precauciones y contraindicaciones finales para su uso
- Efectividad y seguridad en condiciones reales de uso
- Impacto en la necesidad de mantener las medidas no farmacológicas de contención aplicadas hasta el momento
- Cobertura vacunal requerida para alcanzar los beneficios esperados.
- Uso concomitante con otras vacunas, por ejemplo antigripal

- Eficacia comparativa entre diferentes plataformas de vacunas contra SARSCoV 2
- Intercambiabilidad entre vacunas contra SARS Cov-2
- Necesidad de revacunación
- Cambios en caso que haya mutaciones del virus.
- Prevención de infección en individuos inmunosuprimidos
- Beneficio en menores de 16 años
- Beneficios y riesgos en mujeres inadvertidamente embarazadas
- Impacto en los individuos que incumplen las medidas de bioseguridad (mascarillas, distanciamiento físico,
- Efecto en la carga viral o en la probabilidad de contagiosidad de los infectados
- Efectividad en reducir los síntomas prolongados o las secuelas

4. Datos disponibles de las vacunas aprobadas de emergencia

Vacuna de Pfizer

El EA más relevante tras el inicio de su uso ha sido el de alergias, que se han observado en EEUU en una tasa de 11.1 /millón dosis administradas. Por comunicado de prensa de la MHRA, eventos adversos alérgicos que sumaron contraindicación de uso en pacientes con reacciones alérgicas graves y en EEUU como precaución. El SAGE de la OMS contraindica su uso en caso de historia de reacción alérgica severa a cualquier componente de la vacuna, y no debe ser utilizada en personas con historia de alergia severa a polietilenglicol (PEG) o moléculas relacionadas a éste. Y considera una precaución el antecedente de una reacción alérgica grave a otra vacuna o inyectable. Recomienda que estas personas deban permanecer en el lugar de vacunación por 30 minutos, para poder asistir inmediatamente una complicación de este tipo.

Dado que las reacciones de anafilaxia también pueden ocurrir en personas sin el antecedente previo, la OMS recomienda que esta vacuna se administre solo en lugares donde se pueda tratar a un paciente con anafilaxia y que todos los vacunados sean observados por 15 minutos luego de la vacunación.

Al sistema de farmacovigilancia español, entre 27 diciembre y 12 enero 2021, se notificaron 374 notificaciones que correspondería a 79 notificaciones por cada 100.000 personas vacunadas y hasta el 24 de enero asciende a 138 notificaciones por cada 100.000 dosis administradas. El análisis de ESAVI mostró que los eventos más frecuentes fueron los trastornos generales como

fiebre o malestar general, seguidos de los trastornos del sistema nervioso (mayoritariamente cefaleas y mareos) y gastrointestinal (principalmente náuseas y diarrea), independientemente del grupo de edad o del sexo de las personas vacunadas. Hasta el 24 de enero de 2021, se han identificado en España 8 casos que cumplen criterios de anafilaxia (7,2 por millón de dosis administradas). La AEMPS recomienda no administrar una segunda dosis de la vacuna a aquellos pacientes que hayan presentado una reacción alérgica clínicamente relevante (anafilaxia, angioedema, urticaria generalizada, manifestaciones respiratorias como asma o rinitis) tras recibir la primera dosis y derivar al paciente a un servicio de alergología para estudio. En 5 de los casos (63%) constaban antecedentes personales de urticaria o alergia a medicamentos o alimentos. En el 63% de los casos, los síntomas se iniciaron en los primeros 30 minutos tras la vacunación. En el 75% de los casos, se administró adrenalina como tratamiento y todos los pacientes se recuperaron o estaban en recuperación en el momento de la notificación.

El 28 de enero la EMA finalizó la revisión del primer informe mensual de Comirnaty, que analiza los datos de seguridad mundiales del mes de diciembre de 2020. La evaluación del PRAC concluye que los datos revisados están en línea con lo que se conoce sobre el perfil de seguridad de esta vacuna.

Debido a los casos que se notificaron en Noruega en ancianos frágiles vacunados con Comirnaty con desenlace mortal, el PRAC ha revisado todas las notificaciones con este desenlace en personas de cualquier edad a nivel mundial. Estos casos ocurrieron en pacientes con diversos tratamientos y enfermedades de base cuya progresión explica el desenlace, sin que pueda establecerse relación con la vacuna. El Comité concluyó que no es necesario tomar ninguna medida en relación a las recomendaciones de uso para este grupo de edad.

Vacuna Moderna

También se han comunicado casos de alergias graves en EEUU y Canadá. En España al 24 enero se habían comunicado 96 ESAVI por cada 100.000 dosis administradas. Los trastornos generales como fiebre o dolor en la zona de inyección han sido los más frecuentemente notificados, seguidos de los trastornos del sistema nervioso (mayoritariamente, cefaleas y mareos) y del sistema musculoesquelético (principalmente, dolor de la extremidad donde se administró la vacuna y artralgia).

Vacuna Sputnik V (Información de Argentina)

Se cuentan con los informes de Farmacovigilancia del Ministerio de Salud de Argentina que semanalmente van actualizando el número de notificaciones

espontáneas con respecto al número de dosis administradas y el tipo de ESAVI notificado. El último informe al 9/2 de un total de 16.455 ESAVI tras la aplicación de 436.269 dosis reportadas en el Registro Federal de Vacunación Nominalizado (NoMiVac) registradas hasta la fecha señalada. SIIISA. De los eventos notificados, el 99,5 % fueron leves y moderados, 84 eventos (0,5%) fueron hospitalizados para tratamiento sintomático con recuperación. Los más frecuentes fueron fiebre, cefalea, mialgias, reacciones locales, alergia y síntomas gastrointestinales. Los errores programáticos más frecuentes fueron la aplicación de dosis con intervalo menor al recomendado, administración de segundo componente como primera dosis o primer componente como segunda dosis. También se vacunaron inadvertidamente personas gestantes y en periodo de lactancia, que se encuentran en seguimiento clínico. Se han notificado dos casos de Síndrome de Guillen Barre, uno catalogado como indefinidos y otro no concluyente.

5.Sugerencias y recomendaciones

En términos generales las vacunas contra SARS-CoV-2 COVID 19 aprobadas hasta el momento se muestran con perfiles de eficacia y seguridad adecuados. Es destacable que se hayan podido desarrollar en forma rápida, constituyendo una herramienta fundamental para avanzar en el control de la pandemia. Dada la situación epidemiológica, la vacunación contra COVID es una urgencia de salud pública.

Es imprescindible establecer un seguimiento y estricta vigilancia de todos los aspectos (seguridad, inmunogenicidad, impacto, efectividad) una vez iniciada la campaña de vacunación.

Dado las diferentes plataformas y los distintos procesos de desarrollo de estas vacunas, la comparación de eficacia y de seguridad entre vacunas no siempre puede establecerse y debe analizarse con cautela.

Dado que es prioritario lograr la mayor cobertura de los grupos objetivos, y considerando que, dados los mecanismos de acceso actual a vacunas, se deba a recurrir a más de un tipo de vacunas, deberá considerarse muy especialmente la previsión de las diferentes condiciones de las distintas vacunas para minimizar el riesgo de errores programáticos y asegurar la provisión de las dos dosis de la misma vacuna a cada persona.

Es fundamental optimizar la comunicación acerca de todos los aspectos de las vacunas a la población (incluyendo al personal de salud).

Es clave lograr adherencia y alcanzar buenas coberturas para lograr los objetivos planteados con la vacunación.

Aún en el mejor escenario, lograr la inmunidad en la comunidad será un proceso de varios meses, por lo que deberán mantenerse las medidas no farmacológicas de prevención y control.

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II

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Unaccompanied Children Office of the Ombuds (UCOO) Statement of Organization, Functions, and Delegations of Authority

AGENCY: Administration for Children and Families, Department of Health and Human Services (HHS).

ACTION: Notice of reorganization; Establishment of the Unaccompanied Children Office of the Ombuds (UCOO).

SUMMARY: The Administration for Children and Families (ACF) has reorganized to establish the Unaccompanied Children Office of the Ombuds (UCOO) within the Immediate Office of the Assistant Secretary, to be headed by a Director (“Ombuds”), who reports directly to the HHS Assistant Secretary for Children and Families.

FOR FURTHER INFORMATION CONTACT: Leah Chavla, Senior Advisor, Administration for Children and Families, 330 C Street SW, Washington, DC 20201, (202) 838–3307.

SUPPLEMENTARY INFORMATION: This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), as follows: Chapter KA, Immediate Office of the Assistant Secretary as last amended by 88 FR 17229–17233 dated March 22, 2023.

I. Amend Chapter K, Administration for Children and Families, Chapter KA, Office of the Assistant Secretary for Children and Families, Subchapter KA.10 Organization, by Adding

Unaccompanied Children Office of the Ombuds (KAO)

II. Amend Chapter KA, Office of the Assistant Secretary for Children and Families, by Establishing Chapter KAO, Unaccompanied Children Office of the Ombuds

KAO.00 Mission. The Mission of the Unaccompanied Children Office of the Ombuds (UCOO) is to be an independent, impartial office with authority to receive reports, including confidential and informal reports, of concerns regarding the care and custody of unaccompanied children; to investigate such reports; to work collaboratively with the Office of Refugee Resettlement (ORR) to potentially resolve such reports; issue

its own reports concerning UCOO’s efforts; and make recommendations to ORR regarding UC program policies and procedures related to protecting unaccompanied children in the care and custody of ORR.

KAO.10 Organization. The UCOO is headed by a Director (“Ombuds”), who reports directly to the ACF Assistant Secretary, and consists of:

Immediate Office of the Ombuds for Unaccompanied Children (KAO1)
Division of Case Management (KAO2)
Division of Operations (KAO3)

KAO.20 Functions. The UCOO may engage in activities including, but not limited to: (1) Receiving reports from unaccompanied children, potential sponsors, other stakeholders in a child’s case, and the public regarding ORR’s adherence to its regulations and standards; (2) Investigating implementation of or adherence to Federal law and ORR regulations, in response to reports it receives, and meeting with interested parties to receive input on ORR’s compliance with Federal law and ORR policy; (3) Requesting and receiving information or documents, such as the Ombuds deems relevant, from ORR and ORR care provider facilities, to determine implementation of and adherence to Federal law and ORR policy; (4) Preparing formal reports and recommendations on findings to publish or present, including an annual report describing activities conducted in the prior year; (5) Conducting investigations, interviews, and site visits at care provider facilities as necessary to aid in the preparation of reports and recommendations; (6) Visiting ORR care providers in which unaccompanied children are or will be housed; (7) Reviewing individual circumstances, including, but not limited to, concerns about unaccompanied children’s access to services, ability to communicate with service providers, parents/legal guardians of children in ORR custody, sponsors, and matters related to transfers within or discharge from ORR care; (8) Making efforts to resolve complaints or concerns raised by interested parties as it relates to ORR’s implementation or adherence to Federal law or ORR policy; (9) Hiring and retaining others, including, but not limited to, independent experts, specialists, assistants, interpreters, and translators to assist the Ombuds in the performance of their duties; (10) Making non-binding recommendations to ORR regarding its policies and procedures, specific to protecting unaccompanied children in the care of ORR; (11) Providing general educational

information about pertinent laws, regulations, and policies, ORR child advocates, and legal services as appropriate; and (12) Advising and updating the Director of ORR, Assistant Secretary, and the Secretary, as appropriate, on the status of ORR’s implementation and adherence with Federal law or ORR policy.

The Ombuds shall manage the files, records, and other information of the program, regardless of format, and such files must be maintained in a manner that preserves the confidentiality of the records except in instances of imminent harm or judicial action and is prohibited from using or sharing information for any immigration enforcement related purpose.

III. Continuation of Policy

Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

IV. Delegation of Authority

All delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them, or their successors, pending further re-delegations, provided they are consistent with this reorganization.

V. Funds, Personnel, and Equipment

Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This reorganization will be effective upon date of signature.

Xavier Becerra,

Secretary, Health and Human Services.

[FR Doc. 2024–29188 Filed 12–9–24; 11:15 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of amendment.

SUMMARY: The Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to

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extend the duration of the Declaration to December 31, 2029, and to republish the Declaration in full.

DATES: This amendment is effective as of January 1, 2025.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Administration for Strategic Preparedness and Response, U.S. Department of Health and Human Services, 400 7th St. SW, Washington, DC 20024; 202–260–0365, paige.ezernack@hhs.gov.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness (PREP) Act authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving “willful misconduct” as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the former Secretary, Alex M. Azar II, declared a public health emergency (PHE) pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation’s health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the declaration was renewed effective April 26, 2020, July 25, 2020, October 23, 2020, January 21, 2021, April 21, 2021, July 20, 2021, October 15, 2021, January 14, 2022, April 12, 2022, July 15, 2022, October 13, 2022, January 11, 2023, and February 11, 2023. The PHE declared under section 319 of the PHS Act ended on May 11, 2023.

Nonetheless, as stated in section I of this amended PREP Act Declaration, I have

determined there is a credible risk that COVID–19 may in the future constitute such an emergency and am thus amending this Declaration to prepare for and mitigate that risk.

On March 10, 2020, former Secretary Azar issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, 2020, the former Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, 2020, the former Secretary amended the Declaration to clarify that Covered Countermeasures under the Declaration include qualified countermeasures that limit the harm COVID–19 might otherwise cause (85 FR 35100, June 8, 2020). On August 19, 2020, the former Secretary amended the Declaration to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommended the administration or use of the Covered Countermeasures. (85 FR 52136, Aug. 24, 2020).

On December 3, 2020, the former Secretary amended the Declaration to incorporate Advisory Opinions of the General Counsel interpreting the PREP Act and the Secretary’s Declaration and authorizations issued by the Department’s Office of the Assistant Secretary for Health as an Authority Having Jurisdiction to respond; added an additional category of qualified persons under section V of the Declaration, *i.e.*, healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are permitted to practice; made explicit that the Declaration covers all qualified pandemic and epidemic products as defined under the PREP Act; added a third method of distribution to provide liability protections for, among other things, private distribution channels; made explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration’s liability protections; made explicit that there are substantive Federal legal and policy issues and interests in having a unified whole-of-nation response to the COVID–19 pandemic among Federal, state, local, and private-sector entities; revised the effective time period of the Declaration; and republished the Declaration in full (85 FR 79190, Dec. 9, 2020).

On February 2, 2021, the Acting Secretary Norris Cochran amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are Covered Countermeasures under the Declaration (86 FR 7872, Feb. 2, 2021). On February 16, 2021, the Acting Secretary amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under the Declaration (86 FR 9516, Feb. 16, 2021) and on February 22, 2021, the Department filed a notice of correction to the February 2 and February 16 notices correcting effective dates stated in the Declaration, and correcting the description of qualified persons added by the February 16, 2021, amendment (86 FR 10588, Feb. 22, 2021). On March 11, 2021, the Acting Secretary amended the Declaration to add additional Qualified Persons authorized to prescribe, dispense, and administer Covered Countermeasures under the Declaration (86 FR 14462, Mar. 16, 2021).

On August 4, 2021, I amended the Declaration to clarify categories of Qualified Persons and to expand the scope of authority for certain Qualified Persons to administer seasonal influenza vaccines to adults (86 FR 41977, Aug. 4, 2021). On September 14, 2021, I amended the Declaration to expand the scope of authority for certain Qualified Persons to administer COVID–19 therapeutics subcutaneously, intramuscularly, or orally (86 FR 51160, Sept. 14, 2021), and on September 30, 2021, the Department filed a notice of correction to the September 14 notice clarifying the terms “ACIP recommendations” and “ACIP’s standard immunization schedules” (86 FR 54696, Oct. 4, 2021). On January 7, 2022, I amended the Declaration to expand the scope of authority for licensed pharmacists to order and administer and qualified pharmacy interns to administer seasonal influenza vaccines (87 FR 982, January 7, 2022).

On May 9, 2023, I amended the Declaration to update the determination of a PHE to state that COVID–19 continues to present a credible risk of a future PHE after the end of the PHE declared pursuant to section 319 of the PHS Act; to add a new limitation on distribution to provide coverage under the PREP Act Declaration through December 31, 2024, for manufacturing, distribution, administration and use of Covered Countermeasures while they are authorized for emergency use (EUA) by the U.S. Food and Drug

Administration (FDA) pursuant to section 564 of the Federal Food, Drug & Cosmetic (FD&C) Act, regardless of any Federal agreement related to manufacturing, distribution, administration or use of the countermeasures, and regardless of any Federal, regional, state, or local emergency Declaration; **to add a new limitation on distribution to provide coverage under this PREP Act Declaration through December 31, 2024, for manufacturing, distribution, administration and use of Covered Countermeasures that are COVID-19 vaccines licensed by FDA, and any FDA-approved or cleared in vitro diagnostic product or other device used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom regardless of any Federal agreement related to manufacturing, distribution, administration or use of the vaccines, and regardless of any Federal, regional, state, or local emergency Declaration;** to clarify that the category of disease, health condition or health threat includes the burden on healthcare providers caused by coterminous seasonal influenza infections and COVID-19 infections; to extend the time period of PREP Act coverage through December 31, 2024, to Qualified Persons who are licensed pharmacists to order and administer, and pharmacy interns and qualified pharmacy technicians to administer, Covered Countermeasures that are COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests regardless of any Federal agreement related to manufacturing, distribution, administration or use of these Covered Countermeasures and regardless of any Federal, regional, state, or local emergency Declaration or other limitations on distribution stated in section VII of the Declaration; to clarify the time period of coverage for other qualified persons authorized under section V of the Declaration; and to extend the duration of the Declaration to December 2024 (88 FR 30769, May 12, 2023).

I am now amending section XII of the Declaration to extend the time period of PREP Act coverage through December 31, 2029. COVID-19 continues to present a credible risk of a future public health emergency. COVID-19 continues to cause significant serious illness, morbidity, and mortality during outbreaks. The risk of domestic cases is high due to ongoing outbreaks that continue domestically and internationally in the year since the PHE for COVID-19 ended. Development of

and stockpiling vaccines, therapeutics, devices, and diagnostics for COVID-19 continues to be needed for U.S. preparedness against the credible threat of a public health emergency due to outbreaks of COVID-19. Continued coverage under the PREP Act, as provided in this Declaration, is intended to prepare for and mitigate the credible risk presented by COVID-19. This includes extending the time period for PREP Act coverage for licensed pharmacists, pharmacy interns, and qualified technicians, which allows for continued access by the recipient Population to Covered Countermeasures that are COVID-19 vaccines, seasonal influenza vaccines and COVID-19 tests. As stated in prior amendments to this Declaration, licensed pharmacists, pharmacy interns and qualified pharmacy technicians are well positioned to provide continued access to Covered Countermeasures, particularly in certain areas or for certain populations that have too few primary-care providers or that are otherwise medically underserved. As of 2022, nearly 90 percent of Americans lived within five miles of a community pharmacy. During the COVID-19 pandemic, the majority of Americans have received their COVID-19 vaccines and tests from a pharmacy. In addition, continued access by the Population to seasonal influenza vaccines mitigates risks that seasonal influenza infections, in conjunction with COVID-19 infections, could overwhelm healthcare providers.

As qualified persons, these licensed pharmacists, pharmacy interns, and qualified pharmacy technicians will be afforded liability protections in accordance with the PREP Act and the terms of this amended Declaration. To the extent that any State law would otherwise prohibit these healthcare professionals who are a “qualified person” from prescribing, dispensing, or administering Covered Countermeasures that are COVID-19 vaccines, seasonal influenza vaccines or COVID-19 tests, such law is preempted.

Other conforming changes and technical corrections are made throughout the Declaration for consistency and clarity.

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Medical Countermeasures Against COVID-19

To the extent any term previously in the Declaration, including its amendments, is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

This Declaration must be construed in accordance with the Advisory Opinions of the Office of the General Counsel (Advisory Opinions). I incorporate those Advisory Opinions as part of this Declaration. Declaration is a “requirement” under the PREP Act.

I. Determination of Public Health Emergency

42 U.S.C. 247d-6d(b)(1)

I have determined that the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease COVID-19 constitutes a credible risk of a future public health emergency. I have also determined that use of any respiratory protective device approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, was a priority for use during the public health emergency that former Secretary Azar declared on January 31, 2020, under section 319 of the PHS Act for the entire United States to aid in the response of the nation’s healthcare community to the COVID-19 outbreak, and that ended on May 11, 2023.

II. Factors Considered

42 U.S.C. 247d-6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d-6d(b)(1)

I recommend, under the conditions stated in this Declaration, the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures.

IV. Liability Protections

42 U.S.C. 247d-6d(a), 247d-6d(b)(1)

Liability protections as prescribed in the PREP Act and conditions stated in this Declaration are in effect for the Recommended Activities described in Section III.

V. Covered Persons

42 U.S.C. 247d-6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are “manufacturers,” “distributors,” “program planners,” “qualified persons,” and their officials,

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agents, and employees, as those terms are defined in the PREP Act, and the United States.

“Order” as used herein and in guidance issued by the Office of the Assistant Secretary for Health means a provider medication order, which includes prescribing of vaccines, or a laboratory order, which includes prescribing laboratory orders, if required.

“Qualified person” includes (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) “a person within a category of persons so identified in a Declaration by the Secretary” under subsection (b) of the PREP Act. 42 U.S.C. 247d–6d(i)(8)

In addition, I have determined that the following additional persons are qualified persons:

(a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures, and their officials, agents, employees, contractors, and volunteers, following a Declaration of an Emergency, as that term is defined in Section VII of this Declaration;

(b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act.

(c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with section 564A of the FD&C Act.

(d) A State-licensed pharmacist who orders and administers, and pharmacy interns and qualified pharmacy technicians who administer (if the pharmacy intern or technician acts under the supervision of such pharmacist and the pharmacy intern or technician is licensed or registered by his or her State board of pharmacy), (1) vaccines that the Centers for Disease Control and Prevention (CDC)/Advisory Committee on Immunization Practices (ACIP) recommend to persons ages three through 18 according to CDC’s/ACIP’s standard immunization schedule; or (2) seasonal influenza vaccine administered by qualified pharmacy technicians and interns that the CDC/ACIP recommends to persons aged 19 and older according to CDC’s/ACIP’s standard immunization schedule; or (3) FDA-authorized or

FDA-licensed COVID–19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns or technicians under their supervision are qualified persons only if the following requirements are met:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. In the case of a COVID–19 vaccine, the vaccination must be ordered and administered according to CDC’s/ACIP’s COVID–19 vaccine recommendation(s);

iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to CDC’s/ACIP’s standard immunization schedule;

iv. In the case of seasonal influenza vaccine administered by qualified pharmacy technicians and interns, the vaccination must be ordered and administered according to CDC’s/ACIP’s standard immunization schedule;

v. In the case of pharmacy technicians, the supervising pharmacist must be readily and immediately available to the immunizing qualified pharmacy technician;

vi. The licensed pharmacist must have completed the immunization training that the licensing State requires for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a training program must include hands on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

vii. The licensed or registered pharmacy intern and qualified pharmacy technician must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

viii. The licensed pharmacist, licensed or registered pharmacy intern, and qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation;

ix. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;

x. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient’s primary care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine;

xi. The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate; and

xii. The licensed pharmacist, the licensed or registered pharmacy intern and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) as set forth in the CDC COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

(e) Healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are licensed or otherwise permitted to practice. When ordering and administering Covered Countermeasures by means of telehealth to patients in a state where the healthcare personnel are not already permitted to practice, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients by means of telehealth in the state where the healthcare personnel are permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures by means of telehealth is preempted. Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services.

(f) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State as of the effective date of this amendment, or a pharmacist or pharmacy intern as authorized under the section V(d) of this Declaration, who

prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, in association with a COVID-19 vaccination effort by a federal, state, local, tribal, or territorial authority or by an institution in the State in which the COVID-19 vaccine Covered Countermeasure is administered, so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to Documentation of completion of the COVID-19 (CDC) Vaccine Training Modules and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering intramuscular injections is in their ordinary scope of practice, who confirms competency of the healthcare provider in preparation and administration of the COVID-19 vaccine(s) to be administered.

(g) Any member of a uniformed service (including members of the National Guard in a Title 32 duty status) (hereafter in this paragraph "service member") or federal government, employee, contractor, or volunteer who prescribes, administers, delivers, distributes or dispenses a Covered Countermeasure. Such federal government service members, employees, contractors, or volunteers are qualified persons if the following requirement is met: The executive department or agency by or for which the federal service member, employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that service member, employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of the duties or responsibilities of that service member, employee, contractor, or volunteer, even if those authorized duties or responsibilities ordinarily would not extend to members of the public or otherwise would be more limited in scope than the activities such service member, employees, contractors,

or volunteers are authorized to carry out under this Declaration.

(h) The following healthcare professionals and students in a healthcare profession training program subject to the requirements of this paragraph:

1. Any midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist, or veterinarian licensed or certified to practice under the law of any state who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a state, local, tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered;

2. Any physician, advanced practice registered nurse, registered nurse, practical nurse, pharmacist, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, respiratory therapist, dentist, physician assistant, podiatrist, optometrist, or veterinarian who has held an active license or certification under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a state, local, tribal or territorial authority or by an institution in which the COVID-19 vaccine Covered Countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline, or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General;

3. Any medical, nursing, pharmacy, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, physician assistant, respiratory therapy, dental, podiatry, optometry or veterinary student with appropriate training in administering vaccines as determined by his or her school or training program and supervision by a currently practicing healthcare professional experienced in administering intramuscular injections

who administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a state, local, tribal or territorial authority or by an institution in which the COVID-19 vaccine Covered Countermeasure is administered;

Subject to the following requirements:

- i. The vaccine must be authorized, approved, or licensed by the FDA;
- ii. Vaccination must be ordered and administered according to CDC's/ACIP's COVID-19 vaccine recommendation(s);
- iii. The healthcare professionals and students must have documentation of completion of the CDC COVID-19 Vaccine Training Modules; and if applicable, such additional training as may be required by the state, territory, locality, or tribal area in which they are prescribing, dispensing, or administering COVID-19 vaccines;
- iv. The healthcare professionals and students must have documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering vaccinations is in their ordinary scope of practice, who confirms competency of the healthcare provider or student in preparation and administration of the COVID-19 vaccine(s) to be administered and, if applicable, such additional training as may be required by the state, territory, locality, or tribal area in which they are prescribing, dispensing, or administering COVID-19 vaccines;
- v. The healthcare professionals and students must have a current certificate in basic cardiopulmonary resuscitation;
- vi. The healthcare professionals and students must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the state or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and
- vii. The healthcare professionals and students comply with any applicable requirements (or conditions of use) as set forth in the CDC COVID-19 vaccination provider agreement and any other federal requirements that apply to

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the administration of COVID–19 vaccine(s).

(i) A State-licensed pharmacist who orders and administers, and pharmacy interns and qualified pharmacy technicians who administer (if the pharmacy intern or technician acts under the supervision of such pharmacist and the pharmacy intern or technician is licensed or registered by his or her State board of pharmacy) FDA-authorized, approved, or licensed COVID–19 therapeutics. Such State-licensed pharmacists and the State licensed or registered interns or technicians under their supervision are qualified persons only if the following requirements are met:

i. The COVID–19 therapeutic must be authorized, approved, or licensed by the FDA;

ii. In the case of a licensed pharmacist ordering a COVID–19 therapeutic, the therapeutic must be ordered for subcutaneous, intramuscular, or oral administration and in accordance with the FDA approval, authorization, or licensing;

iii. In the case of licensed pharmacists, qualified pharmacy technicians, and licensed or registered pharmacy interns administering the COVID–19 therapeutic, the therapeutic must be administered subcutaneously, intramuscularly, or orally in accordance with the FDA approval, authorization, or licensing;

iv. In the case of qualified pharmacy technicians, the supervising pharmacist must be readily and immediately available to the qualified pharmacy technician;

v. In the case of COVID–19 therapeutics administered through intramuscular or subcutaneous injections, the licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of COVID–19 therapeutics, the recognition and treatment of emergency reactions to COVID–19 therapeutics, and any additional training required in the FDA approval, authorization, or licensing;

vi. The licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation;

vii. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers COVID–19 therapeutics; including informing the patient's

primary-care provider when available and complying with requirements with respect to reporting adverse events; and

viii. The licensed pharmacist, the licensed or registered pharmacy intern and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) that apply to the administration of COVID–19 therapeutics.

(j) Any pharmacist who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State or who is authorized under section V(d) of this Declaration who prescribes, dispenses, or administers seasonal influenza vaccines, or a pharmacy intern as authorized under the section V(d) of this Declaration who administers seasonal influenza vaccines, in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, so long as the license or certification of the pharmacist or pharmacy intern has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General.

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa–10 *et seq.* are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are:

(a) Any antiviral, any drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine manufactured, used, designed, developed, modified, licensed, or procured:

i. To diagnose, mitigate, prevent, treat, or cure COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom; or

ii. to limit the harm that COVID–19, or the transmission of SARS–CoV–2 or

a virus mutating therefrom, might otherwise cause;

(b) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in paragraph (a) above;

(c) a product or technology intended to enhance the use or effect of a product described in paragraph (a) or (b) above; or

(d) any device used in the administration of any such product, and all components and constituent materials of any such product.

To be a Covered Countermeasure under the Declaration, a product must also meet 42 U.S.C. 247d–6d(i)(1)'s definition of "Covered Countermeasure."

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability protections are afforded to Covered Persons only for Recommended Activities involving:

(a) Covered Countermeasures that are related to present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements;

(b) Covered Countermeasures that are related to activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of Emergency;

(c) Covered Countermeasures other than licensed COVID–19 vaccines that are:

i. Licensed, approved, or cleared by the FDA (or that are permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the FD&C Act or PHS Act to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom; or

ii. A respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act to prevent, mitigate, or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom.

To qualify for this third distribution channel, a Covered Person must

manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA licensure, approval, or clearance (or pursuant to an Investigational New Drug Application or Investigational Device Exemption), or the NIOSH approval;

(d) Covered Countermeasures that are authorized by the FDA under section 564 of the FD&C Act to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom. To qualify for this fourth distribution channel, a Covered Person must manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA authorization; or

(e) Covered Countermeasures that are COVID-19 vaccines licensed by the FDA to prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom and any approved or cleared in vitro diagnostic product or other device used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom. To qualify for this fifth distribution channel, a Covered Person must manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA license, clearance, or approval.

As used in this Declaration, the terms “Authority Having Jurisdiction” and “Declaration of Emergency” have the following meanings:

(i) The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.*, city, county, tribal, state, or federal boundary lines) or functional (*e.g.*, law enforcement, public health) range or sphere of authority.

(ii) A Declaration of Emergency means any declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a federal declaration in support of an Emergency Use Authorization under section 564 of the FD&C Act unless such declaration specifies otherwise.

I have also determined that, for governmental program planners only, liability protections are afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (a) donation; (b) commercial sale; (c) deployment of Covered Countermeasures from federal stockpiles; or (d) deployment of

donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is not only COVID-19 caused by SARS-CoV-2, or a virus mutating therefrom, but also other diseases, health conditions, or threats that may have been caused by COVID-19, SARS-CoV-2, or a virus mutating therefrom, including the threat of increased burden on the healthcare system due to seasonal influenza infections occurring at the same time as COVID-19 infections, which will lead to an increase in the rate of infectious diseases.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for the purpose of distributing and dispensing countermeasures. Where there are limited Covered Countermeasures, *not* administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute “relating to . . . the administration to . . . an individual” under 42 U.S.C. 247d–6d. For example, consider a situation where there is only one dose of a COVID-19 vaccine, and a person in a vulnerable population and a person in a less vulnerable population both request it from a healthcare professional. In that situation, the healthcare professional administers the one dose to the person who is more vulnerable to COVID-19. In that circumstance, the failure to administer the COVID-19 vaccine to the person in a less-vulnerable population “relat[es] to . . . the administration to” the person in a vulnerable population. The person in the vulnerable population was able to receive the vaccine only because it was not administered to the person in the less-vulnerable population. Prioritization or purposeful allocation of a Covered Countermeasure, particularly

if done in accordance with a public health authority’s directive, can fall within the PREP Act and this Declaration’s liability protections.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals to whom the liability protections of this Declaration extend include any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability protections are afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability protections are afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability protections are afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability protections are afforded to manufacturers and distributors without regard to whether the Covered Countermeasure is used by or administered in any designated geographic area; liability protections are afforded to program planners and qualified persons when the countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.

COVID-19 is a global challenge that requires a whole-of-nation response. There are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng’g. & Mfg.*, 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities. The world faced an unprecedented pandemic. To effectively respond, there needed to be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world. Thus, there are substantial federal legal and policy issues, and substantial federal legal and policy

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interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mfg.*, 545 U.S. 308 (2005), in having a uniform interpretation of the PREP Act. **Under the PREP Act, the sole exception to the immunity from suit and liability of covered persons under the PREP Act is an exclusive federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct by such covered person.** In all other cases, an injured party's exclusive remedy is an administrative remedy under section 319F-4 of the PHS Act. Through the PREP Act, Congress delegated to me the authority to strike the appropriate federal-state balance with respect to Covered Countermeasures through PREP Act Declarations.

XII. Effective Time Period

42 U.S.C. 247d-6d(b)(2)(B)

The effective time period for Covered Countermeasures and Covered Persons depends on the means of distribution identified in Section VII of this Declaration as applied to categories of Countermeasures and Qualified Persons:

(a) Liability protections for any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, through the means of distribution identified in section VII(a) of this Declaration, begin on March 27, 2020, and extend through December 31, 2029.

(b) Liability protections for all other Covered Countermeasures identified in section VI of this Declaration, through means of distribution identified in section VII(a) of this Declaration, begin on February 4, 2020, and extend through December 31, 2029.

(c) Liability protections for all Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, as identified in section VII(b) of this Declaration, begin with a Declaration of Emergency as that term is defined in section VII (except that, with respect to qualified persons who order or administer a routine childhood vaccination that CDC/ACIP recommends to persons ages three through 18 according to CDC's/ACIP's standard immunization schedule, liability protections began on August 24, 2020), and last through (a) the final day the Declaration of Emergency is in effect, or (b) December 31, 2029, whichever occurs first.

(d) Liability protections for all Covered Countermeasures identified in section VII(c)(i) of this Declaration begin

on December 9, 2020, and last through the final day the Declaration of Emergency is in effect or December 31, 2029, whichever occurs first. Liability protections for all Covered Countermeasures identified in section VII(c)(ii) of this Declaration last for the time period stated in section (a) of this section XII if applicable, or otherwise December 31, 2024.

(e) Liability protections for all Covered Countermeasures identified in section VII(d) of this Declaration begin on December 9, 2020, and last until December 31, 2029, regardless of any Declaration of Emergency that might otherwise terminate the time period of coverage under paragraphs (c) or (d) of this section XII.

(f) Liability protections for all Covered Countermeasures identified in section VII(e) of this Declaration begin on December 9, 2020, and last until December 31, 2029, regardless of any Declaration of Emergency that might otherwise terminate the time period of coverage under paragraphs (c) or (d) of this section XII.

(g) Liability protections for Manufacturers, Distributors, and Program Planners, as defined at 42 U.S.C. 247d-6d(i), begin on February 4, 2020, and last through the time periods stated in paragraphs (a)–(f) of this section XII.

(h) Liability protections for Qualified Persons who are a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed begin on February 4, 2020, and last through the time periods stated in paragraphs (a)–(f) of this section XII.

(i) Liability protections for Additional Qualified Persons identified under section V of the Declaration and in Guidance implementing section V of the Declaration begin on the dates listed below, and last through the time periods stated in paragraphs (a)–(d) of this section XII of the Declaration, unless otherwise stated in this paragraph (i).

i. Liability protections for Qualified Persons under section V(d) of the Declaration who are licensed pharmacists to order and administer, and licensed or registered pharmacy interns and qualified pharmacy technicians to administer CDC/ACIP recommended vaccines for persons aged three through 18 (other than seasonal influenza vaccines and COVID-19 vaccines) begins on August 24, 2020.

ii. Liability protections for Qualified Persons under section V(d) of the Declaration who are licensed

pharmacists to order and administer, and licensed or registered pharmacy interns and qualified pharmacy technicians to administer CDC/ACIP recommended seasonal influenza vaccines for persons aged three through 18 begins on August 24, 2020, and lasts through December 31, 2029, regardless of the time periods stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

iii. Liability protections for Qualified Persons under section V(d) of the Declaration who are licensed pharmacists to order and administer, and pharmacy interns and qualified pharmacy technicians to administer, COVID-19 vaccines to individuals aged three and above begins on February 4, 2020, and lasts through December 31, 2029, regardless of the time periods stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

iv. Liability protections for Qualified Persons under section V(d) of the Declaration who are licensed pharmacists to order and administer, and pharmacy interns and qualified pharmacy technicians to administer, seasonal influenza vaccines to individuals aged nineteen and above begins on August 4, 2021, and lasts through December 31, 2029, regardless of the time periods stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

v. Liability protections for Qualified Persons under section V(e) of the Declaration begin on February 4, 2020.

vi. Liability protections for Qualified Persons under section V(f) of the Declaration begin on February 2, 2021.

vii. Liability protections for Qualified Persons under section V(g) of the Declaration begin on February 16, 2021, and last through December 31, 2029.

viii. Liability protections for Qualified Persons who are physicians, advanced practice registered nurses, registered nurses, or practical nurses under section V(h) of the Declaration begin on February 2, 2021, with additional conditions effective as of March 11, 2021, and liability protections for all other Qualified persons under section V(h) begin on March 11, 2021.

ix. Liability protections for Qualified Persons under section V(i) of the Declaration who are licensed pharmacists to order and administer and qualified pharmacy technicians and licensed or registered pharmacy interns to administer COVID-19 therapeutics identified in section VII(d) of the Declaration begin on September 9, 2021,

and last through December 31, 2029, regardless of time periods stated in paragraphs (c)–(d) of this section or limitations on distribution stated in section VII (a)–(b) of this Declaration.

x. Liability protections for Qualified Persons under section V(i) of the Declaration who are licensed pharmacists to order and administer and qualified pharmacy technicians and licensed or registered pharmacy interns to administer COVID–19 therapeutics identified in section VII(c) of the Declaration begin on September 9, 2021.

xi. Liability protections for Qualified Persons under section V(j) of the Declaration begin on December 30, 2021.

xii. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference, to administer COVID–19 tests who are licensed pharmacists begin April 8, 2020, and last until December 31, 2029, regardless of any limitations stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

xiii. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference, to administer COVID–19 tests who are licensed or registered pharmacy interns or qualified pharmacy technicians begin October 20, 2020, and last until December 31, 2029, regardless of any limitations stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

xiv. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference, who are pharmacies when their staff pharmacists order and administer, or their pharmacy interns and pharmacy technicians administer COVID–19 vaccines to individuals aged three and above, seasonal influenza vaccines to individuals aged three through eighteen, seasonal influenza vaccines to individuals aged nineteen and above, COVID–19 tests, and COVID–19 therapeutics identified in section VII(d) of the Declaration begin October 29, 2020, and last until December 31, 2029, regardless of any limitations stated in paragraphs (c)–(d) of this section XII or limitations on

distribution stated in section VII (a)–(b) of this Declaration.

xv. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference, who are pharmacies when their staff pharmacists order and administer, or their pharmacy interns and pharmacy technicians administer CDC/ACIP recommended vaccines for persons aged three through 18 (other than seasonal influenza vaccines and COVID–19 vaccines) and countermeasures identified in section VII(c) of the Declaration begin October 29, 2020.

xvi. Liability protections for Qualified Persons authorized under Guidance issued by this Department as an Authority Having Jurisdiction to respond to a declared emergency, incorporated into this Declaration by reference to prescribe or administer point-of-care COVID–19 tests, using anterior nares specimen collection or self-collection, for screening in congregate facilities across the Nation who are licensed healthcare practitioners begin August 31, 2020, and last until December 31, 2029, regardless of any limitations stated in paragraphs (c)–(d) of this section XII or limitations on distribution stated in section VII (a)–(b) of this Declaration.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional 12 months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the Strategic National Stockpile (SNS) during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS, including NIOSH Approved® respirators that have been rescinded or are beyond their manufacturers' declared shelf life.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to

certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical, and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the U.S. Department of Health and Human Services. Information about the CICP is available at the toll-free number 1–855–266–2427 or <http://www.hrsa.gov/cicp/>.

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

Amendments to this Declaration will be published in the **Federal Register**, as warranted.

Authority: 42 U.S.C. 247d–6d.

Dated: December 6, 2024.

Xavier Becerra,

Secretary, U.S. Department of Health and Human Services.

[FR Doc. 2024–29108 Filed 12–10–24; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Public Comments on the Scientific Report of the 2025 Dietary Guidelines Advisory Committee

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS); Food, Nutrition, and Consumer Services (FNCS), U.S. Department of Agriculture (USDA).

ACTION: Notice and request for public comments on the Scientific Report of the 2025 Dietary Guidelines Advisory Committee (Scientific Report).

SUMMARY: The Departments of Health and Human Services and Agriculture invite the public to provide written comments and virtual oral comments on the Scientific Report.

DATES: The written and oral comment collection dates are scheduled as follows:

- Once the Scientific Report is published online, the public will have 60 days to provide written comments to HHS and USDA; this public comment period closes on the 60th calendar day

MANUFACTURING AND SUPPLY AGREEMENT

BETWEEN

PFIZER LABORATORIES PROPRIETARY LIMITED

AND

**THE GOVERNMENT OF THE REPUBLIC OF SOUTH AFRICA ACTING THROUGH
THE NATIONAL DEPARTMENT OF HEALTH OF SOUTH AFRICA ("NDOH")**

DATED AS OF

30 March 2021

MANUFACTURING AND SUPPLY AGREEMENT

THIS MANUFACTURING AND SUPPLY AGREEMENT dated as of **30 March 2021** (the “**Effective Date**”) is made by and between PFIZER LABORATORIES (PROPRIETARY) LIMITED with offices at 85 Bute Lane, Sandton, Johannesburg, South Africa (hereinafter “**Pfizer**”) and the Government of the Republic of South Africa acting through the National Department of Health of South Africa (“**NDOH**”), with offices at Dr AB Xuma Building, 1112 Voortrekker Rd, Pretoria Townlands 351-JR, Pretoria, 0187 (hereinafter “**Purchaser**”). Purchaser and Pfizer may be referred to herein individually as a “**Party**” or collectively as the “**Parties**”.

WHEREAS, Pfizer Inc. (“**Pfizer US**”) and BioNTech SE, a company organized and existing under the laws of Germany (“**BioNTech**”), are collaborating to develop a vaccine to address the global COVID-19 pandemic;

WHEREAS, subject to clinical success, Pfizer US and BioNTech shall be responsible for all requirements of the processes of approval of the clinical trials and the marketing authorization of the Product;

WHEREAS, Purchaser desires to purchase the Product for use in South Africa (the “**Territory**”), and subject to clinical success and regulatory approval, Pfizer desires to manufacture and supply such Product to Purchaser; and

WHEREAS, the Parties are willing to carry out the foregoing pursuant to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of these premises and the covenants and agreements set forth herein, the sufficiency of which is hereby acknowledged and agreed, and intending to be legally bound thereby, the Parties hereby agree as follows:

1. DEFINITIONS.

As used in this Agreement, the following terms shall have the meanings set forth below.

- 1.1 “**Adjusted Delivery Schedule**” shall have the meaning set forth in Section 2.4(e).
- 1.2 “**Advance Payment**” shall have the meaning set forth in Section **Error! Reference source not found.**
- 1.3 “**Affiliate(s)**” means, with respect to each Party or, if applicable, BioNTech, any corporation, firm, partnership or other entity or Person which directly or indirectly controls or is controlled by or is under common control with the named Party, including without limitation Pfizer US, or, if applicable, BioNTech. For purposes of this definition, “control” (including, with correlative meaning, the terms “controlled by” and “under common control with”) shall be presumed to exist if one of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors of such corporate entity or any direct or indirect parent of such corporate entity, and (b) in the case of non-

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corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities.

- 1.4 **"Agreement"** means this Manufacturing and Supply Agreement and all Attachments hereto as the same may be amended, amended and restated, supplemented or otherwise replaced from time to time.
- 1.5 **"Allocation"** shall have the meaning set forth in Section 2.5(a).
- 1.6 **"Authorization"** means the Conditional Approval or Marketing Authorization.
- 1.7 **"Batch"** shall have the meaning set forth in Attachment B.
- 1.8 **"BioNTech"** shall have the meaning set forth in the recitals.
- 1.9 **"Binding Term Sheet"** means the binding term sheet entered into by and between the Parties on 15 January 2021.
- 1.10 **"Business Day"** means any day other than Saturday, Sunday or a public holiday in New York, New York or Johannesburg.
- 1.11 **"Commercially Reasonable Efforts"** means with respect to the efforts to be expended by Pfizer to achieve the relevant objective, the activities and degree of effort that a similarly situated party (with respect to size, resources and assets) in the pharmaceutical industry would use to accomplish a similar objective in its own commercial interests under similar circumstances and considering the relevant risks, uncertainties, limitations and challenges of the development, manufacture, commercialization and distribution of a novel COVID-19 vaccine product, taking into account the following factors: actual and potential issues of safety and efficacy, novelty, product profile, the proprietary position, the then current competitive environment for such Product, the likely timing of the Product's entry into the market, the regulatory environment and status of the Product, compliance with Laws, past performance of the Product and other similar products, the ability to produce or obtain adequate supply of the Product or any components or materials used in the manufacture of the Product and other relevant scientific, technical, operational and commercial factors, in each case as measured by the facts and circumstances at the time such efforts are due.
- 1.12 **"Conditional Approval"** means a conditional marketing authorization for the Product granted by the South African Health Products Regulatory Authority ("SAHPRA") and agreed with Pfizer, that permits the supply of the Product in South Africa.
- 1.13 **"Confidential Information"** means all confidential or proprietary information, other than Exempt Information, in any form, directly or indirectly disclosed to Recipient or its Representatives by or on behalf of the Disclosing Party pursuant to this Agreement, regardless of the manner in which such information is disclosed, delivered, furnished, learned, or observed, either marked "Confidential" or, if oral, declared to be confidential when disclosed and confirmed in writing within thirty (30) days of disclosure. Confidential Information includes, without limitation, the terms and conditions of this Agreement.

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Failure to mark Confidential Information disclosed in writing hereunder as “Confidential” shall not cause the information to be considered non-confidential, with the burden on the Disclosing Party to prove such information clearly should have been known by a reasonable person with expertise on the subject matter, based on the nature of the information and the circumstances of its disclosure, to be Confidential Information, provided that the Disclosing Party has otherwise made good faith efforts to clearly mark Confidential Information as such.

- 1.14 “**Contracted Doses**” shall have the meaning set forth in Section 2.3(a).
- 1.15 “**Covax Facility**” means the global procurement mechanism for the procurement and delivery of doses of approved vaccine for COVID-19.
- 1.16 “**Current Good Manufacturing Practices**” or “**cGMP**” means applicable Good Manufacturing Practices as specified in the United States Code of Federal Regulations and/or the EU Good Manufacturing Guidelines, and any successor legislation from time to time, prevailing at the time of the manufacture of the Product.
- 1.17 “**Delivery Price**” shall have the meaning set forth in Section 3.2(a).
- 1.18 “**Delivery Specifications**” shall have the meaning set forth in Section 2.4(d).
- 1.19 “**Disclosing Party**” means the Party or any of its Affiliates that discloses, or causes to be disclosed, Confidential Information to the other Party or any of its Affiliates.
- 1.20 “**Effective Date**” shall have the meaning set forth in the preamble.
- 1.21 “**Exempt Information**” means information that: (a) the Recipient or any of its Representatives lawfully possessed, as demonstrated by competent proof, before the Disclosing Party disclosed such information under this Agreement; or (b) was already generally available and in the public domain at the time of disclosure, or becomes public (other than as a result of breach of this Agreement by the Recipient or its Representatives); (c) the Recipient or any of its Representatives lawfully obtains from a Person not in breach of any confidentiality obligation (or other prohibition from disclosing the information) to the Disclosing Party with respect to such information (and Recipient has made reasonable enquiry with respect thereto); or (d) the Recipient evidences to the reasonable satisfaction of the Disclosing Party is independently developed by or on behalf of the Recipient or its Representatives without the use of, reference to, aid from, or reliance on, the Confidential Information. In clarification of the foregoing, a general disclosure in the public domain will not cause more specific (but related) information to be deemed Exempt Information under one of the above exceptions; similarly, a combination of several pieces of information, which individually would be deemed Exempt Information, will not be deemed Exempt Information unless the combination itself is in the public domain, independently developed by the Recipient or its Representatives or otherwise lawfully in the possession of the Recipient or any of its Representatives.

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- 1.22 **"Facilities"** means Pfizer's manufacturing sites in Kalamazoo (Michigan) and Puurs, Belgium and BioNTech's two manufacturing sites, in Mainz and Idar Oberstein in Germany or such other manufacturing site used in connection with the manufacture of the Product supplied by Pfizer hereunder.
- 1.23 **"Force Majeure Event"** shall have the meaning set forth in Section 12.8.
- 1.24 **"Forms"** shall have the meaning set forth in Section 12.12.
- 1.25 **"Government"** means all levels and subdivisions of government (i.e., local, regional, national, provincial, federal, administrative, legislative, or executive) of South Africa.
- 1.26 **"ICC"** shall have the meaning set forth in Section 12.2.
- 1.27 **"Indemnified Claims"** shall have the meaning set forth in Section 8.2.
- 1.28 **"Indemnitees"** shall have the meaning set forth in Section 8.1.
- 1.29 **"Interim Delivery Schedule"** shall have the meaning set forth in Section 2.4(d).
- 1.30 **"Intellectual Property"** means (a) any processes, trade secrets, inventions, industrial models, designs, methodologies, drawings, discoveries, result, materials, formulae, procedures, techniques, clinical data or technical or other information or data, manufacturing, engineering and technical drawings, including proprietary rights in any of the foregoing, and (b) registered trademarks, trade mark applications, unregistered marks, trade dress, copyrights, know-how, patents, patent applications, and any and all provisionals, divisions, continuations, continuations in part, extensions, substitutions, renewals, registrations, revalidations, reissues or additions, including certificates of supplementary protection, of or to any of the aforesaid patents and patent applications, and all foreign counterparts of any, or to any, of the aforesaid patents and patent applications.
- 1.31 **"Labelling and Packaging Specifications"** shall have the meaning set forth in Section 2.4(e).
- 1.32 **"Latent Defect"** means a defect causing the Product to not conform to the applicable Specifications that Purchaser can show was present at the time of Pfizer's delivery of the Product to Purchaser and which could not have been detected by Purchaser, its designee, or their Personnel at delivery through diligent inspection.
- 1.33 **"Law/s"** means, collectively, all applicable national and local laws, common laws, statutes, ordinances, codes, rules, regulations, orders, decrees or other pronouncements of any government, administrative or judicial authority having the effect of law.
- 1.34 **"Losses"** shall have the meaning set forth in Section 8.1.
- 1.35 **"Marketing Authorization"** means the marketing authorization or such other permission having similar effect, in respect of the Product, granted by the South African Health Products Regulatory Authority, as amended or varied by the South African Health Products

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Regulatory Authority from time to time, and which is acceptable to Pfizer; that allows the Product to be placed on the market in South Africa according to Law.

- 1.36 **“Non-Complying Product”** shall have the meaning set forth in Section 4.4(a).
- 1.37 **“Party”** or **“Parties”** shall have the meaning set forth in the preamble.
- 1.38 **“Person”** means any natural person, entity, corporation, general partnership, limited partnership, limited liability partnership, joint venture or similar entity or organization, joint stock company, proprietorship, other business organization, trust, union, association or Government.
- 1.39 **“Personnel”** means all Affiliates, subcontractors, or other third parties, and employees and agents of each of them, used by either Party in the performance of services or obligations or in connection with this Agreement.
- 1.40 **“Pfizer”** shall have the meaning set forth in the preamble.
- 1.41 **“Pfizer US”** shall have the meaning set forth in the preamble.
- 1.42 **“Price”** shall have the meaning set forth in Section 3.1.
- 1.43 **“Privileges and Immunities”** means any privileges, immunities, or legislation in the Republic of South Africa, including, without limitation, no-fault vaccine compensation programs, pandemic insurance programs, immunities from suit or liability, or any protections, defenses, or limitations-of-liability (whether statutory, regulatory, common law or otherwise), existing or future, that may separately protect Indemnitees from Losses.
- 1.44 **“Product”** means the medicinal product being BNT162b2, a nucleoside-modified messenger RNA (mRNA) vaccine that encodes an optimised SARS-CoV-2 full length spike glycoprotein (S) in an unpreserved frozen multi-dose vial that must be diluted, for which Authorisation has been granted or is being sought, for the prevention of COVID-19, including any subsequent non-material variations as reasonably determined by Pfizer and approved by the relevant regulatory authority. For the avoidance of doubt, changes to the active substance or antigenic characteristics of BNT162b2 encoding a variant or new strain of SARS-CoV-2 as well as any new formulation of BNT162b2 are explicitly excluded from the scope of the “Product” as defined here, as are any other significant product changes as Pfizer may reasonably determine.
- 1.45 **“Product Materials”** means all packaging materials and components needed for delivery of the Product.
- 1.46 **“Purchase Order”** means a written or electronic order form submitted by Purchaser to Pfizer in accordance with the terms of this Agreement authorizing the manufacture and supply of the Product, in substantially the form attached as Attachment G (as may be updated from time to time by Pfizer upon notice to Purchaser).
- 1.47 **“Purchaser”** shall have the meaning set forth in the preamble.

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- 1.48 **"Recipient"** means the Party who receives Confidential Information from the other Party.
- 1.49 **"Records"** means books, documents, and other data, of all matters relating to performance of obligations under this Agreement.
- 1.50 **"Representatives"** means, with respect to Recipient, its Affiliates and its and their respective directors, officers, and employees, agents, contractors, consultants, advisors and representatives who (a) are subject to an obligation of confidentiality protecting the Confidential Information on terms no less restrictive than those contained in this Agreement; and (b) have a need to know the Confidential Information in connection with this Agreement.
- 1.51 **"Specifications"** means the material specifications for the manufacture, processing, packaging, labeling, testing and testing procedures, shipping, storage and supply of the Product as will be set out in Attachment A following the Effective Date (and in any event before supply in accordance with the agreed Interim Delivery Schedule), and as such specifications may be amended, supplemented or otherwise modified by Pfizer and communicated to Purchaser.
- 1.52 **"Taxes"** shall have the meaning set forth in Section 3.4.
- 1.53 **"Term"**, with respect to this Agreement, shall have the meaning set forth in Section 6.1.
- 1.54 **"Third Party Beneficiary"** or **"Third Party Beneficiaries"** shall have the meaning set forth in Section 12.5(a).
- 1.55 **"USD"** means the lawful currency of the United States of America.
- 1.56 **"Vaccine"** shall include (a) all vaccines manufactured, in whole or in part, or supplied, directly or indirectly, by or on behalf of Pfizer or BioNTech or any of their Affiliates that are intended for the prevention of the human disease COVID-19 or any other human disease, in each case which is caused by any of the virus SARS-CoV-2, and/or any or all related strains, mutations, modifications or derivatives of the foregoing that are procured by Purchaser, its Affiliates or agents by any means (whether pursuant to the Agreement or by way of any purchase or donation from any third party or otherwise, whether or not authorized pursuant to Section 2.1) or that are administered within the Territory, and whether procured or administered prior to or following execution of this Agreement, (b) any device, technology, or product used in the administration of or to enhance the use or effect of, such vaccine, (c) any component or constituent material of (a) or (b), or (d) any use or application of any product referred to in (a)-(b).
- 1.57 **"VAT"** means Value Added Tax.

Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as

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the word “shall”, (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Attachments shall be construed to refer to Sections or Attachments of this Agreement, and references to this Agreement include all Attachments hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof and (j) the term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or”.

2. SUPPLY OF PRODUCT.**2.1 Agreement to Supply.**

- (a) During the Term, Pfizer shall use Commercially Reasonable Efforts to supply or have supplied the Product to Purchaser, and Purchaser shall purchase the Product, subject to and in accordance with the terms and conditions of this Agreement.
- (b) Purchaser acknowledges and agrees that (i) Pfizer’s efforts to develop and manufacture the Product are aspirational in nature and subject to significant risks and uncertainties, and (ii) the fact that any other drug or vaccine to prevent, treat or cure COVID-19 infection is successfully developed or granted authorization earlier than the granting of Authorization for the Product shall not change the current situation of urgent needs for prevention of the spread of the COVID-19 infection that poses serious threats to and harmful effects on the lives and health of the general public.
- (c) Notwithstanding the efforts and any estimated dates set forth in the Interim Delivery Schedule, the Parties recognize that the Product has completed Phase 2b/3 clinical trials and that, despite the efforts of Pfizer in research, and development and manufacturing, the Product may not be successful due to technical, clinical, regulatory, manufacturing, shipping, storage, or other challenges or failures.
- (d) Accordingly, Pfizer and its Affiliates shall have no liability for any failure by Pfizer or its Affiliates to develop or obtain Authorization of the Product in accordance with the estimated dates described in this Agreement. Even if the Product is successfully developed and obtains Authorization, Pfizer shall have no liability for any failure to deliver doses in accordance with any estimated delivery dates set forth herein (other than as expressly set out in this Agreement), nor shall any such failure give Purchaser any right to cancel orders for any quantities of Product.

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Further, Pfizer shall have no obligation to deliver the Product to Purchaser unless and until the Indemnification Agreement is executed between the Parties in accordance with Section 8 (Indemnification).

- (e) Pfizer shall keep Purchaser apprised of the progress of the material development of the Product and shall provide Purchaser with such information regarding that development as Purchaser reasonably requests.
- (f) Purchaser, including any related Person or any agents of Purchaser, covenants to exclusively obtain all of its supply of any vaccine of Pfizer, BioNTech or their respective Affiliates intended for the prevention of the human disease COVID-19 (including the Product) either (i) directly from Pfizer or from Pfizer through the COVAX Facility, or (ii) from a Third Party, whether by donation, resale or otherwise, only if Purchaser has obtained Pfizer's prior written consent. Any breach of this Section 2.1(f) shall be deemed an uncurable material breach of this Agreement, and Pfizer may immediately terminate this Agreement pursuant to Section 6.2. For clarity, nothing in this Section 2.1(f) shall prevent Purchaser from purchasing competing vaccine products of any Third Party.

2.2 Capacity.

Pfizer shall use Commercially Reasonable Efforts to build or obtain manufacturing capacity to be capable of manufacturing and supplying the Product to Purchaser in accordance with the provisions of this Agreement.

2.3 Purchase Orders.

- (a) On the Effective Date, Purchaser shall submit to Pfizer a legally binding and irrevocable Purchase Order(s) for Twenty million one thousand one hundred fifty (20,001,150) doses ("**Contracted Doses**") of the Product. Subject to Section 2.4(c) of this Agreement, Pfizer shall have the right, at its sole discretion, to update the Contracted Doses to the nearest possible number that is divisible by the Minimum Order Quantity.
- (b) The Purchase Order shall be provided together with Purchaser's order number, VAT number, and invoice address. Pfizer shall accept the Purchase Order conforming to the terms set forth in this Agreement in writing, and the confirmed Purchase Order shall be binding upon the Parties and subject to the terms and conditions set out in this Agreement.
- (c) The Purchaser may request additional doses during the Term of the Agreement through a legally binding and irrevocable Purchase Order(s), but only upon being advised that: (i) Pfizer has availability of supply of such additional requested doses (the "**Additional Order**") and (ii) Pfizer agrees, in its sole discretion, to allocate such Additional Order to Purchaser. Each Additional Order will be subject to the same terms and conditions set forth in the Agreement (and any subsequent amendments thereto), as applicable; provided such Additional Order must be placed during the Term of the Agreement. In such event, the doses subject to the

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accepted Additional Order shall be Contracted Doses. After submission to, and acceptance by, Pfizer of an Additional Order, Purchaser shall pay Pfizer such additional advance payment within thirty (30) days of the purchase order of such Additional Order in accordance with the terms of Section 3.2 ("**Additional Advance Payment**"). Purchaser shall pay such Additional Advance Payment, and Pfizer shall provide an updated Attachment B to reflect such Additional Order. Full payment of the Additional Advance Payment is a condition to supply any doses subject to the Additional Order. If any failure by Purchaser to pay Pfizer for the Additional Advance Payment results in a delay in delivery, the undelivered doses will be at the sole risk of Purchaser, and Pfizer shall have no liability to Purchaser regarding such delay or further inability to supply by Pfizer.

2.4 Delivery Schedule.

- (a) Pfizer shall deliver the Product Delivery at Place ("**DAP**") Incoterms 2020.
- (b) The Parties shall reasonably agree, in writing, on the location(s) (including number of locations) for delivery of shipments of Product ("**Place(s) of Destination**") within five (5) Business Days from the Effective Date for the first expected shipment of Product, and for any subsequent delivery, at least eight (8) weeks prior to shipment of the Product; provided that, in each case: (i) each Place of Destination meets the requirements set forth in Attachment D, and (ii) the Place(s) of Destination are serviced by a contracted transportation carrier of Pfizer, and (iii) each Place of Destination is an authorized location to receive the Product, evidence of which shall be presented to Pfizer on Purchaser's official letterhead and Purchaser shall provide any additional information, as reasonably requested by Pfizer in advance of delivery, to verify such authorization ("**Shipping Agent**"). Pfizer shall have the ability, acting reasonably, to restrict the number of Places of Destination where shipments of Product shall be delivered. However, the Parties agree that Purchaser shall have full liability and responsibility for any further transportation and distribution following delivery to Place of Destination that is not a point of use of the Product, including but not limited to ensuring compliance with Attachment D. For the purposes of this Section 2.4(b), Pfizer agrees that it shall provide the Purchaser with such information as Pfizer considers necessary for the Purchaser to comply with the provisions of this section, to the extent in Pfizer's control and/or possession at the time, including details on the proposed Shipping Agent as part of Pfizer's logistics planning information.
- (c) All shipment of Product shall be comprised of quantity of Product in increments of 195 vials/1170 doses ("**Minimum Order Quantity**"). Pfizer shall have the right to update such Minimum Order Quantity at its sole discretion from time to time upon notice to Purchaser.
- (d) Pfizer may deliver the Product by separate installments and shall use Commercially Reasonable Efforts to meet the estimated delivery schedule set out in Attachment B (the "**Interim Delivery Schedule**"), provided that no Product shall be shipped until Authorization is received and Purchaser is compliant, in Pfizer's discretion, with

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the terms and conditions of this Agreement. All deliveries shall be accompanied by the documentation specified in Attachment C (which may be updated from time to time by Pfizer upon notice to Purchaser), and shall be in accordance with, and subject to, the delivery specifications to be set forth in Attachment D (as may be updated from time to time by Pfizer upon notice to Purchaser) ("**Delivery Specifications**").

- (e) The Product shall be labelled and packaged in accordance with the packaging specifications to be set forth in Attachment E (which shall be populated following the Effective Date, but in any event before supply in line with the agreed Interim Delivery Schedule, and as may be updated from time to time by Pfizer upon notice to Purchaser) ("**Labelling and Packaging Specifications**").
- (f) If an Authorization is granted after 15 February 2021 but before 30 September 2021, then the Interim Delivery Schedule will be revised to add the period of time between 15 February 2021 and the date of the Authorization ("**Adjusted Delivery Schedule**"). In the event that the Authorization is granted prior to 15 February 2021, Pfizer has no obligation to accelerate shipment of Product.
- (g) If Authorization is received by 30 September 2021, but Pfizer is unable to deliver any Contracted Doses for technical or other reasons from the Facilities intended to produce the Contracted Doses under this Agreement, Pfizer agrees to use Commercially Reasonable Efforts to obtain supply of the Product from another location, subject to availability of supply.
- (h) If Authorization is received by 30 September 2021, but by 31 March 2022 Pfizer is unable to manufacture or deliver any Contracted Doses for technical or other reasons from any Facilities, Pfizer will have no obligation to deliver against the Interim Delivery Schedule, Adjusted Delivery Schedule or a Purchase Order.

2.5 Product Shortages.

- (a) If Authorization is received but there is insufficient supply to deliver the full number of Contracted Doses on the Interim Delivery Schedule (including the Adjusted Delivery Schedule), including to the extent any shortage is due to a requirement of Pfizer to divert available supply of the Product to another market, Pfizer shall work collaboratively to provide notice (and manage any communications associated with any Product shortages). Following receipt of such notification, Purchaser shall execute any instructions set out in the notice in a timely fashion (and in no event longer than 24 hours). Subject to the foregoing, including any requirement by Pfizer to divert Product to another market, Pfizer shall decide on necessary adjustments to the number of Contracted Doses and Interim Delivery Schedule due to the Purchaser to reflect such shortages based on principles to be determined by Pfizer under the then existing circumstances ("**Allocation**") which shall be set out in such notice. Purchaser shall be deemed to agree to any revision.

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- (b) Purchaser hereby waives all rights and remedies that it may have at Law, in equity or otherwise, arising from or relating to: (i) any failure by Pfizer to develop or obtain Authorization of the Product in accordance with the estimated dates described in this Agreement; or (ii) any failure by Pfizer to deliver the Contracted Doses in accordance with the Interim Delivery Schedule. In the event of an inconsistency between the provisions of this Section 2.5 (Product Shortages) and those of other sections of this Agreement, the provisions of this Section 2.5 (Product Shortages) shall control and supersede over those of other sections of this Agreement to the extent of such inconsistency.

2.6 Delivery Delays.

Under no circumstances will Pfizer be subject to or liable for any late delivery penalties.

2.7 Product Handling.

- (a) Pfizer shall use Commercially Reasonable Efforts to assure the Product is manufactured in accordance with material Specifications and cGMP.
- (b) Upon delivery of Product to Purchaser at the Place(s) of Destination and, to the extent applicable, for any onward distribution and/or transportation to a Place of Destination that is not a point of use of the Product, Purchaser shall store and handle the Product in the manner set forth in the Specifications, instructions on Attachment D and the instructions provided by Pfizer to ensure stability and integrity of the Product.
- (c) For the avoidance of doubt, Purchaser shall bear all expenses for use of the Product upon delivery by Pfizer at the Place(s) of Destination, including, but not limited to, those for storage of the Product and distribution and administration of the Product (if applicable) in South Africa.
- (d) Purchaser shall be solely responsible and liable for the proper storage, handling, distribution, transportation, administration, use and disposal of the Product in South Africa following delivery of the Product to Purchaser or its designee at the Place(s) of Destination. Without prejudice to the generality of the foregoing, Purchaser shall ensure that: (a) recipients of the Product shall follow the return and disposal instructions in Attachment F (which may be updated from time to time by Pfizer upon notice to Purchaser) when disposing of open and unused Product and its packaging components; and (b) such return and disposal complies with Laws regarding pharmaceutical waste, medical waste, or hazardous waste, as appropriate. Attachment F provides the ability for Pfizer to charge Purchaser for the cost of such packaging components, without limiting any other remedies available to Pfizer, in the event that Purchaser fails to comply with the return requirement set forth in Attachment F.
- (e) Purchaser shall be responsible for and shall ensure that any equipment used to deliver the Product, for example the shipper(s) and monitoring device(s), are stored in an appropriate clean and secure location to protect and maintain the functionality

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of such equipment (in controlled conditions, with no exposure to weather or pests, etc.). Within thirty (30) days of delivery of the Product at the Place(s) of Destination, subject to Section 4.4(b), Purchaser shall organize safe return of all such equipment, including the shipper and monitoring device, in accordance with Attachment F.

- (f) Pfizer may provide Safety Data Sheets and other information to Purchaser to assist Purchaser to develop processes and procedures, including training, to handle the Product and Product Materials in a safe manner and in compliance with Laws, including occupational health and safety Laws. Purchaser represents and warrants that Purchaser has and shall ensure that all recipients of the Product and Product Materials have the requisite expertise to develop and implement appropriate procedures and training programs to enable proper handling of the Product and Product Materials in a safe and lawful manner.

2.8 Title to Product, Risk of Loss.

- (a) Title to the Product, and risk of loss or damage shall pass to Purchaser at the Place(s) of Destination in accordance with Section 2.4(b). Pfizer reserves the right to change any supply point (being the point from which Pfizer shall supply the Product) by giving Purchaser adequate notice as acceptable under the Laws. Prices are quoted on DAP Place(s) of Destination basis in effect at the time and Place(s) of Destination. For purposes of this Agreement, the terms DAP shall have the meaning ascribed thereto in INCOTERMS 2020 as published by the ICC, Paris, France.
- (b) Pfizer shall be the importer of the Product in front of the relevant customs authorities in the Territory ("**Importer of Record**") and shall be responsible to obtain, where applicable, any import license or other official authorization and to carry out all customs formalities for the import of the Product in South Africa. Pfizer shall also be responsible to pay, where applicable, all duties, taxes and other charges, as well as the costs of carrying out customs formalities payable upon import of the Products. Given the nature of the Product, Purchaser undertakes to support Pfizer and its appointed Shipping Agent to swiftly clear the Product from the relevant customs authorities within twenty four (24) hours from the arrival of the Product at the customs authorities, and to obtain any waivers required; and Purchaser acknowledges that any delay in such clearance process might affect the overall shelf-life of the Products. Both Parties confirm that the required documents for customs clearance of the Product are indicated in Attachment H of this Agreement. Without prejudice to the generality of the foregoing, Purchaser undertakes to take appropriate measures and exercise its reasonable efforts to ensure the smooth and efficient passage of the Product through the port of entry in accordance with applicable Laws of South Africa.
- (c) Purchaser shall be responsible for the unloading of such Product from the transportation carrier. For the sake of clarity, Purchaser shall be responsible for unloading the Product from the transportation carrier and Pfizer's liability shall

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cease, and risk of loss or damage shall transfer, upon carrier's arrival at the Place(s) of Destination and immediately prior to the unloading of the Product. Without prejudice to the generality of the foregoing, following delivery of the Product to Purchaser, Purchaser shall be fully responsible for and liable in relation to any Product wastage, and for ensuring appropriate disposal in accordance with Sections 2.7(d) and 2.7(e). Pfizer will not be liable for any risks of loss or damage to the Product after delivering the Product at the Place(s) of Destination, including without limitation, temperature excursions, theft, or damages of any kind to the Product.

- (d) Without prejudice to Section **Error! Reference source not found.**, Purchaser acknowledges that Pfizer will not, in any circumstances, accept any returns of Product (or any dose). In particular, following receipt of the Product in accordance with this Section 2.8, no Product returns may take place under any circumstances (inclusive of future changes in stock, expired Products, changes in Product allocation, delivery, demand or new product launch).

3. **PRICE AND PAYMENT.**

3.1 **Purchase Price.**

Purchaser shall purchase the Product from Pfizer at the price per dose set out in Attachment B, excluding VAT (the "**Price**") and in accordance with the terms of this Agreement. The Price shall include all of Pfizer's internal costs associated with the manufacturing and delivery of the Product to the Place(s) of Destination in accordance with this Agreement. The Price shall be firm for the Term.

3.2 **Invoices and Payment.**

- (a) In partial consideration of the Contracted Doses, on the Effective Date, Pfizer shall invoice Purchaser, and Purchaser shall pay, an upfront payment of Forty Million two thousand three hundred US Dollars (USD 40,002,300) (calculated as two (2) USD per dose multiplied by the Contracted Doses) (the "**Advance Payment**"). Purchaser shall pay the Advance Payment within thirty (30) days from the Effective Date; provided, however, that Pfizer shall have no obligation to deliver any Product until receipt of the Advance Payment by Pfizer. All amounts due hereunder shall be converted to South African Rand which shall be determined based on the exchange rate used by Bloomberg BFIX at the close of business on the day prior to the invoice date 4:00 pm London time.
- (b) Pfizer shall invoice Purchaser for the remainder of the Price for the Contracted Doses (the "**Delivery Price**") in advance of each calendar quarter during the Term. Purchaser shall pay all undisputed (in good faith) amounts on the first (1st) Business Day of the first (1st) month of each calendar quarter for the Batch of Contracted Doses to be delivered in such calendar quarter, or in the case of Batch 1, within five (5) Business Days of the issuance of Conditional Approval. All such amounts shall be due prior to delivery of the volume of anticipated doses to be delivered in

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such delivery, which Delivery Price shall be equal to the difference of the Price for the number of the Contracted Doses being delivered in such delivery and an apportionment of the Advance Payment based on the number of Contracted Doses in such delivery. Full payment of each prior shipment is a condition to Pfizer's obligation to supply any future shipment. If any failure by Purchaser to pay Pfizer for the Contracted Doses results in a delay in delivery, the undelivered doses will be at the sole risk of Purchaser, and Pfizer shall have no liability to Purchaser regarding such delay or further inability to supply by Pfizer.

- (c) Invoices shall be provided to the Purchaser at the address set forth in the preamble of this Agreement. Pfizer shall include the following information on all invoices: the Purchase Order number and billing address; and shall also include, where applicable, the type description, part number (if any) and number of Contracted Doses delivered; the delivery date; the actual date of shipment; the Price; any applicable taxes or other charges provided for in the Purchase Order; and the ship-to destination.

3.3 Method of Payment.

- (a) All amounts due under this Agreement shall be paid by the Purchaser to Pfizer in accordance with the provisions of Section 3.2(a) and 3.2(b). Payment shall be remitted by wire transfer in immediately available funds to the Pfizer bank account indicated below. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day. Any dispute by Purchaser of an invoice shall be provided to Pfizer in writing (along with substantiating documentation and a reasonably detailed description of the dispute) within five (5) Business Days from the date of such invoice. Purchaser will be deemed to have accepted all invoices for which Pfizer does not receive timely notification of disputes, and shall pay all undisputed amounts due under such invoices within the period set forth in this Section 3.3(a). The Parties shall seek to resolve all such disputes expeditiously and in good faith.

BANK NAME:
BRANCH:
BRANCH NUMBER:
CURRENCY:
ACCOUNT NUMBER:
SWIFT CODE:

Citibank
Johannesburg
350005
ZAR
[REDACTED]
CITIZAJX

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4 Sept 2023

- (b) Any amount required to be paid by a Party hereunder which is not paid on the date due shall bear interest, to the extent permitted by law, at five percent (5%) above South African Reserve Bank Repo Rate (or any successor to such rate) effective for the date such payment was due, as reported in the Wall Street Journal (<https://www.wsj.com/market-data/bonds>). Such interest shall be computed on the basis of a year of three hundred sixty (360) days for the actual number of days payment is delinquent. In addition to all other remedies available under this

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Agreement or at Law, if Purchaser fails to pay any undisputed amounts when due under this Agreement, Pfizer may (i) suspend the delivery of the Product or (ii) terminate this Agreement.

- (c) Purchaser shall not, and acknowledges that it will have no right, under this Agreement, any Purchase Order, any other agreement, document or Law, to withhold, offset, recoup or debit any amounts owed (or to become due and owing) to Pfizer, whether under this Agreement or otherwise, against any other amount owed (or to become due and owing) to it by Pfizer or a Pfizer Affiliate.

3.4 Taxes.

It is understood and agreed between the Parties that any payments made and other consideration provided under this Agreement are exclusive of any VAT or similar tax and all other taxes which are incurred as a result of manufacturing and supplying the Product (including, without limitation, custom duties, levies and charges and all local taxes) ("**Taxes**"), which shall be added thereon as applicable. Where Taxes are properly chargeable on a payment made or consideration provided under this Agreement, the Party making the payment or providing the consideration will pay the amount of Taxes in accordance with the laws and regulations of the country in which the Taxes are chargeable.

In the event any payments made pursuant to this Agreement become subject to withholding taxes under the laws or regulation of any jurisdiction, the Party making such payment shall deduct and withhold the amount of such taxes for the account of the payee to the extent required by Law and such amounts payable to the payee shall be reduced by the amount of taxes deducted and withheld. Any such withholding taxes required under Law to be paid or withheld shall be an expense of, and borne solely by, the payee.

4. MANUFACTURING STANDARDS AND QUALITY ASSURANCE.

4.1 Manufacturing Standards.

Pfizer shall manufacture and supply the Product in material accordance with the Specifications and cGMP. Such Specifications may be revised through written notification by Pfizer to Purchaser to conform to the Authorization or changes to the manufacturing or distribution of the Product.

4.2 Legal and Regulatory Filings and Requests.

- (a) Pfizer shall (a) comply with all regulatory or government licenses and permits, and (b) comply with all cGMP with respect to its manufacturing and packaging processes, the Facilities or otherwise, to permit the performance of its obligations hereunder.
- (b) Pfizer shall ensure that all Product is properly labelled and packaged in accordance with the applicable Authorization, Specifications and material cGMP standards.

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- (c) Prior to delivery, Pfizer shall comply with all conditions (in the relevant timescales) set out in the Authorization; provided, however, that Purchaser shall grant, or obtain on Pfizer's behalf, all exemptions, exceptions, and waivers of country specific requirements for the Product granted or permitted by the Government authority (including but not limited to serialization, applicable laboratory or quality testing and/or marketing information form submission and approval), which requirements, absent an exemption, exception or waiver, would prevent Pfizer from supplying and releasing the Product in South Africa upon receipt of the Authorization. Purchaser acknowledges the Product will be supplied without serialization. Purchaser agrees to exercise its best efforts to cause the relevant Government authorities to facilitate the issuance of appropriate waivers and/or approvals in case of active serialization, track & trace, and/or 2D coding mandates within 24 hours. In order to maintain an efficient supply chain for the manufacture, release and supply of the Product, Pfizer will be solely responsible for determination of manufacturing and testing locations and will conduct testing in accordance with the Authorization. The Parties have agreed that Pfizer will not be required to respond to, or provide Product or method transfer in connection with, requests for local testing, requests for lot release protocols or requests for registration samples in this Agreement or in subsequent amendments or extensions of this Agreement.
- (d) Due to the current pandemic situation and the fact that any anticipated Authorization will be initially under a Conditional Approval in conjunction with the agreement that Pfizer will only supply the Purchaser directly, the Purchaser agrees to the below conditions as a condition precedent to supply of the Product. Purchaser will issue, or make any other Government authority to issue, any necessary approvals to ensure enforceability of the same:
- i. During the Term, Pfizer will not be required by the Purchaser or any other Government authority to appoint a local agent or distributor, including without limitation, for purposes of selling or supplying the Product or applying for the Authorization, unless Pfizer, in its discretion during the Term, appoints a local agent or distributor. For the avoidance of doubt, Purchaser also agrees that as of the Effective Date (1) Pfizer or any of its Affiliates will be the entity applying and submitting any regulatory files required for issuance of the Conditional Approval; and (2) the Conditional Approval will be issued under Pfizer's or any of its Affiliates name.
 - ii. During the Term, Pfizer will not be required by the Purchaser or any other Government authority to submit a price reference certificate for purposes of applying for the Conditional Approval or otherwise.
 - iii. In the event that during the Term a third party is the applicant or holder of the Authorization, any obligation on Pfizer under this Agreement shall be taken as a requirement on Pfizer to use Commercially Reasonable Efforts to procure the compliance of such third party Authorization applicant or

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holder with such obligations to the extent necessary to ensure the relevant obligation is fully met.

4.3 Quality Tests and Checks.

Pfizer shall perform all bulk holding stability, manufacturing trials, validation (including, but not limited to, method, process and equipment cleaning validation), raw material, in-process, bulk finished product and stability (chemical or microbial) tests or checks required to assure the quality of the Product and tests or checks required by the Specifications and cGMP.

4.4 Rejection of Product; Disposal of Rejected Shipments.

- (a) Purchaser may reject any Product that does not materially conform to Specifications or cGMP ("**Non-Complying Product**") by providing written notice of rejection to Pfizer and setting out detailed reasons for such rejection: (i) immediately (and in no event more than 24 hours) upon delivery of such Non-Complying Product to Purchaser; or (ii) immediately and in no event more than 24 hours upon its first knowledge of a Latent Defect. Pfizer shall respond to any rejection and notice of Non-Complying Product from Purchaser in a timely manner. For clarity, Purchaser shall not be entitled to reject any Product based on service complaints unless a Product does not materially conform to Specifications or cGMP.
- (b) Pfizer shall conduct an analysis of the causes of any such quality-related complaint, and shall report to Purchaser on any corrective action taken. If Pfizer's inspection and testing reveals, to Pfizer's reasonable satisfaction, that such items of the Product are Non-Complying Product and that any such non-conformity or defect has not been caused or contributed to by any abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Pfizer, Pfizer shall use Commercially Reasonable Efforts to replace such Non-Complying Product as soon as practicable at no additional charge to Purchaser. In such circumstances, Pfizer will further arrange for reverse logistics for Product collection and manage the destruction of the Non-Complying Product. Until collection, Purchaser shall store and maintain the relevant Non-Complying Product in appropriately secure locations and in accordance with the manufacturers' specifications. Notwithstanding any other provision of this Agreement, this Section 4.4(b) contains Purchaser's sole and exclusive remedy for Non-Complying Product. The provisions of this Section 4.4 (Rejection of Product; Disposal of Rejected Shipments) shall survive termination or expiration of this Agreement.

4.5 Maintenance and Retention of Records.

- (a) Each Party shall maintain detailed Records with respect to its activities under this Agreement as required by Laws.
- (b) Purchaser will maintain a quality system for receipt, inspection, storage, traceability to further delivery points, and recall activities. If Purchaser does not

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have a quality system for the activities defined, Pfizer may share details of a proposed quality system for Purchaser's compliance.

4.6 Diversion Issues.

All Product delivered to Purchaser shall be: (a) stored securely by Purchaser; and (b) distributed by Purchaser only in South Africa in a secure manner appropriate to the transportation route and destination, in each case (a) and (b) to guard against and deter theft, diversion, tampering, substitution (with, for example, counterfeits) resale or export out of South Africa, and to protect and preserve the integrity and efficacy of the Product. Purchaser shall promptly notify Pfizer Quality Department ProductComplaintsZAF@pfizer.com and Pfizer Adverse Events Reporting by email ZAF.AEReporting@pfizer.com within forty-eight (48) hours (with follow up in writing in line with the notice provisions of this Agreement) if at any time Purchaser believes that any of the Product has been stolen, diverted, tampered with, substituted, or otherwise subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Pfizer. The notice shall provide all information relating to the Product diversion, including, but not limited to, detailed information including the date, time, location, number, batch number(s), expiration date, circumstances, and contact person(s) information. Purchaser shall cooperate with Pfizer or its designee, upon Pfizer's request, to cooperate in connection with such Product diversion. Purchaser shall not directly or indirectly resell, export, transfer, donate, or otherwise distribute Product outside of the Territory without Pfizer's prior written consent.

4.7 Recalls.

Purchaser shall be responsible for all costs of any recall or market withdrawal of the Product in South Africa, including, without limitation, reasonable costs incurred by or on behalf of Pfizer and its Affiliates or BioNTech and its Affiliates, except to the extent that such recall or market withdrawal results from willful misconduct (being a wrongful act, willingly and knowingly committed without legal or factual justification, with the intent to cause the harmful effects) on the part of, Pfizer or any of its Affiliates or any of their respective Personnel, in which event Pfizer will be responsible solely for: (a) any reasonable and documented out of pocket expenses directly incurred by Purchaser to third parties in implementing such recall or market withdrawal; and (b) replacing, at Pfizer's expense, the Product which has to be recalled.

5. REPRESENTATIONS & WARRANTIES.**5.1 Mutual Representations and Warranties.** Pfizer and Purchaser each represents and warrants to each other the following:

- (a) Organization and Authority. It has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement, including, in the case of Purchaser, that all necessary authorizations and approvals have been obtained by Purchaser to authorize its performance of all of its

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obligations contained herein, that Purchaser has the authority to bind the Republic of South Africa and that Purchaser has exercised that authority to bind the Republic of South Africa as to each of the provisions and terms and conditions set forth in this Agreement;

- (b) No Conflicts or Violations. The execution and delivery of this Agreement by such Party and the performance of such Party's obligations hereunder (i) do not conflict with or violate any Laws existing as of the Effective Date and applicable to such Party and (ii) do not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such Party existing as of the Effective Date; and
- (c) Valid Execution. Such Party is duly authorized to execute and deliver this Agreement, and the Person executing this Agreement on behalf of such Party is duly authorized to execute and bind such Party to the terms set forth herein.

5.2 Warranties of Pfizer.

Pfizer warrants to Purchaser that:

- (a) At the time of delivery, the Product (except for any non-compliance or failure to meet the relevant standard or requirement that could not be reasonably discovered given the state of medical, scientific or technical knowledge at the time when Pfizer delivered the Product):
 - (i) complies in a material manner with the relevant Specifications; and
 - (ii) has been manufactured in material accordance with current Good Manufacturing Practices.
- (b) Subject to Pfizer's disclaimer of non-infringement of Intellectual Property rights of a third party (at Section 5.4(a) and (b) below), it has good title to the Product delivered to Purchaser pursuant to this Agreement and shall pass such title to Purchaser free and clear of any security interests, liens, or other encumbrances.
- (c) The execution, delivery and performance of this Agreement by Pfizer will not violate any agreement or instrument to which Pfizer is a party.

5.3 Anti-Bribery/Anti-Corruption and Global Trade Controls.

- (a) The Parties represent and warrant that, beyond the mutual consideration set forth in this Agreement, neither they nor their agents have provided or requested, or will provide or request, any additional incentive or benefit to or from the other Party or its agents to induce either Party to enter this Agreement or perform any part of this Agreement.
- (b) Pfizer has not made, and will not make, in the performance of this Agreement directly or indirectly any payment, offer, promise, or authorization of payment of money or anything of value to a Government official, political party, candidate for

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political office, or any other Person, and has not sought and will not seek improperly or corruptly to influence any Government official, political party, candidate for political office, or any other Person, in order to gain an improper business advantage.

- (c) The Parties will comply with applicable economic sanctions, import, and export control laws, regulations, and orders in the performance of this Agreement.
- (d) Activities performed under this Agreement will not involve Restricted Parties (defined as the list of sanctioned parties maintained by the United Nations; the Specially Designated Nationals List and the Sectoral Sanctions Identifications List, as administered by the U.S. Department of the Treasury Office of Foreign Assets Control; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; the entities subject to restrictive measures and the Consolidated List of Persons, Groups and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy; and similar lists of restricted parties maintained by relevant governmental entities).
- (e) Notwithstanding any other provision of this Agreement, Pfizer shall not be required to take or refrain from taking any action prohibited or penalized under the laws of the United States or any applicable non-United States jurisdiction, including, without limitation, the antiboycott laws administered by the U.S. Commerce and Treasury Departments.

5.4 No Other Warranty.

Except to the extent set out expressly in this Agreement, all conditions, warranties or other terms which might have effect between the Parties or be implied or incorporated into this Agreement (whether by statute, common law or otherwise) are hereby excluded to the fullest extent permitted by Laws. Without prejudice to the general nature of the previous sentence, unless this Agreement specifically states otherwise and to the maximum extent permitted by Law, Pfizer expressly disclaims any representations or warranties with respect to the Product, including, but not limited to, any representation, warranties or undertaking as to (a) non-infringement of Intellectual Property rights of any third party, (b) that there is no requirement to obtain a license of third party Intellectual Property rights to enable the use or receipt of the Product, (c) merchantability, or (d) fitness for a particular purpose.

5.5 Purchaser Acknowledgement.

Purchaser acknowledges that the Vaccine and materials related to the Vaccine, and their components and constituent materials are being rapidly developed due to the emergency circumstances of the COVID-19 pandemic and will continue to be studied after provision of the Vaccine to Purchaser under this Agreement. Purchaser further acknowledges that the long-term effects and efficacy of the Vaccine are not currently known and that there may be adverse effects of the Vaccine that are not currently known. Further, to the extent applicable, Purchaser acknowledges that the Product shall not be serialized.

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This Agreement shall commence on the Effective Date and shall continue until the later of (a) delivery of the Contracted Doses of the Product under the accepted Purchase Order submitted on the Effective Date, and (b) twenty-four (24) months from the Effective Date, unless extended or terminated pursuant to this Section 6 (Term; Termination) or the mutual written agreement of the Parties ("**Term**").

6.2 Termination for Cause.

Either Party may terminate this Agreement immediately upon written notice to the other Party in the event of a material breach by the other Party of any term of this Agreement, which breach remains uncured for thirty (30) days following written notice to the other Party of such material breach. Notwithstanding the foregoing, if such material breach, by its nature, cannot be cured, the terminating Party may terminate this Agreement immediately upon written notice to the other Party. In the event that this Agreement is terminated by Pfizer under this Section 6.2, Purchaser shall pay within thirty (30) days of the date of notice of termination of this Agreement the full Price for all Contracted Doses less amounts already paid to Pfizer as of such date.

6.3 Mutual Termination Rights.

(a) In the event: (i) the Authorization has not been obtained in the Territory by 30 September 2021 (except in a case where such event is mainly or solely attributable to Purchaser or any ministry or secretary of the Government of the Republic of South Africa) Pfizer has supplied to Purchaser no doses of Product by 30 September 2021, subject to the extensions set forth in Section 2.4 (Delivery Schedule), or (ii) Pfizer is unable to supply all of the Contracted Doses by December 31, 2022, then either Party may terminate this Agreement upon written notice to the other Party. Purchaser may invoice Pfizer for a refund of fifty percent (50%) of the Advance Payment for the Contracted Doses not delivered (as determined ratably for the doses not delivered) except for cases where the cause of the termination is mainly or solely attributable to Purchaser. In the event this Agreement is terminated pursuant to this Section 6.3, the return of fifty percent (50%) Advance Payment shall be Purchaser's sole and exclusive remedy for the failure to deliver any Contracted Doses.

6.4 Termination in Event of Insolvency.

In the event that Pfizer: (a) becomes insolvent, or institutes or has instituted against it a petition for bankruptcy or is adjudicated bankrupt; or (b) executes a bill of sale, deed of trust, or a general assignment for the benefit of creditors; or (c) is dissolved or transfers a substantial portion of its assets to a third party (excluding any of Pfizer's Affiliates); or (d) has a receiver appointed for the benefit of its creditors, or has a receiver appointed on account of insolvency; then Pfizer shall immediately notify Purchaser of such event and Purchaser shall be entitled to terminate this Agreement.

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- (a) Upon expiry or termination of this Agreement for any reason:
 - (i) Purchaser shall pay any sums owed to Pfizer pursuant to this Agreement within thirty (30) days of the date of invoice for the same; and
 - (ii) each Party shall use Commercially Reasonable Efforts to mitigate both (1) the damages that would otherwise be recoverable from the other pursuant to this Agreement, and (2) any costs, fees, expenses or losses that may be incurred by a Party, or for which a Party may be responsible, under this Agreement, by taking appropriate and reasonable actions to reduce or limit the amount of such damages, costs, fees, expenses or losses.
- (b) The termination or expiration of this Agreement shall not affect the survival and continuing validity of Sections 1, 2.1(b)-(d), 2.5(b), 2.6, 2.7(b)-(e), 2.8, 3.1, 3.3, 3.4, 4.4, 4.5, 4.6, 4.7, 5.4, 5.5, 6.2 (final sentence), 6.5, 7, 8, 9.2, 9.3, 9.4, 9.5, 9.6, 10, 11, 12 or of any other provision which is expressly or by implication intended to continue in force after such termination or expiration.
- (c) Expiry or termination of this Agreement for any reason shall be without prejudice to either Party's other rights and remedies or to any accrued rights and liabilities as the date of such expiry or termination; provided that (i) Pfizer shall have no liability for any failure by Pfizer to develop or obtain Authorization of the Product in accordance with the estimated dates described in this Agreement and (ii) even if the Product is successfully developed and Pfizer obtains Authorization, Pfizer shall have no liability for any failure to deliver Contracted Doses in accordance with any estimated delivery dates set forth herein.

7. INTELLECTUAL PROPERTY.

Pfizer US will be the sole owner of all Intellectual Property it generates during the development, manufacture, and supply of the Product or otherwise related to the Product. Neither Party will gain any rights of ownership to or use of any property or Intellectual Property owned by the other (whether by virtue of this Agreement, by implication or otherwise).

8. INDEMNIFICATION.

- 8.1 Indemnification by Purchaser. Purchaser hereby agrees to indemnify, defend and hold harmless Pfizer, BioNTech, each of their Affiliates, contractors, sub-contractors, licensors, licensees, sub-licensees, distributors, contract manufacturers, services providers, clinical trial researchers, third parties to whom Pfizer or BioNTech or any of their respective Affiliates may directly or indirectly owe an indemnity based on the research, development, manufacture, distribution, commercialization or use of the Vaccine, and each of the officers, directors, employees and other agents and representatives, and the respective predecessors, successors and assigns of any of the foregoing ("**Indemnitees**"), from and against any and all suits, claims, actions, demands, losses, damages, liabilities, settlements,

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penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' and other counsels' fees and other expenses of an investigation or litigation), whether sounding in contract, tort (delict), intellectual property, or any other theory, and whether legal, statutory, equitable or otherwise by any natural or legal person (collectively, "Losses") caused by, arising out of, relating to, or resulting from the Vaccine, including but not limited to any stage of design, development, investigation, formulation, testing, clinical testing, manufacture, labeling, packaging, transport, storage, distribution, marketing, promotion, sale, purchase, licensing, donation, dispensing, prescribing, administration, provision, or use of the Vaccine, any information, instructions, advice or guidance provided by Pfizer, or BioNTech or any of their respective Affiliates and relating to the use of the Vaccine, or any processing or transfer of anyone's personal information processed and transferred by Purchaser to the Indemnitees ("Covered Activities").

- 8.2 Assumption of Defense by Purchaser. The Indemnitee(s) shall notify Purchaser of Losses for which it is seeking indemnification pursuant hereto ("**Indemnified Claims**"). Upon such notification, the Indemnitee(s) shall have the option to conduct and control the defense or to require Purchaser to promptly assume conduct and control of the defense of such Indemnified Claims with counsel acceptable to Indemnitee(s), whether or not the Indemnified Claim is rightfully brought; provided, however, that Purchaser shall provide advance notice in writing of any proposed compromise or settlement of any Indemnified Claim and in no event may Purchaser compromise or settle any Indemnified Claim without Indemnitee(s)'s prior written consent, such consent not to be unreasonably withheld. Indemnitee(s) shall reasonably cooperate with Purchaser in the defense of any Indemnified Claims conducted and controlled by Purchaser.
- 8.3 Participation Rights. Each Indemnitee shall have the right to retain its own counsel and to participate in Purchaser's defense of any Indemnified Claim, at its own cost and expense except as set forth below. A failure by the Indemnitee(s) to give notice of Indemnified Claims or to offer to tender the defense of the action or suit pursuant to this Section 8.3 (Participation Rights) shall not limit the obligation of Purchaser under this Section 8 (Indemnification), except and only to the extent Purchaser is actually prejudiced thereby.
- 8.4 Assumption of Defense. Notwithstanding the foregoing and without prejudice to Section 12.5, Pfizer, directly or through any of its Affiliates or through BioNTech, may elect to assume control of the defense of an Indemnified Claim (a) within thirty (30) days of Indemnitee's notice to Purchaser of the Indemnified Claim or (b) at any time if, in Pfizer's sole discretion: (i) Purchaser fails to timely assume the defense of or reasonably defend such Indemnified Claim(s) in good faith to the satisfaction of Pfizer (or Pfizer's Affiliates and BioNTech); or (ii) Pfizer believes (or any of Pfizer's Affiliates or BioNTech believe) in good faith that a bona fide conflict exists between Indemnitee(s) and Purchaser with respect to an Indemnified Claim hereunder. Upon written notice of such election, Pfizer shall have the right to assume control of such defense (directly or through either one of its Affiliates or BioNTech), and Purchaser shall pay (as incurred and on demand), all Losses, including, without limitation, the reasonable attorneys' fees and other expenses incurred by Indemnitee(s), in connection with the Indemnified Claim. In all events, Purchaser shall cooperate with Indemnitee(s) in the defense, settlement or compromise of the Indemnified Claim.

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- 8.5 Privileges and Immunities. Purchaser acknowledges that its indemnification obligations under this Agreement are (a) expressly in addition to, and not limited by, any Privileges and Immunities, and (b) do not waive or relinquish Indemnitees' rights to any Privileges and Immunities.
- 8.6 Costs. Costs and expenses, including, without limitation, fees and disbursements of counsel, incurred by the Indemnatee(s) in connection with any Indemnified Claim shall be reimbursed on a quarterly basis by Purchaser, without prejudice to Purchaser's right to refund in the event that Purchaser is ultimately held in a final, non-appealable judgment or award to be not obligated to indemnify the Indemnatee(s).

9. **INSURANCE AND LIABILITY.**

9.1 Insurance.

During the Term, Pfizer or its Affiliates shall self-insure or procure and maintain such types and amounts of general liability insurance to cover liabilities related to its activities under this Agreement as is normal and customary in the pharmaceutical industry generally for companies that are similarly situated and providing similar manufacturing and supply services. For absolute clarity, this shall not include, nor constitute, product liability insurance to cover any third party/patients claims and such general liability insurance shall be without prejudice to Purchaser's indemnification obligation as set out in this Agreement.

9.2 Limits on Liability.

- (a) Subject to the exclusions set forth in Section 9.3, in no circumstances shall (i) either Party be liable to the other Party or its Affiliates, whether arising in tort (including, without limitation, negligence), contract or otherwise, for any indirect, special, consequential, incidental or punitive damages, whether in contract, warranty, tort, negligence, strict liability or otherwise arising out of or relating to this Agreement, the transactions contemplated therein or any breach thereof (whether or not reasonably foreseeable and even if the first Party had been advised of the possibility of the other Party incurring such loss or type of loss), and (ii) in the case of Pfizer and its Affiliates, in no event shall Pfizer be liable to Purchaser for any direct damages except to the extent such direct damages were a result of a material breach of a representation or warranty by Pfizer under this Agreement that directly and solely caused the damage. In no instance shall Pfizer and its Affiliates be liable to Purchaser (whether arising in warranty, tort (including, without limitation, negligence), contract, strict liability or otherwise) for any liabilities of Purchaser to any third party, including, without limitation, through contribution, indemnity, or for any claim for which Purchaser would have to indemnify Pfizer if that claim were brought directly against Pfizer.
- (b) The aggregate liability of Pfizer and its Affiliates (whether arising in warranty, tort (including, without limitation, negligence, contract, strict liability or otherwise) arising out of, under or in connection with this Agreement shall not exceed a sum

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equivalent to one hundred percent (100%) of the total Price actually received by Pfizer under this Agreement for the Contracted Doses.

9.3 Excluded Liability.

Nothing in this Agreement excludes or limits the liability of either Party for:

- (i) fraud or fraudulent misrepresentation;
- (ii) any breach of Section 10 (Confidential Information);
- (iii) in the case of Purchaser, the indemnity given by it under Section 8 (Indemnification); or
- (iv) in the case of Purchaser, failure to pay the Price for the Product or any other sums properly owing to Pfizer under this Agreement.

9.4 Waiver of Sovereign Immunity. Purchaser, on behalf of itself and the Republic of South Africa, expressly and irrevocably waives any right of immunity which either it or its assets may have or acquire in the future (whether characterized as sovereign immunity or any other type of immunity), including any assets controlled by any agency, instrumentality, central bank, or monetary authority of the Republic of South Africa as specified by 28 U.S.C. § 1611 in respect of any arbitration pursuant to Section 12.2 (Arbitration) or any other legal procedure initiated to confirm or enforce any arbitral decision, order or award, or any settlement in connection with any arbitration pursuant to Section 12.2 (Arbitration), whether in the Republic of South Africa or any other foreign jurisdiction, including but not limited to immunity against service of process, immunity of jurisdiction, immunity against any judgment rendered by a court or tribunal (including any interim award or decision), immunity against any order to enforce the judgment, and immunity against precautionary seizure of any of its assets. Purchaser, on behalf of itself and the Republic of South Africa, further covenants and agrees not to assert any such immunity in any proceeding in connection with this Agreement. Purchaser, on behalf of itself and the Republic of South Africa expressly and irrevocably submits to the jurisdiction of the courts of New York, or any other court of competent jurisdiction, for the purposes of enforcing any arbitral decision, order or award, or any settlement in connection with any arbitration pursuant to Section 12.2 and represents and warrants that the person signing this Agreement on its behalf has actual authority to submit to such jurisdiction. Purchaser also expressly and irrevocably waives the application of any Law in any jurisdiction that may otherwise limit or cap its obligation to pay damages arising from or in connection with any Indemnified Claims. Purchaser represents and warrants that the person signing this Agreement on its behalf has actual authority to waive such immunity and bind Purchaser and the Republic of South Africa to the limitations of liability and liability waivers set forth herein.

9.5 Vaccine Compensation Program. Purchaser covenants and agrees that Purchaser shall, by no later than **April 30, 2021**, create, dedicate, and maintain a no-fault compensation fund sufficient to undertake and completely fulfil the indemnification obligations in the Definitive Agreement (the "**Dedicated Fund**"). Purchaser shall provide that any claim for damage, injury, or harm arising out of, relating to, or resulting from the development,

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administration, or use of the Vaccine in the Territory or supplied under this Definitive Agreement - whether occurring before or after the creation of the Dedicated Fund - shall be within the scope of, and eligible for compensation under, the Dedicated Fund.

9.6 Conditions Precedent to Supply.

- (a) Purchaser represents that it has and will continue to have adequate statutory or regulatory authority and adequate funding appropriation to undertake and completely fulfil the indemnification obligations and provide adequate protection to Pfizer and all Indemnitees from liability for claims and all Losses arising out of or in connection with the Vaccine or its use.
- (b) Purchaser hereby covenants, acknowledges, and agrees that the following are conditions precedent to supply of the Vaccine:
 - (i) Purchaser shall implement and maintain in effect such statutory or regulatory requirements or funding appropriation sufficient to meet its obligations in this Agreement prior to supply of the Product by Pfizer and thereafter shall maintain such statutory and regulatory requirement and funding appropriation, each as applicable, for so long as necessary to meet all of Purchaser's obligations under this Agreement, including, without limitation, any such obligations that, pursuant to Section 6.5, survive expiration or termination of this Agreement;
 - (ii) Purchaser shall implement and maintain the Dedicated Fund pursuant to Section 9.5 of this Agreement; and
 - (iii) Purchaser must demonstrate, in a manner satisfactory to Pfizer, that Pfizer and its affiliates will have adequate protection, as determined in Pfizer's sole discretion, from liability for claims arising out of or in connection with the Vaccine or its use, including but not limited to, that the Republic of South Africa will continue funding the Dedicated Fund to meet any and all indemnification obligations, and will provide as a condition precedent to the signing of this Agreement and supply of doses, documentation showing authorization for the indemnification obligations.
- (c) Purchaser acknowledges that (a) Pfizer's supply of Product hereunder is in reliance (without any duty of investigation or confirmation by or on behalf of Pfizer or its Affiliates), *inter alia*, on Purchaser's representations and covenants under this Section 9.6, Purchaser implementing and maintaining in effect the requirements and funding appropriation described in this Section 9.6 and the other representations and warranties made by Purchaser under this Agreement, and (b) in assessing the cost and pricing of the Vaccine pursuant to this Agreement, Pfizer took into account the above-mentioned indemnity and liability protections and accordingly consider such indemnity and liability protection as fundamental elements of this Agreement.

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- (d) For the avoidance of doubt, each of the requirements under this Section 9.6 must be satisfied before supply or continued supply of the Vaccine. The satisfaction of all such conditions precedent shall be determined by Pfizer, at its sole discretion. If any condition precedent is not satisfied, Pfizer may nonetheless elect to supply doses, at its sole discretion. Pfizer's partial performance under this Agreement, including any elective supply under this Section 9.6(d) shall not constitute waiver. If Pfizer determines in its sole discretion that fulfilment of any condition under this Section 9.6 lapses or otherwise becomes unsatisfactory, then Pfizer shall not be obligated to supply any further Vaccine

10. CONFIDENTIAL INFORMATION.**10.1 Non-Use and Non-Disclosure.**

Each Recipient shall, and shall cause its Representatives which have access to the Disclosing Party's Confidential Information to, maintain in strict confidence, and shall not disclose to any third party, all Confidential Information observed by or disclosed to it by or on behalf of the Disclosing Party pursuant to this Agreement. Each Recipient shall not use or disclose such Confidential Information except as permitted by this Agreement. Each Recipient shall safeguard the confidential and proprietary nature of the Disclosing Party's Confidential Information with at least the same degree of care as it holds its own confidential or proprietary information of like kind, which shall be no less than a reasonable degree of care. The Recipient and its Representatives may use, copy, and make extracts of the Disclosing Party's Confidential Information only in connection with fulfilling its obligations under this Agreement and, without limiting the foregoing, shall not use the Confidential Information for the benefit of the Recipient or any of its Representatives, or for the benefit of any other Person. In the event that Recipient becomes aware of any breach of the obligations contained in this Section 10 (Confidential Information) by it or its Representatives, Recipient shall promptly notify the Disclosing Party in writing of such breach and all facts known to Recipient regarding same. In addition, if Recipient is required to disclose the Disclosing Party's Confidential Information in connection with any court order, statute or Government directive or requirement under any Law, Recipient shall give the Disclosing Party notice of such request, as soon as practicable, before such Confidential Information is disclosed so that the Disclosing Party may seek an appropriate protective order or other remedy, or waive compliance with the relevant provisions of this Agreement. If the Disclosing Party seeks a protective order or other remedy, Recipient shall promptly cooperate with and reasonably assist the Disclosing Party (at the Disclosing Party's cost) in such efforts. If the Disclosing Party fails to obtain a protective order or waives compliance with the relevant provisions of this Agreement, Recipient shall disclose only that portion of Confidential Information which its legal counsel determines it is required to disclose. Neither this Agreement nor the performance by either Party hereunder shall transfer to the Recipient any proprietary right, title, interest or claim in or to any of the Disclosing Party's Confidential Information (including, but not limited to, any Intellectual Property rights subsisting therein) or be construed as granting a license in its Confidential Information. Notwithstanding the foregoing, in all cases, (a) Purchaser may not disclose any of the financial or indemnification provisions contained in this Agreement, including, without limitation, the price per dose of Product or refundability of the Advance

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Payment or any information that could reasonably ascertain the price per dose of Product, without the prior written consent of Pfizer, and (b) Pfizer may disclose (i) Confidential Information to its Affiliates and BioNTech without prior written consent of Purchaser, and (ii) upon foreign government request, financial information relating to this Agreement, including cost per dose.

10.2 Recipient Precautions.

In order to comply with the obligations contained in this Section 10 (Confidential Information), Recipient shall take at least the following precautions: (a) Recipient shall exercise all reasonable efforts to prevent unauthorized employees and unauthorized third parties from gaining access to Confidential Information (and in no event less than reasonable care); (b) Recipient shall disclose Confidential Information only to such of its Representatives who have a need to know such Confidential Information to fulfill its obligations under this Agreement; provided, however, before any disclosure of Confidential Information, Recipient shall bind its Representatives receiving such Confidential Information to a written agreement of confidentiality at least as restrictive as this Agreement; and (c) prior to any disclosure, Recipient shall instruct its Representatives of the confidential nature of, and to maintain the confidentiality of, the Confidential Information. Recipient shall be responsible for all actions of its Representatives, including, without limitation, any breach of the terms hereof, regardless of whether or not such Representatives remain employed or in contractual privity with the Recipient.

10.3 Return of Confidential Information.

Upon the written request of the Disclosing Party, Recipient shall promptly return or, at the Recipient's option, delete or destroy all Confidential Information of the Disclosing Party (including, without limitation, all copies in whatever medium provided to, or made by, such recipient); provided, however, that, subject to the terms of this Agreement, (i) Recipient shall be entitled to retain one archival copy of such Confidential Information for purposes of determining its obligations under this Agreement; and (ii) Recipient shall not be required to destroy any computer files stored securely by the Recipients or its Affiliates that are created during automatic system back up, or retained for legal purposes by the legal division of the Recipient and its Affiliates, provided that such retained Confidential Information shall remain subject to the terms of this Agreement. Notwithstanding Recipient's return or destruction of Confidential Information, Recipient shall continue to be bound by its obligation of confidentiality and non-use under this Agreement.

10.4 Survival.

The provisions of this Section 10 (Confidential Information) shall survive the termination or expiration of the this Agreement for a period of ten (10) years, except with respect to any information that constitutes a trade secret (as defined under Law), in which case the recipient of such information will continue to be bound by its obligations under this Section 10 (Confidential Information) for so long as such information continues to constitute a trade secret, but in no event for a period of less than the ten (10)-year period specified above.

CONFIDENTIAL**11. NOTICES.**

Any notice required to be given hereunder shall be in writing and deemed to have been sufficiently given, (a) when delivered in person, (b) on the next Business Day after mailing by overnight courier service, or, where overnight courier service is unavailable, by other expedited delivery provided by a recognized express courier, or (c) when delivered via e-mail, provided the original is delivered via one of the preceding methods on or prior to the fifth (5th) Business Day after transmission of the e-mail, to the addresses specified below. Each notice shall specify the name and date of and parties to this Agreement.

If to Purchaser:

Dr AB Xuma Building
1112 Voortrekker Rd
Pretoria Townlands 351-JR
Pretoria
0187
Attention: The Director General

(As at the Effective Date, being:
Dr SSS Buthelezi
[REDACTED])

With a copy (which shall not constitute notice) to:

Dr AB Xuma Building
1112 Voortrekker Rd
Pretoria Townlands 351-JR
Pretoria
0187
Attention: Director, Affordable Medicines

(As at the Effective Date, being:
Khadija Jamaloodien
[REDACTED])

Redacted by HJI
4 Sept 2023

If to Pfizer:

Pfizer Laboratories (Pty) Ltd
85 Bute Lane
Sandton
Johannesburg
South Africa
2196
Attention: Country Manager

With a copy (which shall not constitute notice) to:

Pfizer Laboratories (Pty) Ltd
85 Bute Lane
Sandton
Johannesburg
South Africa
2196
Attention: Legal Director

Either Party may, by notice to the other Party, change the addresses and names given above.

12. MISCELLANEOUS.**12.1 Negotiations of Dispute.**

Prior to commencing any arbitration with respect to any controversy, claim, counterclaim, dispute, difference or misunderstanding arising out of or relating to the interpretation or application of any term or provisions of this Agreement, a Party shall provide written notice

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to the other Party of the existence of such dispute. The Parties shall for a period of thirty (30) days following such notice enter into good faith discussions and negotiations in an attempt to resolve such dispute. If, by the end of such thirty (30) day period, unless such period is extended by mutual written agreement of the Parties, the Parties have been unable to resolve such dispute, either Party may initiate arbitration in accordance with the procedures set forth in Section 12.2 (Arbitration). The procedures specified in this Section 12.1 (Negotiations of Dispute) are a precondition to the initiation of arbitration by a Party, in connection with disputes between the Parties arising from or related to this Agreement or a Purchase Order; provided, however, that a Party may seek a preliminary injunction or other preliminary judicial relief, without attempting to resolve such dispute as provided in this Section 12.1 (Negotiations of Dispute), if in its judgment such action is necessary to avoid irreparable harm. The Parties expressly and irrevocably submit to the jurisdiction of the courts of New York, New York, U.S.A. for any such injunctive relief. Further, the requirement to attempt to resolve a dispute in accordance with this Section 12.1 (Negotiations of Dispute) does not affect a Party's right to terminate this Agreement as provided in Section 6 hereof, and neither Party shall be required to follow these procedures prior to terminating the Agreement. The failure of either Party to participate in good faith discussions and negotiations in an attempt to resolve such dispute shall not delay the date by which the other Party may initiate arbitration under this Section 12.1 (Negotiations of Dispute).

12.2 Arbitration.

Any dispute, controversy, or claim arising out of, relating to, or in connection with this Agreement, including with respect to the formation, applicability, breach, termination, validity or enforceability thereof, or relating to arbitrability or the scope and application of this Section 12.2 (Arbitration), shall be finally resolved by arbitration. The arbitration shall be conducted by three arbitrators, in accordance with the Rules of Arbitration of the International Chamber of Commerce ("ICC"). The claimant shall nominate an arbitrator in its request for arbitration. The respondent shall nominate an arbitrator within thirty (30) days of the receipt of the request for arbitration. The two (2) arbitrators nominated by the Parties shall nominate a third arbitrator, in consultation with the Parties, within thirty (30) days after the confirmation of the later-nominated arbitrator. The third arbitrator shall act as chair of the tribunal. If any of the three (3) arbitrators are not nominated within the time prescribed above, then the ICC shall appoint the arbitrator(s). The seat of the arbitration shall be New York, New York, U.S.A. and it shall be conducted in the English language. The Parties undertake to maintain confidentiality as to all aspects of the arbitration, including its existence, content and result, and as to all submissions, correspondence and evidence relating to the arbitration proceedings. The foregoing sentence shall survive the termination of the arbitral proceedings. Notwithstanding the foregoing, a Party may disclose information relating to the arbitration proceedings to the extent that disclosure is required to protect or pursue a legal right related to the arbitration; enforce or challenge an award in bona fide legal proceedings; respond to a bona fide compulsory order or request for information of a governmental or regulatory body; make a disclosure required by securities laws, rules of a securities exchange, or other similar laws, regulations, or rules; or seek legal, accounting, or other professional services. The costs of the arbitration, including, without limitation, the Parties' reasonable legal fees, shall be borne by the

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unsuccessful Party or Parties. However, the arbitral tribunal may apportion such costs between the Parties if it determines that apportionment is reasonable, taking into account the circumstances of the case. The arbitration award shall be final and binding on the Parties, and the parties undertake to carry out any award without delay. Judgment upon the award may be entered by any court having jurisdiction of the award or having jurisdiction over the relevant party or its assets.

12.3 Publicity.

A Party shall not use the name, trade name, service marks, trademarks, trade dress or logos of the other Party in publicity releases, advertising or any other publication, without the other Party's prior written consent in each instance.

12.4 Governing Law.

All disputes shall be governed by the Laws of the State of New York, USA, without regard to conflict of Law principles other than Section 5-1401 of the New York General Obligations Law, except that any dispute regarding the arbitrability or the scope and application of this Section shall be governed by the Federal Arbitration Act of the United States.

12.5 Third Party Rights.

- (a) Purchaser agrees the applicable rights granted or provided to Pfizer under this Agreement are also granted or provided to Pfizer's Affiliates or to BioNTech to the extent that those rights relate to such Affiliates or BioNTech, including but not limited to the indemnification in Section 8(a) (each a "**Third Party Beneficiary**" and together the "**Third Party Beneficiaries**"). Each Third Party Beneficiary shall be entitled to enforce the terms of this Agreement; provided that, to the extent permissible by Law and where reasonably practicable, any claims, demands or actions from any Third Party Beneficiary shall be brought by Pfizer itself on behalf of the relevant Third Party Beneficiary.
- (b) Any Losses suffered by a Third Party Beneficiary will not be treated as being indirect solely because it has been suffered by a Third Party Beneficiary and not by Pfizer directly.

12.6 Relationship of the Parties.

The relationship hereby established between Purchaser and Pfizer is solely that of independent contractors. Neither Party has authority to act or make any agreements or representations on behalf of the other Party. This Agreement is not intended to create, and shall not be construed as creating, between Pfizer and Purchaser, the relationship of principal and agent, employer and employee, joint venturers, co-partners, or any other such relationship, the existence of which is expressly denied.

CONFIDENTIAL**12.7 Assignment; Binding Effect.**

Neither Purchaser nor Pfizer shall assign any of its rights or delegate or subcontract any of its duties and obligations under this Agreement without the prior written consent of the other Party, which may be withheld at such Party's discretion, provided that Pfizer, without Purchaser's consent, may assign, delegate or subcontract any of its duties and obligations under this Agreement to an Affiliate of Pfizer, BioNTech or an Affiliate of BioNTech. Any such attempted assignment of rights or delegation or subcontracting of duties without the required prior written consent of the other Party shall be void and ineffective. Any such assignment, delegation or subcontracting consented to by a Party in writing shall not relieve the other Party of its responsibilities and liabilities hereunder and such assigning Party shall remain liable to other Party for the conduct and performance of each permitted assignee, delegate and subcontractor hereunder. This Agreement shall apply to, inure to the benefit of and be binding upon the Parties hereto and their respective successors and permitted assigns. The Parties agree that this Agreement is not intended by either Party to give any benefits, rights, privileges, actions or remedies to any Person or entity, partnership, firm or corporation as a third party beneficiary or otherwise under any theory of Law.

12.8 Force Majeure.

Neither Party shall be liable for any failure to perform or any delays in performance, and neither Party shall be deemed to be in breach or default of its obligations set forth in this Agreement, if, to the extent and for so long as, such failure or delay is due to any causes that are beyond its reasonable control and not to its acts or omissions, including, without limitation, such causes as acts of God, natural disasters, flood, severe storm, earthquake, civil disturbance, lockout, riot, order of any court or administrative body, embargo, acts of Government (other than Purchaser), war (whether or not declared), acts of terrorism, the impact on a Party of an outbreak of any disease or an epidemic or pandemic or other similar causes ("Force Majeure Event"). Failure or inability to pay shall not be a basis for a Force Majeure Event under this Agreement. In the event of a Force Majeure Event, the Party prevented from or delayed in performing shall promptly give notice to the other Party and shall use Commercially Reasonable Efforts to avoid or minimize the delay.

12.9 Severability.

If and solely to the extent that any court or tribunal of competent jurisdiction holds any provision of this Agreement to be unenforceable in a final non-appealable order, such unenforceable provision shall be stricken and the remainder of this Agreement shall not be affected thereby. In such event, the Parties shall in good faith attempt to replace any unenforceable provision of this Agreement with a provision that is enforceable and that comes as close as possible to expressing the intention of the original provision.

12.10 Non-Waiver; Remedies.

A waiver by any Party of any term or condition of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach thereof. All remedies specified in this Agreement shall be cumulative

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and in addition to any other remedies provided at Law or in equity.

12.11 Further Documents.

Each Party hereto agrees to execute such further documents and take such further steps as may be reasonably necessary or desirable to effectuate the purposes of this Agreement.

12.12 Forms.

The Parties recognize that, during the Term, a Purchase Order acknowledgment form or similar routine document (collectively, "**Forms**") may be used to implement or administer provisions of this Agreement. The Parties agree that the terms of this Agreement shall prevail in the event of any conflict between terms of this Agreement and the terms of such Forms, and any additional or different terms contained in such Forms shall not apply to this Agreement.

12.13 Headings.

Headings of Sections or other parts of this Agreement are included herein for convenience of reference only and shall not constitute a part of this Agreement or change the meaning of this Agreement.

12.14 Counterparts.

This Agreement may be executed in two or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement, and shall become effective when signed by each of the Parties hereto and delivered to the other Party in accordance with the means set forth in Section 11 (Notices) or by reliable electronic means (with receipt electronically confirmed).

12.15 Electronic Delivery and Storage.

Delivery of a signed Agreement by reliable electronic means, including facsimile or email (with receipt electronically confirmed), shall be an effective method of delivery of the executed Agreement. This Agreement may be stored by electronic means and either an original or an electronically stored copy of this Agreement can be used for all purposes, including in any proceeding to enforce the rights or obligations of the Parties to this Agreement.

12.16 Entire Agreement; Amendments.

This Agreement, together with any attachments and amendments (and as such attachments may be amended, amended and restated or replaced from time to time), which are hereby incorporated by reference, constitute the entire agreement of the Parties with respect to its subject matter and merges and supersedes all prior discussions and writings with respect to thereto, including the Binding Term Sheet. Except as otherwise set out herein; no modification or alteration of this Agreement shall be binding upon the Parties unless contained in a writing signed by a duly authorized agent for each respective Party and

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specifically referring hereto or thereto.

12.17 Rule of Construction.

The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event that an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.

12.18 English Language.

This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

12.19 Legal Costs.

Each Party will bear its own legal costs in preparing and concluding this Agreement.

[signature on following page]

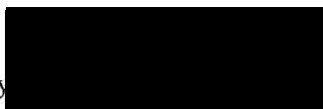
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IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed and delivered as of the date first written above.

**PFIZER LABORATORIES
(PROPRIETARY) LIMITED**

Redacted by HJI
4 Sept 2023

By



01/04/2021

Name: Rhulani Nhlaniki

Title: Cluster Lead: SSA and Country
Manager: South Africa

**THE GOVERNMENT OF THE
REPUBLIC OF SOUTH AFRICA
ACTING THROUGH THE NATIONAL
DEPARTMENT OF HEALTH OF
SOUTH AFRICA**



01-04-2021

Name: Dr. Sandile S.S. Buthelezi

Title: Director General of Health

Attachment A - Specifications

To be inserted following the Effective Date

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CONFIDENTIAL**Attachment B - Interim Delivery Schedule and Price**

Quarter	Q2 2021 Batch 1	Q3 2021 Batch 2	Q4 2021 Batch 3	Total
Doses	4,484,610	8,519,940	6,996,600	20,001,150
Price per dose	\$10	\$10	\$10	\$200,011,500

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Attachment C - Delivery Documentation**Documentation and Delivery Notes****Thermal Shipper Documentation**

It is currently envisaged that the following will be provided with each shipment of the Products:

1. Fact Sheets/Leaflets – Five (5) fact sheets folded 3x2" in a plastic bag
2. Pfizer Brochure – One (1) per thermal shipper container containing product storage and handling information including:
 - Dry Ice Handling Insert
 - Safety Data Sheet (SDS) for Dry Ice
 - Return instructions for GPS loggers and thermal shipping system
 - A stand-alone SDS for Dry Ice
 - Blank label – purpose of the blank label: for carriers to mark out the dry ice label to indicate that the thermal shipper containers are empty (not containing dry ice)
3. Return Shipping Label – One (1)
4. Outbound Shipping Label – One (1), standard label on thermal shipper
5. Contents Label – One (1) label on inside flap, picking label details how many carton trays are in thermal shipper

Proof of Delivery Documentation

Currently, Pfizer intends to use the carrier delivery signal as proof of delivery.

Proof of delivery document that can be accessed online based on track and trace number. See UPS example* below:

The screenshot shows the UPS tracking interface. At the top, there's a navigation bar with 'Quick Start', 'Tracking', 'Shipping', and 'Services'. Below this, the tracking number '1Z86958Y2460508262' is displayed. The status is 'Delivered' with a 'Proof of Delivery' link. A 'Received By' section shows 'SIG ON FILE' and a list of names. The 'Delivered To' section lists 'CORDANA SPECIALTY PHARMACY' at '1200 CORONA POINTE CT, CORONA, CA, US 92629'. The 'Delivered Date/Time' is '08/27/2020, 11:24 AM' and the 'Delivery Location' is 'Inside Delivery'. On the right side, there are two pop-up boxes: 'Need to send notifications?' and 'Need to Make a Claim'.

*The above proof of delivery image is an example only.

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Attachment D - Delivery Specification**Product Delivery, Storage & Handling Specifications**

Shipments will arrive in a long-distance thermal shipping container as provided by Pfizer in accordance with the Labelling and Packaging Specifications set forth in Attachment E ("**Thermal Shipper**"). At this time, the minimum package in any shipment shall be one (1) tray with 195 vials/1170 doses of Product.

Purchaser ensures that at the expected time of arrival at the Place(s) of Destination a dedicated person will be available to receive the Product, sign acceptance for delivery, and, immediately, no later than 24 hours of delivery, switch off the temperature logger located in the Thermal Shipper, and:

- (a) transfer the Product to:
 - (i) a -75 °C (+/- 15 °C) ultra-low temperature ("**ULT**") freezer; or
 - (ii) a 2-8 °C refrigerator; or
- (b) maintain the Product with sufficient supply of dry ice in accordance with the protocols for re-icing set forth below with such initial re-icing to occur no later than 24 hours from signature of acceptance of delivery.

Purchaser acknowledges the following stability timelines as of the Effective Date:

- The Product has a shelf-life of up to 6 months when stored at a constant -75 °C (+/- 15 °C)
- The Thermal Shipper can be used as temporary storage for up to 30 days, as long as dry ice is replenished upon receipt and at least every five (5) days per Pfizer's guidelines.
- The Product has an effective life of up to 5 days when stored at refrigerator temperatures 2-8°C
- Once the Product is defrosted and reconstituted it can be retained for up to 6 hours at standard ambient room temperatures (2-25°C)

Any further shipment or distribution of the Product by Purchaser from the Place(s) of Destination shall be through a certified shipping service, or use of its own logistics system, that will ensure next day delivery from the Place(s) of Destination to point of use of the Product; and Purchaser shall be liable for ensuring continual compliance with the Good Distribution Practices ("**GDP**") including cold chain requirements for any further distribution following delivery to a Place of Destination that is not a point of use of the Product. In all cases, Purchaser shall ensure that all Product is transported via a GDP qualified shipping system. Purchaser acknowledges that the Thermal Shipper (including Pfizer temperature monitoring devices) shall not be utilized for any in-market transportation and/or distribution by the Purchaser and shall be returned to Pfizer in accordance with Attachment F – Return and Disposal of Product Materials of this Agreement. Subject to the terms of the Agreement, all costs associated with receiving, handling, storing and further delivery of the Product shall be the responsibility of Purchaser, and Purchaser shall ensure that all locations where any Product is delivered by, or on behalf of Purchaser, shall comply with the requirements set forth in this Attachment D and shall meet the standards set forth herein.

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Protocols for Unpacking Product and Re-icing: See Exhibits 1 and 2 of Attachment D

Requirements of Delivery Location:

1. Marketing Authorization and/or Conditional approval, pre-approval, post-approval vaccination points with -75 °C (+/- 15 °C) ULT freezer
2. Marketing Authorisation and/or Conditional Approval, pre-approval, post-approval vaccination points with sufficient access and supply of dry-ice
3. Marketing Authorization and/or Conditional Approval, pre-approval, post-approval vaccination points with 2-8°C refrigerator

Attachment D – Delivery Specification

Exhibit 1 – Unpacking and Re-icing: Thermal Shipper A



Shipper A.pdf

Attachment D – Delivery Specification

Exhibit 2 – Unpacking and Re-icing: Thermal Shipper B



Shipper B.pdf

Vaccine Preparation & Administration Instructions

Removing the Vials to Thaw

- From storage, remove 1 vial for every 6 recipients according to planned vaccinations schedule.
- Vials may be stored in the refrigerator for 5 days (120 hours).

Diluting the Vaccine

- Obtain 0.9% Sodium Chloride Injection, for use as a diluent. Do not use any alternate diluents.
- Dilute the thawed vial by adding **1.8 mL of 0.9% Sodium Chloride Injection** into the vial.
- Ensure vial pressure is equalized by **withdrawing 1.8 mL air** into the empty diluent syringe before removing the needle from the vial.

SSS
R

CONFIDENTIAL**Preparing the Dose**

- Draw up **0.3 mL** of the **diluted dosing solution** into a new sterile dosing syringe with a needle appropriate for intramuscular injection.
- For each additional dose, use a new sterile syringe and needle and ensure the vial stopper is cleansed with antiseptic before each withdrawal.

Vaccine Administration

- Diluted vials must be used within 6 hours from the time of dilution and stored between 2-25 °C (35-77°F).
- A single 30 mcg/0.3 mL dose is followed by a second dose 21 days later.

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Attachment E - Labelling and Packaging Specifications**Product Labelling Specifications**

Product labels for primary, secondary and tertiary packaging will be shared closer to country regulatory filings.

It is currently envisaged that the following will be part of the initial product artwork:

Primary Packaging (Vial):

- Linear barcode: Scans as the Global Trade Item Number (GTIN) that includes the human-readable National Drug Code (NDC) number.

Secondary Packaging (Carton Tray):

- Linear barcode: Scans as the GTIN number that includes the human-readable NDC number.
- QR code: When scanned, this code links to a landing page where a copy of the Fact Sheets for the Healthcare Provider, patient/recipient, and Product Insert (i.e. e-leaflet) will be available.
- 2D GS1 DataMatrix: Scan of the 2D code will include the GTIN number, lot and expiry information.

Product Packaging Specifications**Primary Packaging**

- 2 mL type I glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 6 doses per vial

Secondary Packaging "Single Tray"

- Single tray holds 195 vials
- 1170 doses per tray
- Tray (white box) dimensions: 229 X 229 x 40 mm

Tertiary Container: Thermal Shipper (Softbox)

- Minimum 1 tray (1170 doses) or up to 5 trays (max 5850) stacked in a payload area of the shipper
- Payload carton submerged in 23 Kg of dry ice pellets (9 mm – 16 mm pellets)
- Thermal shipper dimensions:
 - Internal Dimensions: 245mm X 245mm X 241mm
 - External Dimensions: 400mm X 400mm X 560mm

Attachment F - Return and Disposal of Product Materials**A. Return**

“**Logistics Delivery Equipment**” refers to the long-distance thermal shipping container (“**Thermal Shipper**”) used for shipping and the temperature data logger/monitoring device attached to such Thermal Shipper.

Once dry ice is no longer needed, open the **Logistics Delivery Equipment** and leave it at room temperature in a well-ventilated area. The dry ice will readily sublime from a solid to a gas. DO NOT leave dry ice unattended.

Store the empty **Logistics Delivery Equipment** until return in an appropriate clean and secure location to protect and maintain the functionality of the equipment (e.g., do not store outside under uncontrolled conditions, exposed to weather, exposed to pests, etc.).

Return of the **Logistics Delivery Equipment** to be undertaken within 30 days following delivery of the Product to the Purchaser’s recipient at Place(s) of Destination. Instructions and logistics for return will be provided on the interior of the Thermal Shipper and will also be available on Pfizer’s website. In the event that either: (a) the **Logistics Delivery Equipment** (or any part thereof), is not (i) delivered to the return carrier within 30 days following delivery of the Product or (ii) received by Pfizer within five (5) days following the date of Purchaser’s return shipment; or (b) the **Logistics Delivery Equipment** (or any part thereof), is damaged in any way (determined in Pfizer’s sole discretion), Pfizer shall be entitled to charge Purchaser \$450 (exclusive of VAT) per Thermal Shipper and temperature data logger/monitoring device; which Purchaser shall pay within 30 days of the date of any invoice for such amount(s). Purchaser acknowledges that such amount represents a reasonable pre-estimate of replacement cost such Logistics Delivery Equipment as a result of Purchaser’s default, act or omission.

B. Disposal

“**Primary Container Units**” refers to the vials that contain the Product.

Destruction of the **Primary Container Units** that have been opened or are unused must take place at a facility appropriately licensed to handle and destroy pharmaceutical waste, medical waste, and/or hazardous waste, and destruction must be by means of grinding or incineration.

“**Secondary Cartons**” refers to the immediate boxes that contain the vials of Product.

Secondary Cartons must be defaced and destroyed in accordance with local clinical dosing facility waste management services, and **Secondary Cartons** may not be disposed of in routine household waste collection or recycling centers.

Attachment G - Form of Purchase Order

- Purchase details
- PO Number
- Currency
- Creation Date
- Requested Date
- Incoterm
- Ship-To location details
- Item Description
- Quantity
- Price and Total Value
- Payment terms

CONFIDENTIAL**Attachment H - Customs Clearance Documentation**

1. Shipping Document/Airway Bill "AWB"
2. Commercial Invoice
3. Packing List
4. Copy of the Certificate of Analysis "COA"

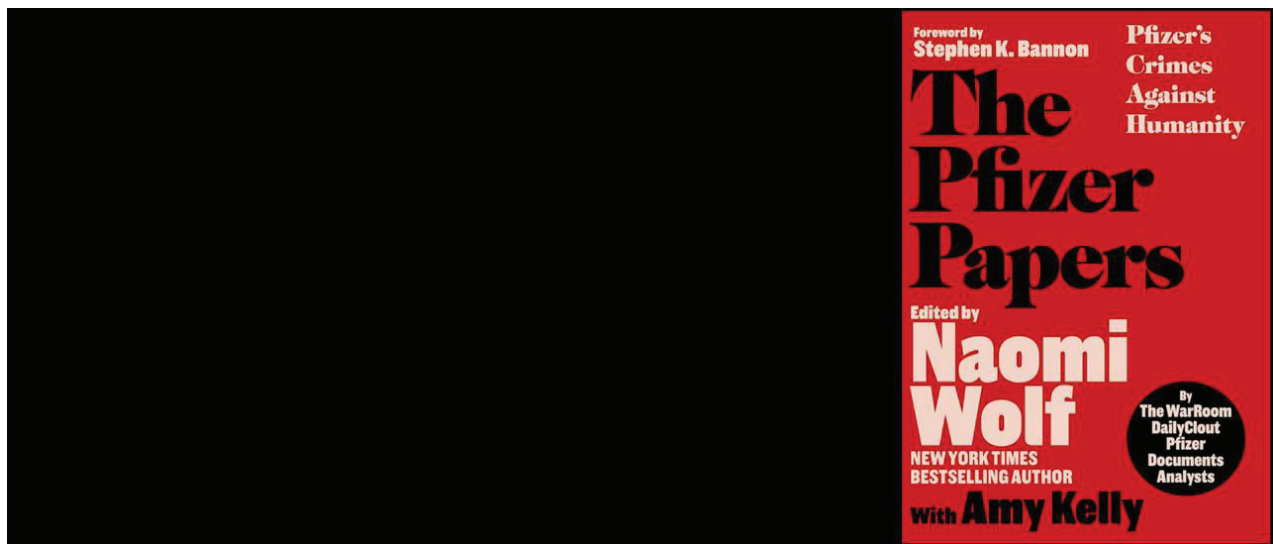
During the Term of the Agreement:

- Any other documents not included in the above-mentioned list of documents, including but not limited to import permits, will be waived by the Purchaser or any other Government authority.
- Any notarization, legalization and/or certification of the above-mentioned list of documents will be waived by the Purchaser or any other Government authority.
- Any required analysis to release any of the shipments upon arrival at the port of entry and/or Place(s) of Destination will be waived by the Purchaser or any other Government authority.

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Apareció en Estados Unidos "Los Papeles de Pfizer". Todos los horrores de las inyecciones Covid según consta en los documentos de la propia empresa fabricante, ahora a disposición del público



NAOMI WOLF – MICHAEL CAPUZZO / Asombroso extracto del nuevo libro de Naomi Wolf y Amy Kelly que echa por tierra el encubrimiento mundial del crimen del siglo por parte de las grandes farmacéuticas, el gobierno estadounidense y los grandes medios de comunicación.

*** Un equipo multidisciplinario compuesto de 3250 voluntarios reunidos en un proyecto de crowdsourcing analiza durante dos años 450.000 documentos liberados por Pfizer luego de una orden judicial, y produce informes -hoy publicados- que demuestran el comportamiento criminal de la farmacéutica y los estados cómplice**

*** El equipo fue coordinado por una mujer ícono de la izquierda feminista norteamericana, preocupada por los efectos de las inyecciones en el ciclo menstrual y la salud femenina, junto a un periodista y activista de ultraderecha. Esta alianza inesperada es hoy común en el mundo, y parece sugerir lo que esta revista proclama desde el primer día: la decadencia terminal de las viejas**

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ideologías occidentales

**** Nos enteramos de que Pfizer sabía, dentro de los tres meses después de la puesta en marcha de la vacunación en diciembre de 2020, que las vacunas no habían funcionado para detener COVID. El lenguaje de Pfizer fue «fracaso de la vacuna» y «fracaso de la eficacia». Uno de los «eventos adversos» más comunes en los documentos de Pfizer es «COVID».***

****Según consta en los documentos, "Pfizer sabía que los materiales de la vacuna - nanopartículas lipídicas, una grasa industrial, recubiertas de polietilenglicol, un subproducto del petróleo; ARNm; y proteína spike- no permanecían en el músculo deltoides, como afirmaban todos los portavoces. Por el contrario, se dispersaba por todo el cuerpo en cuarenta y ocho horas «como un disparo de escopeta», como dijo uno de los autores, el Dr. Robert Chandler; atravesaba todas las membranas del cuerpo humano -incluida la barrera hematoencefálica- y se acumulaba en el hígado, las glándulas suprarrenales, el bazo, el cerebro y, si se es mujer, en los ovarios. El Dr. Chandler no vio ningún mecanismo por el que esos materiales abandonaran el cuerpo, de modo que cada inyección parece acumular más materiales de ese tipo en los órganos."***

**** Pfizer contrató a 2.400 empleados a tiempo completo para ayudar a procesar «el gran aumento de informes de acontecimientos adversos» que se estaban enviando a la base de datos de Seguridad Mundial de la empresa.***

**** Pfizer sabía en abril de 2021 que las inyecciones dañaban el corazón de los jóvenes.***

**** Pfizer sabía el 28 de febrero de 2021 -sólo noventa días después del lanzamiento público de su vacuna COVID- que su inyección estaba vinculada a una miríada de acontecimientos adversos. Lejos de ser «escalofríos», «fiebre», «fatiga», como los***

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CDC y otras autoridades afirmaban que eran los efectos secundarios más preocupantes, los efectos secundarios reales eran catastróficamente graves. Estos efectos secundarios incluían: la muerte (que Pfizer sí cataloga como «efecto adverso grave»); COVID-19 grave; lesión hepática; efectos adversos neurológicos; parálisis facial; lesión renal; enfermedades autoinmunes; sabañones (una forma localizada de vasculitis que afecta a los dedos de manos y pies); síndrome de disfunción orgánica múltiple (cuando falla más de un sistema orgánico a la vez); activación de infecciones latentes por herpes zoster; lesiones cutáneas y de las mucosas; problemas respiratorios; estructura pulmonar dañada; insuficiencia respiratoria; síndrome de distrés respiratorio agudo (lesión pulmonar en la que el líquido se filtra de los vasos sanguíneos al tejido pulmonar, causando rigidez que dificulta la respiración y provoca una reducción del intercambio de oxígeno y dióxido de carbono); y SARS (o SARS-CoV-1, que no se había visto en el mundo desde 2004, pero que aparece en los documentos de Pfizer como efecto secundario de las inyecciones)... enfermedades de la sangre a escala industrial: coágulos sanguíneos, coágulos pulmonares, coágulos en las piernas; trombocitopenia trombótica, una enfermedad de coagulación de los vasos sanguíneos; vasculitis (la destrucción de los vasos sanguíneos a través de la inflamación); tasas astronómicas de trastornos neurológicos-demencias, temblores, Parkinson, Alzheimer, epilepsias. Afecciones cutáneas terribles. Una plétora florida de problemas cardíacos; miocarditis, pericarditis, taquicardia, arritmia, etc. La mitad de los efectos adversos graves relacionados con el hígado, incluida la muerte, se producían en las setenta y dos horas siguientes a la inyección. La mitad de los accidentes cerebrovasculares tuvieron lugar en las cuarenta y ocho horas siguientes a la inyección.

PORTADA

He aquí un extracto del libro de Naomi Wolf y Amy Kelly que expone el encubrimiento de Pfizer de su ineficaz y mortal vacuna «segura y eficaz» Covid-19, *The Pfizer Papers: Pfizer's Crimes Against Humanity*. . Este libro

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expone el asalto mundial a la humanidad por parte de una empresa farmacéutica y por los gobiernos occidentales, asalto que ha matado y mutilado a millones de personas y deja pequeña la cifra de muertes y encubrimiento de la guerra de Vietnam, que fueran expuestos por Los Archivos del Pentágono.».

Esta joya del periodismo de investigación surgió de la asociación más improbable: la icónica periodista feminista de izquierdas Naomi Wolf, y el ex asesor de Trump Steve Bannon. Su alianza trasciende la izquierda y la derecha, ha sido construida con ocasión del sufrimiento y la muerte de una América que está oculta, un mundo invisible, y anticipó la igualmente improbable unión política de Donald J. Trump y Robert F. Kennedy Jr.

El proyecto fue dirigido por la voluntaria «Amazing Amy» Kelly, una gerente de Mountain West que abandonó su vida privada para responder a la llamada de Wolf y liderar a otros 3.250 voluntarios, entre ellos distinguidos médicos y científicos, para descifrar e informar sobre 450.000 páginas de documentos enterrados de Pfizer. Mientras tanto, el editor del *New York Times* dirigía a sus 1.700 periodistas para que reimprimieran los comunicados de prensa de Pfizer y la propaganda gubernamental, con el fin de seguir enterrando lesiones y muertes masivas. Shakespeare dijo que el asesinato, «*aunque no tenga lengua, hablará con el órgano más milagroso*». *The Pfizer Papers* es un libro grande, de más de un kg de peso, con una tarea monumental. Únase a mí aquí para pedir su copia y ayudar a llevar esa carga. Tendrá en sus manos nada menos que la estremecedora muerte del viejo mundo y el tumultuoso nacimiento del nuevo. Y la prueba de la existencia de ese «órgano milagroso» del corazón humano que clama al cielo por la justicia, la verdadera fuerza que ha cambiado el mundo y volverá a hacerlo. —

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Los Papeles de Pfizer: Los crímenes de Pfizer contra la humanidad

Prólogo

Por Dra. Naomi Wolf

Nuestro libro, *The Pfizer Papers: Pfizer's Crime Against Humanity* contra la humanidad, se publicó el 15 de octubre y se convirtió inmediatamente en un éxito de ventas. Se trata de un libro que tres gobiernos –el de Estados Unidos, el del Reino Unido y el de Australia– trataron de suprimir. La historia de cómo llegó a publicarse es extraordinaria: 3.250 médicos y científicos altamente cualificados, bajo la dirección de una mujer extraordinaria, Amy Kelly, trabajaron durante dos años en los 450.000 documentos internos de Pfizer publicados por orden judicial a raíz de una demanda presentada con éxito por el abogado Aaron Siri. En el proceso, estos voluntarios confirmaron el mayor crimen contra la humanidad de todos los tiempos. Le cuento cómo ocurrió.

Este libro que tiene en sus manos es el resultado de un extraordinario conjunto de confluencias. También presenta, en un formato disponible en librerías por primera vez, un material que ya ha cambiado la historia.

Como lector, está a punto de embarcarse en un viaje a través de una historia extraordinaria, cuyos elementos casi desafían cualquier creencia.

The Pfizer Papers es el resultado de un grupo de desconocidos –personas extraordinarias con habilidades extraordinarias, ubicadas en diferentes lugares del mundo, con diferentes antecedentes e intereses– que se reunieron, sin ningún tipo de dinero o recompensa profesional; por la bondad de sus corazones, y motivados por el amor a la verdadera medicina y la verdadera ciencia, para emprender un proyecto de investigación riguroso, dolorosamente detallado y complejo, que abarcó desde el año 2022, y que continúa hasta el día de hoy.

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El material que leyeron y analizaron incluía 450.000 páginas de documentos, todos ellos escritos en un lenguaje extremadamente denso y técnico.

Este proyecto de investigación de largo alcance y continuado sin descanso – bajo el liderazgo de la directora de operaciones de DailyClout, la extraordinariamente dotada directora de proyectos Amy Kelly– puso de rodillas a una de las instituciones más grandes y corruptas del mundo, Pfizer. Este proyecto, llevado a cabo por 3.250 desconocidos que trabajaron virtualmente y se convirtieron en amigos y colegas, llevó a un gigante farmacéutico mundial a perder miles de millones de dólares en ingresos. Hizo fracasar los planes de los políticos más poderosos del planeta. Eludió la censura de las empresas tecnológicas más poderosas del planeta. Es la historia definitiva de David y Goliat.

Esa historia comenzó cuando el abogado Aaron Siri demandó con éxito a la Administración de Alimentos y Medicamentos (FDA), para obligarles a publicar «Los documentos de Pfizer». Se trata de los documentos internos de Pfizer – como ya se ha dicho, 450.000 páginas– que detallan los ensayos clínicos que Pfizer llevó a cabo en relación con su inyección de ARNm COVID. Estos ensayos se llevaron a cabo para asegurar el premio final para una compañía farmacéutica, la «EUA» , Autorización de Uso de Emergencia, por parte de la FDA. La FDA concedió la EUA para mayores de 16 años a Pfizer en diciembre de 2020. La «pandemia», por supuesto una crisis en la salud pública que un libro mío, *The Bodies of Others*, confirmó, implicó datos de «infecciones» exagerados y manipulados y documentación de mortalidad sesgada. Tal mortalidad sesgada se convirtió en el pretexto para la «urgencia» que llevó a la FDA a otorgar la EUA al nuevo medicamento de Pfizer (y Moderna). La EUA es esencialmente el pase que permite a Pfizer lanzarse al mercado con un producto que no ha sido completamente probado.

Los documentos de Pfizer también contienen documentación de lo que sucedió en la «post-comercialización», es decir, en los tres meses, de diciembre de

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2020 a febrero de 2021, cuando la vacuna fue lanzada al público. Todos los portavoces principales, y los medios de comunicación comprados, llamaron a la inyección «segura y eficaz», leyendo de lo que era un guión centralizado. Muchas de las personas que se inyectaron la vacuna en 2020-2021-2022 y hasta la fecha, no se dieron cuenta de que las pruebas normales de seguridad de una nueva vacuna -pruebas que suelen durar de diez a doce años- simplemente se habían evitado a través de los mecanismos del «estado de emergencia» y la «Autorización de Uso de Emergencia» de la FDA. No entendían que las verdaderas «pruebas» eran en realidad Pfizer y la FDA observando lo que les ocurría a ellos y a sus seres queridos, después de que estos ciudadanos se arremangaran y se sometieran a la inyección. Como nunca podemos olvidar, muchos millones de estas personas que se sometieron a la inyección fueron «obligadas» a tomarla, enfrentándose a la amenaza de perder su trabajo, suspender su educación o perder sus puestos militares si se negaban; en algunos estados de EE.UU. y países de ultramar, las personas también se enfrentaron a la suspensión de sus derechos a tomar el transporte, cruzar fronteras, ir a la escuela o la universidad, recibir ciertos procedimientos médicos, o entrar en edificios como iglesias y sinagogas, restaurantes y gimnasios, si se negaban.

La FDA pidió al juez del caso Aaron Siri que retuviera la publicación de los documentos de Pfizer durante setenta y cinco años. ¿Por qué querría una agencia gubernamental ocultar cierto material hasta que la generación actual, los afectados por lo que contienen estos documentos, esté muerta y desaparecida? No puede haber una buena respuesta a esa pregunta.

Afortunadamente para la historia, y afortunadamente para millones de personas cuyas vidas se salvaron gracias a esta decisión, el juez rechazó la petición de la FDA y obligó a publicar los documentos; un tramo de 55.000 páginas al mes.

Sin embargo, cuando me enteré, me preocupé como periodista. Sabía que

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ningún reportero disponía del ancho de banda necesario para revisar material de este volumen. También sabía que prácticamente ningún periodista tenía la formación o los conocimientos necesarios para entender el lenguaje multidimensional y técnicamente muy especializado de los informes. Para entender los informes, se necesitan conocimientos de inmunología, estadística, bioestadística, patología, oncología, medicina deportiva, obstetricia, neurología, cardiología, farmacología, biología celular, química y muchas otras especialidades. Además de médicos y científicos, para entender lo que realmente ocurría en los documentos de Pfizer, también se necesitaría gente con profundos conocimientos sobre los procesos reguladores del gobierno y de la industria farmacéutica; se necesitaría gente que entendiera el proceso de aprobación de la FDA; se necesitarían especialistas en fraudes médicos; y finalmente, para entender qué delitos se habían cometido en los Papers, se necesitarían abogados.

Me preocupaba que, sin personas con todas esas aptitudes que leyeran los documentos, su volumen y complejidad los hicieran desaparecer por «el agujero de la memoria».

Entra entonces en escena Steve Bannon, el ex oficial naval, ex banquero de inversión de Goldman Sachs, ex asesor del presidente Trump y actual presentador del podcast político más popular de Estados Unidos y uno de los más escuchados en todo el mundo, *WarRoom*.

Él y yo venimos de extremos opuestos del espectro político. Yo había sido demócrata toda la vida, asesor de la campaña de reelección del presidente Bill Clinton y de la campaña presidencial de Al Gore. Él, por supuesto, es un republicano acérrimo reconvertido en MAGA. Yo había sido deplorada en junio de 2021, antes de que salieran a la luz los documentos de Pfizer, por el delito de advertir que las mujeres informaban de desregulación menstrual tras haber recibido las inyecciones de ARNm. Como escritora durante toda mi carrera sobre temas de salud sexual y reproductiva de la mujer, sabía que esto era una

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señal de peligro grave y que este efecto secundario afectaría a la fertilidad. (Cualquier estudiante de octavo grado debería ser capaz de prever eso también.) Después de haber publicado esta advertencia, se me prohibió el acceso a Twitter, Facebook, YouTube y otras plataformas. Fui atacada globalmente, de golpe, como «anti-vaxxer» y «teórica de la conspiración»; y mi vida como autora feminista conocida y superventas, dentro de los medios de comunicación heredados, terminó. Ya nadie en ese mundo me hablaba, publicaba mi obra o me devolvía las llamadas. Me quedé sin mi persona pública.

(Resultó, después de dos demandas exitosas en 2023 por los fiscales generales de Missouri y Louisiana, que en realidad era la Casa Blanca, el CDC, y los altos dirigentes de otros organismos gubernamentales, incluido el Departamento de Seguridad Nacional, quienes ilegalmente presionaron a Twitter y Facebook para eliminar ese tweet de advertencia mío, para cerrarme. Esta supresión es ahora objeto de una decisión pendiente del Tribunal Supremo sobre si violó o no la Primera Enmienda).

En esta época oscura de mi vida, para mi sorpresa, recibí un mensaje del productor de Steve Bannon, que me invitaba a *WarRoom*. Le planteé mi preocupación por la salud reproductiva de las mujeres tras la inyección de ARNm y, para mi sorpresa, se mostró respetuoso, reflexionó sobre las implicaciones y se tomó el tema muy en serio. Volví una y otra vez para exponer a su audiencia esa y otras preocupaciones que iban surgiendo en relación con las inyecciones de ARNm. Me sentí aliviada de disponer de una plataforma en la que poder compartir estas advertencias urgentes. Al mismo tiempo, me entristecía que a la izquierda, que se suponía que defendía el feminismo, pareciera no importarle en absoluto los graves riesgos para las mujeres y los bebés nonatos. Reconocí la ironía de que una persona a la que me habían enseñado a creer que era el diablo encarnado, en realidad se preocupara más por las mujeres y los bebés que todas mis antiguas colegas de izquierdas,

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incluido el establishment sanitario feminista, que siempre había hablado tan alto sobre el bienestar y los derechos de las mujeres.

Dadas mis apariciones en *WarRoom* antes de 2022, era natural que el tema de los documentos de Pfizer saliera en ese programa cuando se publicaron los documentos. Compartí mi preocupación de que se perdieran para la historia debido a su volumen y lenguaje técnico. Bannon dijo algo así como: «*Bueno, haréis un proyecto de crowdsourcing para leerlos*».

Me quedé desconcertada, ya que no tenía ninguna habilidad ni conocimiento sobre cómo hacer algo así. Respondí algo así como: «*Por supuesto*».

Entonces, mi plataforma de noticias y opinión DailyClout recibió un aluvión de ofertas de todo el mundo, de oyentes de *WarRoom* con las habilidades necesarias, para descifrar los documentos de Pfizer. Yo estaba aterrorizada. Era un caos. Tenía gente excelente en mi equipo. Pero ninguno de nosotros sabía cómo gestionar o incluso organizar el diluvio de correos electrónicos; no sabíamos cómo evaluar los miles de CV; e incluso una vez que habíamos «embarcado» a estas miles de personas, en diferentes zonas horarias, en «el proyecto», nuestras bandejas de entrada se volvieron aún más aterradoras, ya que era literalmente imposible organizar a 3.250 expertos en un organigrama que pudiera trabajar sistemáticamente a través de estos documentos. Los correos electrónicos se enredaban o quedaban sin respuesta. La gente hacía preguntas que no podíamos responder. No teníamos ni idea de qué estructura podría permitir que un número tan enorme de expertos dispares trabajaran a través del vasto tesoro de material.

A las pocas semanas, cuando ya estaba desesperado, Bannon me volvió a llamar. Me preguntó por la marcha del proyecto y le contesté, más optimista de lo que me sentía, que se nos había unido mucha gente y que estaban empezando a leer. «*Por supuesto, empezarás a entregar informes*», me incitó.

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«*Por supuesto*», respondí, horrorizada de estar tan metida en esto.

Nunca he tenido un trabajo de empresa, así que ni siquiera se me había ocurrido que una serie de informes fuera el formato que debían adoptar los análisis de los documentos.

Entonces ocurrió algo que sólo puedo calificar de providencial. Hicimos un llamamiento a los voluntarios para que buscaran un gestor de proyectos, y Amy Kelly se puso en contacto conmigo. Kelly es gestora de proyectos certificada por Six Sigma, con amplia experiencia en telecomunicaciones y gestión de proyectos tecnológicos. También es una líder inexplicablemente eficaz. El día que puso la mano en el caos de las bandejas de entrada, las aguas se calmaron. Reinaron la paz y la productividad. De algún modo, la Sra. Kelly organizó sin esfuerzo a los voluntarios en seis grupos de trabajo, con un supra-comité a la cabeza de cada uno, y comenzó el trabajo propiamente dicho.

Sólo puedo explicar el alcance, la fluidez y la eficacia del trabajo que siguió como algo que ocurrió en estado de gracia.

En los dos años que la Sra. Kelly y los voluntarios llevan trabajando juntos, han revisado 2.369 documentos y archivos de datos que suman cientos de miles de páginas y han emitido casi un centenar de informes. Enseñé a los voluntarios a redactarlos en un lenguaje comprensible para todos, lo que me pareció muy importante para maximizar su impacto. Y Amy Kelly revisó y editó meticulosamente casi todos ellos.

Los primeros cuarenta y seis informes se publicaron en un formato autoeditado. Para nosotros era muy importante que aparecieran en un formato físico y no sólo digital, ya que queríamos algo que la gente pudiera entregar a sus médicos, a sus seres queridos, a sus representantes en el Congreso. Estos cuarenta y seis informes dieron a conocer grandes historias. Nos enteramos de que Pfizer sabía dentro de los tres meses después de la puesta en marcha en diciembre de 2020, que las vacunas no habían funcionado para

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detener COVID. El lenguaje de Pfizer fue «*fracaso de la vacuna*» y «*fracaso de la eficacia*». Uno de los «*eventos adversos*» más comunes en los documentos de Pfizer es «COVID».

Pfizer sabía que los materiales de la vacuna –nanopartículas lipídicas, una grasa industrial, recubiertas de polietilenglicol, un subproducto del petróleo; ARNm; y proteína spike– no permanecían en el músculo deltoides, como afirmaban todos los portavoces. Por el contrario, se dispersaba por todo el cuerpo en cuarenta y ocho horas «*como un disparo de escopeta*», como dijo uno de los autores, el Dr. Robert Chandler; atravesaba todas las membranas del cuerpo humano –incluida la barrera hematoencefálica– y se acumulaba en el hígado, las glándulas suprarrenales, el bazo, el cerebro y, si se es mujer, en los ovarios. El Dr. Chandler no vio ningún mecanismo por el que esos materiales abandonaran el cuerpo, de modo que cada inyección parece acumular más materiales de ese tipo en los órganos.

Pfizer contrató a 2.400 empleados a tiempo completo para ayudar a procesar «el gran aumento de informes de acontecimientos adversos» que se estaban enviando a la base de datos de Seguridad Mundial de la empresa.

Pfizer sabía en abril de 2021 que las inyecciones dañaban el corazón de los jóvenes.

Pfizer sabía el 28 de febrero de 2021 –sólo noventa días después del lanzamiento público de su vacuna COVID– que su inyección estaba vinculada a una miríada de acontecimientos adversos. Lejos de ser «escalofríos», «fiebre», «fatiga», como los CDC y otras autoridades afirmaban que eran los efectos secundarios más preocupantes, los efectos secundarios reales eran catastróficamente graves.

Estos efectos secundarios incluían: la muerte (que Pfizer sí cataloga como «efecto adverso grave»); COVID-19 grave; lesión hepática; efectos adversos

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neurológicos; parálisis facial; lesión renal; enfermedades autoinmunes; sabañones (una forma localizada de vasculitis que afecta a los dedos de manos y pies); síndrome de disfunción orgánica múltiple (cuando falla más de un sistema orgánico a la vez); activación de infecciones latentes por herpes zoster; lesiones cutáneas y de las mucosas; problemas respiratorios; estructura pulmonar dañada; insuficiencia respiratoria; síndrome de distrés respiratorio agudo (lesión pulmonar en la que el líquido se filtra de los vasos sanguíneos al tejido pulmonar, causando rigidez que dificulta la respiración y provoca una reducción del intercambio de oxígeno y dióxido de carbono); y SARS (o SARS-CoV-1, que no se había visto en el mundo desde 2004, pero que aparece en los documentos de Pfizer como efecto secundario de las inyecciones).

Se registraron miles de personas con dolores articulares de tipo artrítico, uno de los efectos secundarios más comunes. Otros miles con dolores musculares, el segundo más común. Luego, enfermedades de la sangre a escala industrial: coágulos sanguíneos, coágulos pulmonares, coágulos en las piernas; trombocitopenia trombótica, una enfermedad de coagulación de los vasos sanguíneos; vasculitis (la destrucción de los vasos sanguíneos a través de la inflamación); tasas astronómicas de trastornos neurológicos-demencias, temblores, Parkinson, Alzheimer, epilepsias. Afecciones cutáneas terribles. Una plétora florida de problemas cardíacos; miocarditis, pericarditis, taquicardia, arritmia, etc. La mitad de los efectos adversos graves relacionados con el hígado, incluida la muerte, se producían en las setenta y dos horas siguientes a la inyección. La mitad de los accidentes cerebrovasculares tuvieron lugar en las cuarenta y ocho horas siguientes a la inyección.

Pero lo que realmente surgió de los primeros cuarenta y seis informes, fue el hecho de que aunque COVID es ostensiblemente una enfermedad respiratoria, los documentos no se centraron en los pulmones o las membranas mucosas, sino que se centran, de forma espeluznante y consistente, en la alteración de la reproducción humana.

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En el momento en que la vacuna de Pfizer se hizo pública, el gigante farmacéutico sabía que estaría matando bebés y perjudicando significativamente la reproducción de mujeres y hombres. El material de los documentos deja claro que dañar la capacidad de reproducción humana y provocar abortos espontáneos de bebés «no es un error, es una característica».

Pfizer indicó a los hombres vacunados que utilizaran dos métodos anticonceptivos fiables o que, de lo contrario, se abstuvieran de mantener relaciones sexuales con mujeres en edad fértil. En su protocolo, la empresa definió la «exposición» a la vacuna como el contacto piel con piel, la inhalación y el contacto sexual. Pfizer emparejó ratas hembra vacunadas y ratas macho «no tratadas», y luego examinó a esos machos, hembras y sus crías en busca de «toxicidad» relacionada con la vacuna. Basándose en sólo cuarenta y cuatro ratas (y ningún ser humano), Pfizer declaró que no había resultados negativos en «... el rendimiento del apareamiento, la fertilidad o cualquier parámetro ovárico o uterino ... ni en la supervivencia, crecimiento o desarrollo embrionario-fetal o postnatal», lo que implicaba que su vacuna COVID era segura durante el embarazo y no dañaba a los bebés. Pfizer sabía que desde hace años se sabe que las nanopartículas lipídicas degradan los sistemas sexuales y, de hecho, Amy Kelly descubrió que las nanopartículas, de las que las nanopartículas lipídicas son un subtipo, atraviesan la barrera sangre-testis y dañan las células de Sertoli, las células de Leydig y las células germinales de los hombres. Esas son las fábricas de la masculinidad, que afectan a las hormonas que convierten a los niños en la adolescencia en hombres, con voces graves, hombros anchos y la capacidad de engendrar hijos. Por tanto, no tenemos ni idea de si los bebés nacidos de madres vacunadas se convertirán en adultos reconociblemente masculinos y fértiles. Pfizer enumeró los daños menstruales que sabía que estaba causando a miles de mujeres, y los daños van desde mujeres que sangran todos los días, a tener dos periodos al mes, a no tener ningún periodo; a mujeres con hemorragias y expulsión de tejido; a mujeres

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menopáusicas y postmenopáusicas que empiezan a sangrar de nuevo. Los científicos de Pfizer observaron y tomaron nota de todo con calma, pero no se lo dijeron a las mujeres.

Los bebés sufrieron y murieron. En una sección de los documentos, más del 80% de los embarazos seguidos acabaron en aborto espontáneo. En otra sección de los documentos, dos recién nacidos murieron y Pfizer describió la causa de la muerte como «exposición materna» a la vacuna.

Pfizer sabía que los materiales de la vacuna entraban en la leche materna de las madres vacunadas y envenenaban a los bebés. La leche materna de cuatro mujeres se volvió «azul verdosa». Pfizer elaboró un gráfico de bebés enfermos, que enfermaron al ser amamantados por madres vacunadas, con síntomas que iban desde fiebre a edema (carne hinchada), urticaria o vómitos. Otro bebé tuvo convulsiones y fue llevado a urgencias, donde murió de un fallo multiorgánico. A continuación les remito a los treinta y seis informes que encontrarán en este libro. Algunos de los titulares de los informes que siguen son:

El 28 de febrero de 2021, Pfizer produjo «*Pregnancy and Lactation Cumulative Review*» mostrando que después de la vacunación de las madres con su vacuna:

Se produjeron eventos adversos en más del 54 por ciento de los casos de «exposición materna» a la vacuna e incluyeron 53 informes de aborto espontáneo (51)/ aborto (1)/ aborto retenido (1) después de la vacunación. Se produjeron casos de parto prematuro, así como dos muertes de recién nacidos.

Algunos recién nacidos sufrieron graves dificultades respiratorias o «enfermedad» tras la exposición a través de la leche materna.

Se produjeron descensos «sustanciales» de la tasa de natalidad en trece países: países de Europa, así como Gran Bretaña, Australia y Taiwán, en los nueve meses siguientes a la implantación pública de la vacuna.

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Aproximadamente el 70% de los efectos adversos relacionados con la vacuna de Pfizer se producen en mujeres.

La proteína de la espiga y la inflamación seguían presentes en el tejido cardíaco un año después de recibir la vacuna COVID de ARNm.

En el ensayo clínico de Pfizer, hubo más muertes entre los participantes vacunados que entre los que recibieron placebo. Sin embargo, Pfizer presentó datos inexactos, que mostraban más muertes en el grupo placebo, a la FDA cuando solicitó la autorización de uso de emergencia.

Lactantes y niños menores de doce años recibieron la vacuna de Pfizer siete meses antes de la aprobación de una vacuna pediátrica, lo que provocó:

- Apoplejía.
- Parálisis facial.
- Lesión o fallo renal.

Hubo un aumento de más de 3,7 veces en el número de muertes debidas a eventos cardiovasculares en sujetos de ensayos clínicos vacunados en comparación con sujetos placebo.

La vacuna que Pfizer puso a disposición del público era diferente de la formulación utilizada en la mayoría de los participantes en los ensayos clínicos, y el público no fue informado de ello.

Los análisis histopatológicos (la tinción de tejidos para mostrar estados de enfermedad) muestran claras evidencias de patología autoinmune inducida por la vacuna en múltiples órganos; erosión de los vasos sanguíneos, el corazón y los vasos linfáticos causada por la proteína de la espiga; amiloides en múltiples tejidos; cánceres inusuales y agresivos; y formaciones atípicas de «coágulos».

Tras la vacunación, los pacientes más jóvenes empezaron a presentar cánceres; los tumores eran más grandes y crecían de forma más agresiva y rápida que los cánceres antes de la inoculación masiva de las poblaciones; la aparición co-temporal (la aparición de más de un cáncer al mismo tiempo) de los cánceres se hizo más común -una situación que era típicamente muy

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inusual antes del lanzamiento de las vacunas de ARNm. El crecimiento de los tumores benignos se aceleró.

El 12 de marzo de 2021, los investigadores de Pfizer vacunaron a casi toda la cohorte placebo (no vacunada) del ensayo, aunque Pfizer se había comprometido previamente a realizar un seguimiento de las cohortes vacunadas y placebo durante dos años. Inmediatamente después de recibir la Autorización de Uso de Emergencia, Pfizer presionó a la FDA para que le permitiera vacunar a la cohorte no vacunada por razones «humanitarias». La vacunación del grupo placebo puso fin a la posibilidad de realizar estudios de seguridad a lo largo del tiempo.

Los casos de autoinmunidad reportados al Sistema de Notificación de Eventos Adversos a las Vacunas (VAERS) aumentaron 24 veces de 2020 a 2021, y las muertes anuales relacionadas con la autoinmunidad aumentaron 37 veces en el mismo período de tiempo.

En la presentación de datos y documentos de autorización de uso de emergencia de Pfizer de octubre de 2021 para niños de cinco a once años, los investigadores de Pfizer especularon por escrito que los daños subclínicos se manifestarían en los pacientes a largo plazo, lo que implica que las dosis continuas con daños subclínicos eventualmente se manifestarían como daños clínicos.

En los estudios de ensayo, la vacuna Moderna mRNA COVID-19 dañó la reproducción de los mamíferos, provocando un 22% menos de embarazos, malformaciones esqueléticas y problemas de lactancia.

Se produjeron cientos de posibles casos de enfermedad potenciada asociada a la vacuna (VAED) en los tres primeros meses de despliegue de la vacuna ARNm COVID de Pfizer. Los portavoces de la sanidad pública minimizaron su gravedad llamándolos «casos COVID avanzados».

Pfizer ocultó ocho muertes de vacunados que se produjeron durante el ensayo clínico con el fin de que sus resultados parecieran favorables para recibir su EUA para mayores de 16 años

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Las fuerzas más poderosas del mundo –incluida la Casa Blanca, el personal del propio presidente de los Estados Unidos; la Dra. Rochelle Walensky de los CDC; el jefe de la FDA, el Dr. Robert M Califf; el Dr. Anthony Fauci; Twitter y Facebook; los medios de comunicación tradicionales, incluidos el *New York Times*, la BBC, *The Guardian* y NPR; OfCom, la agencia británica reguladora de los medios de comunicación; organizaciones profesionales como el Colegio Americano de Obstetras y Ginecólogos, y la Agencia Europea de Medicamentos, el equivalente europeo de la FDA, y la Administración de Productos Terapéuticos, el equivalente australiano de la FDA – **todos trataron de suprimir la información** que Amy Kelly, los voluntarios de la investigación, y yo trajimos al mundo a partir de 2022, y que usted está a punto de absorber en las páginas siguientes.

Sin embargo, a pesar de la más poderosa campaña de censura y retribución lanzada en la historia de la humanidad –más poderosa que las anteriores por los efectos amplificadores de los medios sociales y la IA–, los hallazgos de estos voluntarios no fueron suprimidos finalmente, y sobrevivieron en medios alternativos, y en nuestro sitio DailyClout.io; para ser compartidos de boca en boca, salvando millones de vidas.

Avancemos rápidamente hasta acontecimientos más recientes. ¿Cuál ha sido el papel de esta información para detener este mayor crimen jamás cometido contra la humanidad?

Ha ocurrido lo peor. Las discapacidades aumentan en un millón al mes en Estados Unidos, según el ex gestor de fondos de cobertura de BlackRock Edward Dowd. El exceso de muertes ha aumentado mucho en Estados Unidos y Europa Occidental. Las tasas de natalidad han caído en picado, según el

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matemático Igor Chudov (y el investigador voluntario de WarRoom/DailyClout Dr. Robert Chandler) entre un 13% y un 20% desde 2021, según las bases de datos gubernamentales. Los atletas están cayendo muertos. Aumentan los turbo-cánceres. Los médicos convencionales pueden estar «desconcertados» por todo esto, pero tristemente, nosotros, gracias a Amy Kelly y los voluntarios, entendemos exactamente lo que está sucediendo.

Nuestro incesante esfuerzo por hacer llegar esta información al mundo, de forma intachable, ha dado por fin sus frutos. La captación de reforzadores es ahora del 4%. Muy pocas personas «reforzaron» a sus hijos. La mayoría de las universidades de Estados Unidos retiraron sus «mandatos» de vacunación. Los ingresos netos de Pfizer cayeron en el primer trimestre de 2024 a niveles anteriores a 2016. OfCom, que había atacado a Mark Steyn por «dar plataforma» en su programa mi descripción de los daños reproductivos y de otro tipo en los documentos de Pfizer, está siendo demandado por Steyn. La BBC tuvo que informar de que los daños de las vacunas son reales, al igual que el *New York Times*. La vacuna COVID de AstraZeneca, con una configuración algo diferente en Europa, fue retirada del mercado en mayo de 2024, tras las demandas por trombocitopenia trombótica (un efecto secundario sobre el que nuestra voluntaria de investigación, la Dra. Carol Taccetta, había informado a la FDA por carta en 2022), y la Agencia Europea del Medicamento retiró notablemente su EUA para AstraZeneca. Tres días después de que publicáramos nuestro informe que mostraba que la FDA y los CDC habían recibido la «Revisión acumulativa sobre embarazo y lactancia» de ocho páginas que confirmaba que la Dra. Walensky conocía la letalidad de la vacuna cuando dio su conferencia de prensa diciendo a las mujeres embarazadas que se pusieran la inyección, la Dra. Walensky dimitió.

Es realmente difícil enfrentarse a este material en los papeles que desempeñamos Amy Kelly y yo. Sin duda, para los voluntarios, desenterrar

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estas pruebas criminales es realmente doloroso. Puede ser difícil leer algo de lo que sigue. Como he dicho en otro lugar, ver este material es como estar entre los soldados aliados que abrieron por primera vez las puertas de Auschwitz. Pero hay que contar la verdad.

Entre otras razones importantes para contar estas verdades, la gente fue herida y asesinada con una tecnología novedosa que no se había utilizado antes en medicina; y estas páginas contienen pistas importantes sobre los mecanismos de estas lesiones, y por lo tanto, proporcionan muchas señales para los médicos y científicos en el futuro, para el tratamiento de las muchas lesiones que estas nuevas tecnologías de ARNm, inyectadas en los cuerpos de las personas, han provocado.

Debemos compartir la verdad, ya que la verdad salva y sostiene; y finalmente, la verdad curará.

La batalla continúa. Nadie que haya cometido este crimen masivo contra la humanidad está en la cárcel, ni siquiera se enfrenta a cargos civiles o penales. Hay al menos tres demandas contra Pfizer -dos nuestras y una de Brook Jackson- pero, hasta la fecha, ninguna ha prosperado por completo. El litigio se prolonga.

No obstante, a pesar de todo. Se corre la voz.

Amy Kelly y yo recibimos cientos de correos electrónicos de familias agradecidas, que nos hablan de sus bebés o nietos sanos y nos dan las gracias por haber salvado a esos bebés, o hijos e hijas y nueras, y sabemos que este proyecto ha salvado muchas vidas; quizá cientos de miles de vidas y puede que haya salvado a millones de personas de lesiones incapacitantes. Steve Bannon, que lo empezó todo, salvó cientos de miles de vidas y salvó a sus oyentes y a los

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nuestros de sufrir millones de lesiones. Dios sabe cuántos bebés nacerán en el futuro, sanos y salvos, gracias a nuestro trabajo colectivo, arduo y muy dirigido. La historia de este proyecto no ha terminado. Sus propias acciones, estimado lector, tras haber leído estos informes, forman parte de las ondas continuas de este trabajo.

ANEXO 1 Y 2

ANEXO 1

Efectos Adversos con algunas referencias bibliográficas seleccionadas (revisiones, meta-análisis y artículos de análisis de casos o estadísticos).

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ANEXO 2

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ANEXO

3

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ANEXO

4

Artículos científicos

Tasas de letalidad covid-19 y otros factores contribuyentes a la mortalidad.

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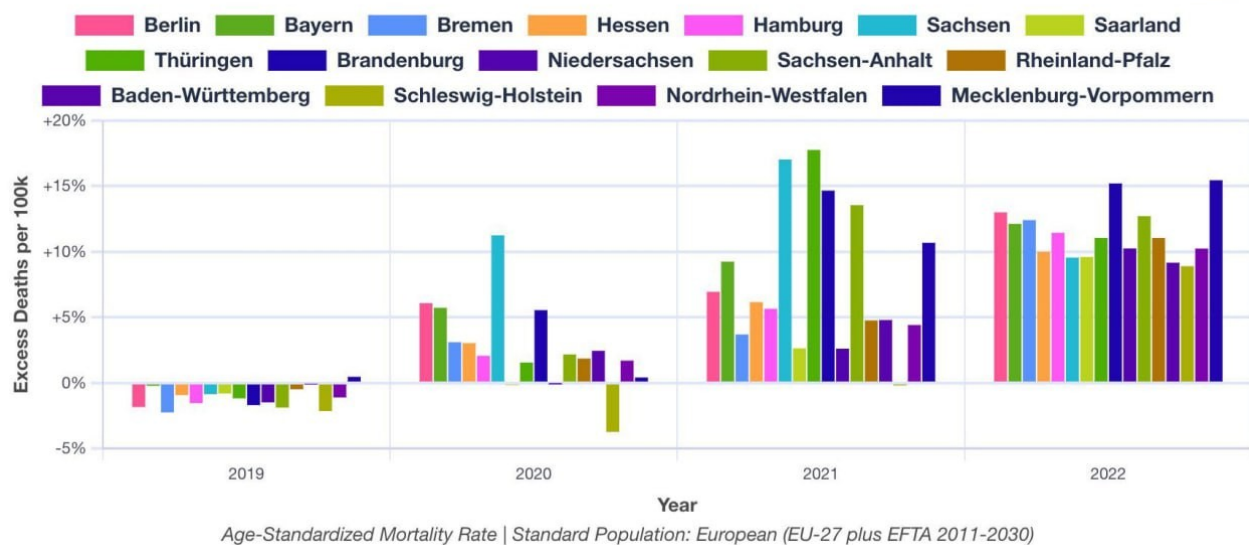
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Alemania



Excess Age-Std. Mortality (ASMR)



En el video inmediatamente debajo, el analista de datos alemán Tom Lausen, hablando frente a una audiencia en el parlamento federal del país, ofrece [su análisis de los datos de mortalidad](#) recopilados de la Asociación Nacional de Médicos de Seguros de Salud Estatutarios (o KBV). Y, como muestran sus gráficos, claramente, hubo aumentos asombrosos en las muertes atribuidas a causas desconocidas, muertes que ocurrieron 24 horas después del inicio de los síntomas y “**muertes súbitas**” todo perfectamente sincronizado con el lanzamiento de las inyecciones de COVID en el país.

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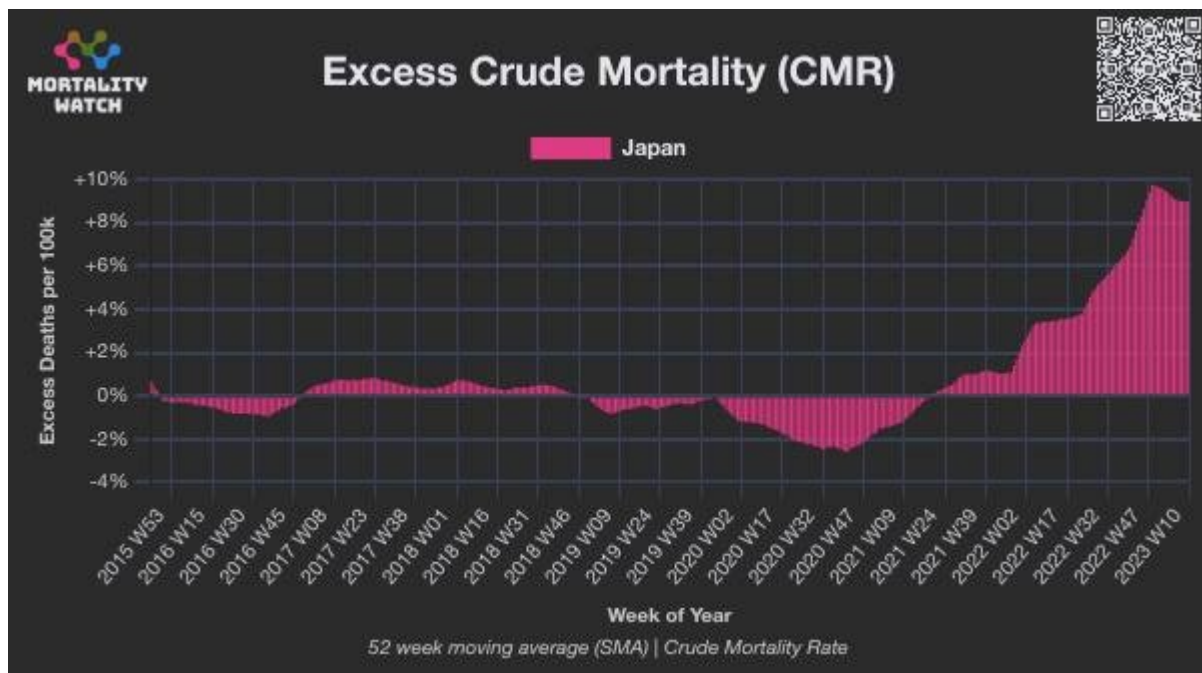
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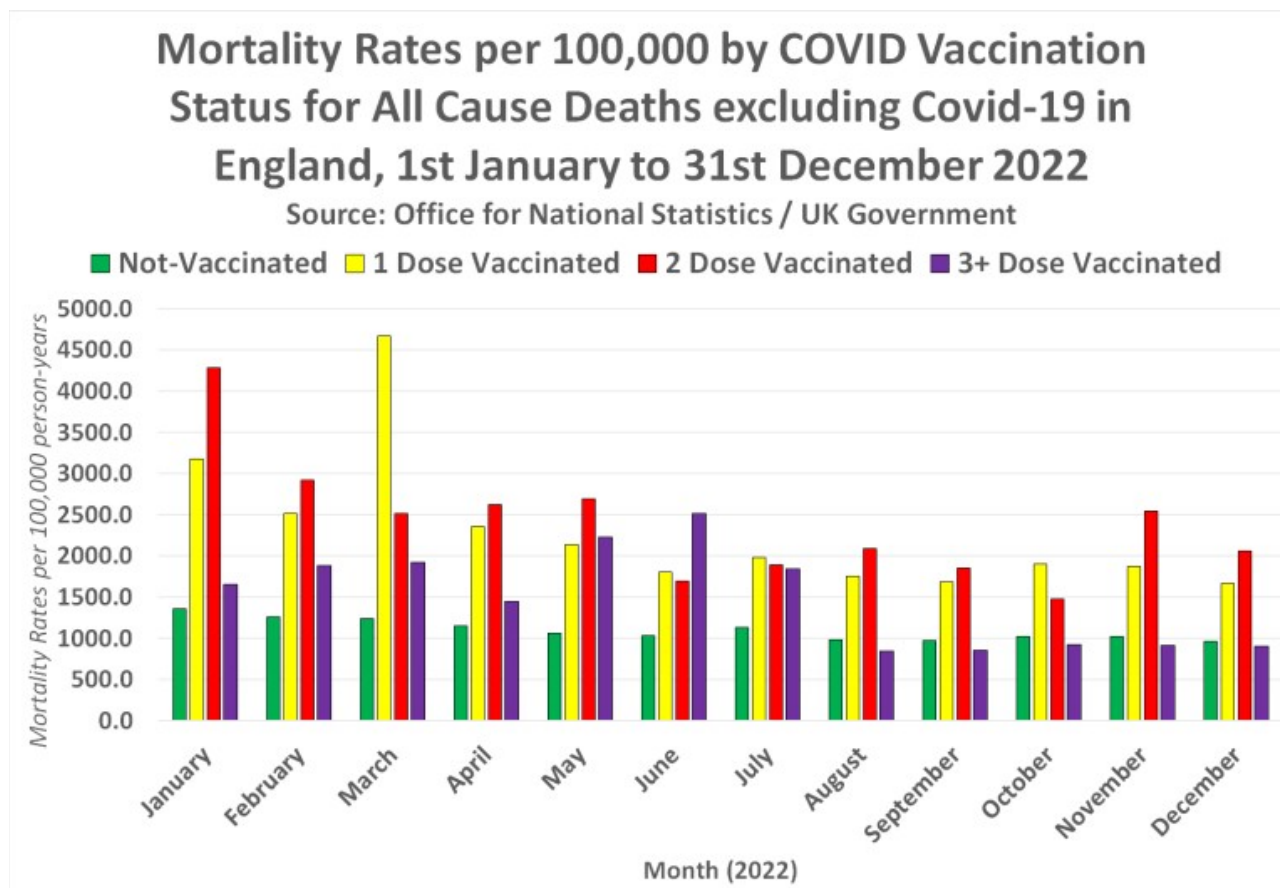
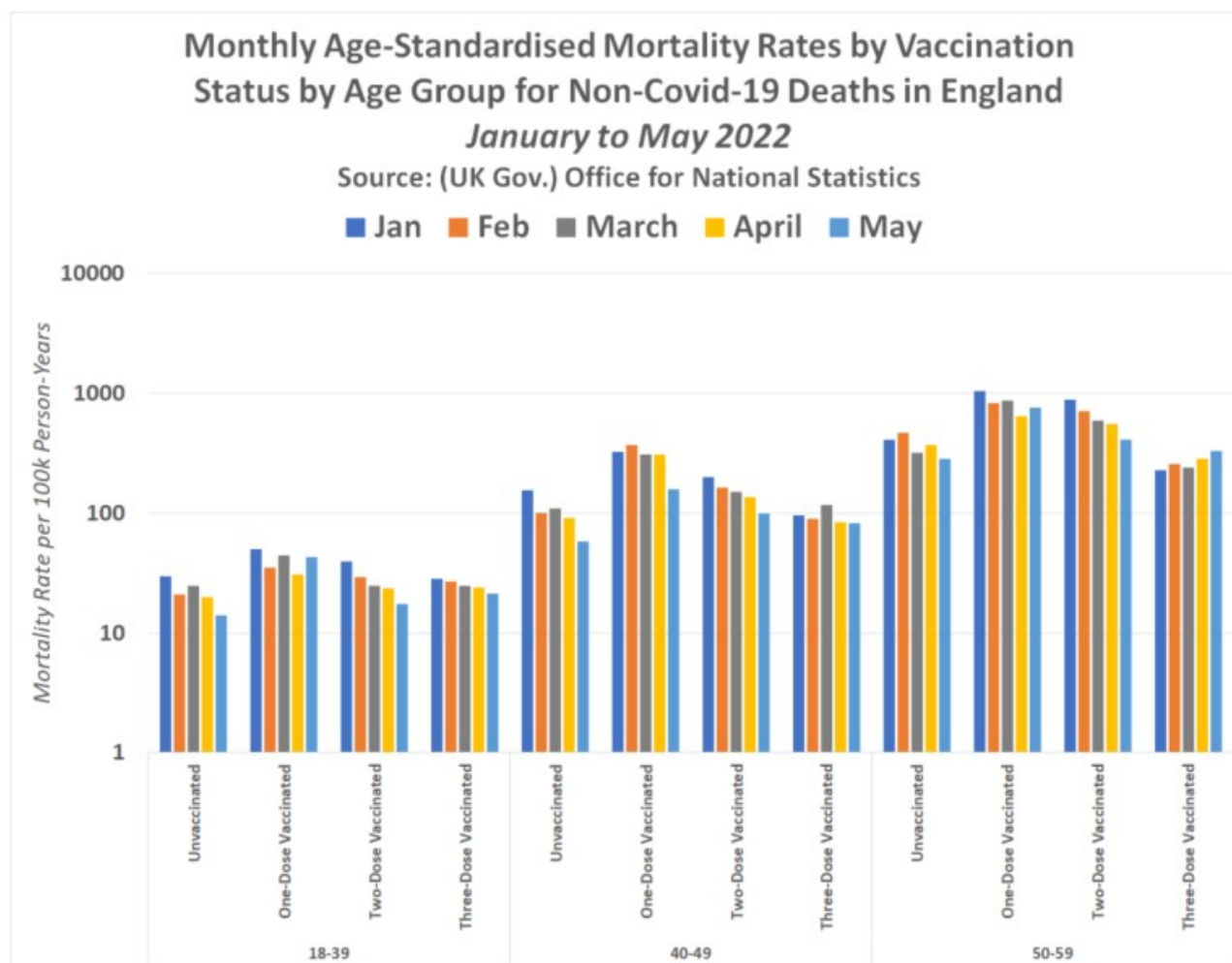
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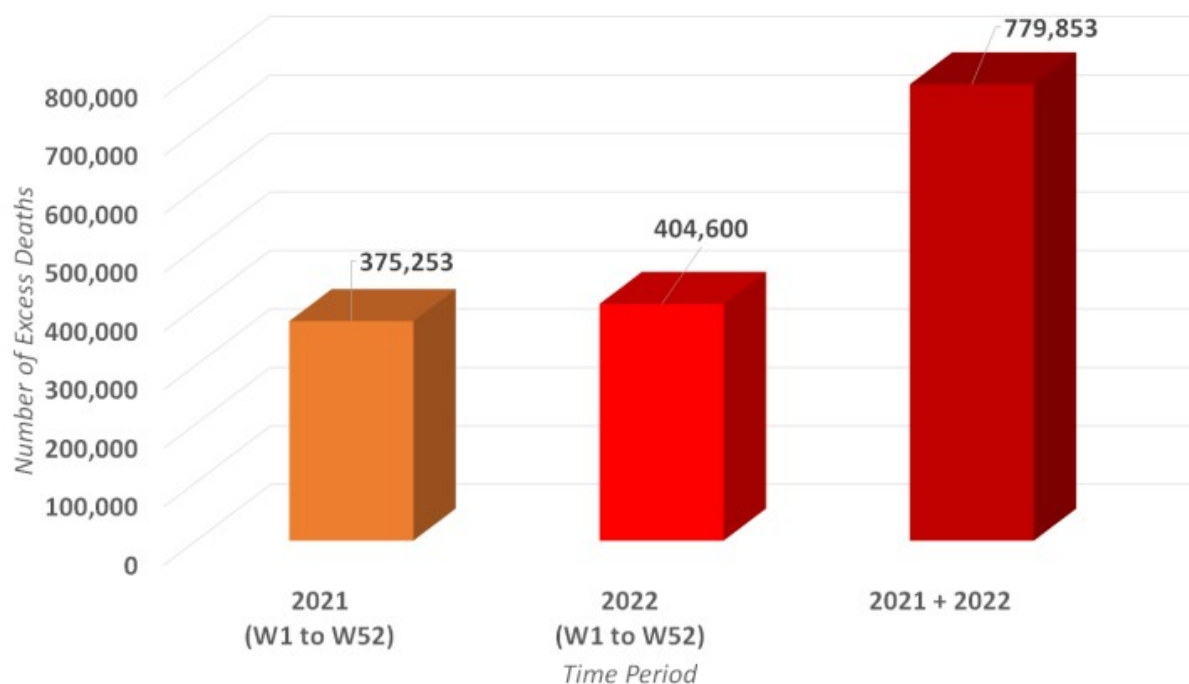
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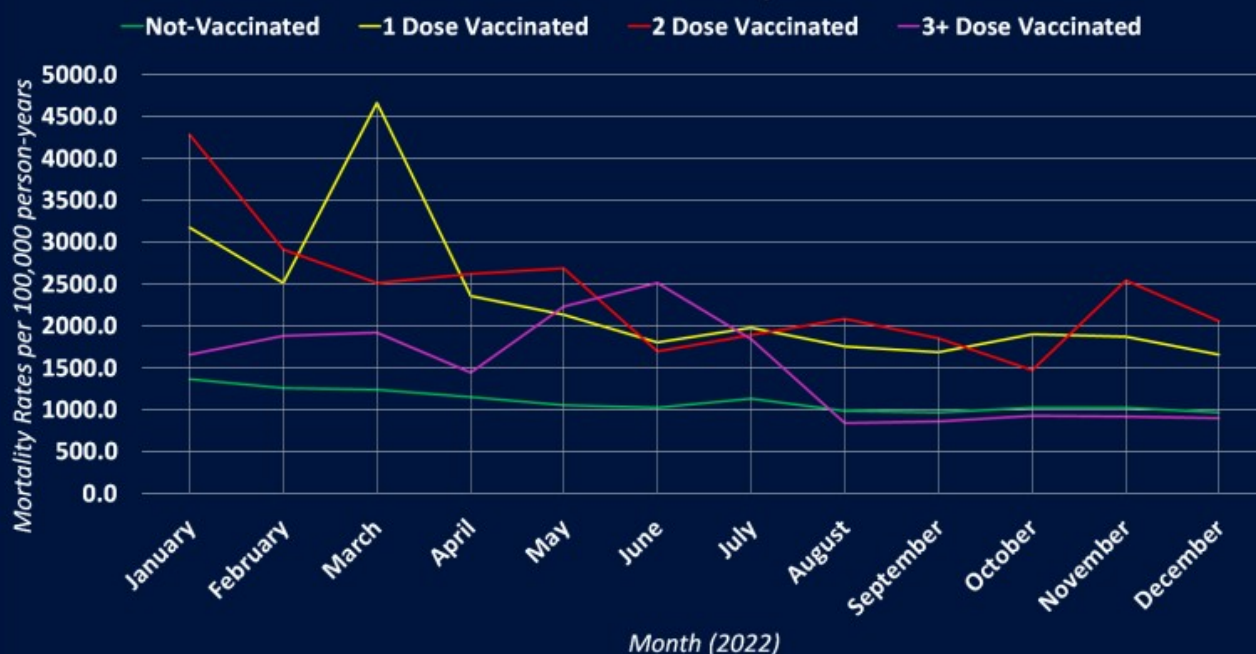
Excess Deaths in Europe, 2021 + 2022 (UK + 26 Countries inc. France, Germany, Spain, Italy etc. / excluding Ukraine)

Source: Government of each country / EuroMOMO



Mortality Rates per 100,000 by COVID Vaccination Status for All Cause Deaths excluding Covid-19 in England, 1st January to 31st December 2022

Source: Office for National Statistics / UK Government



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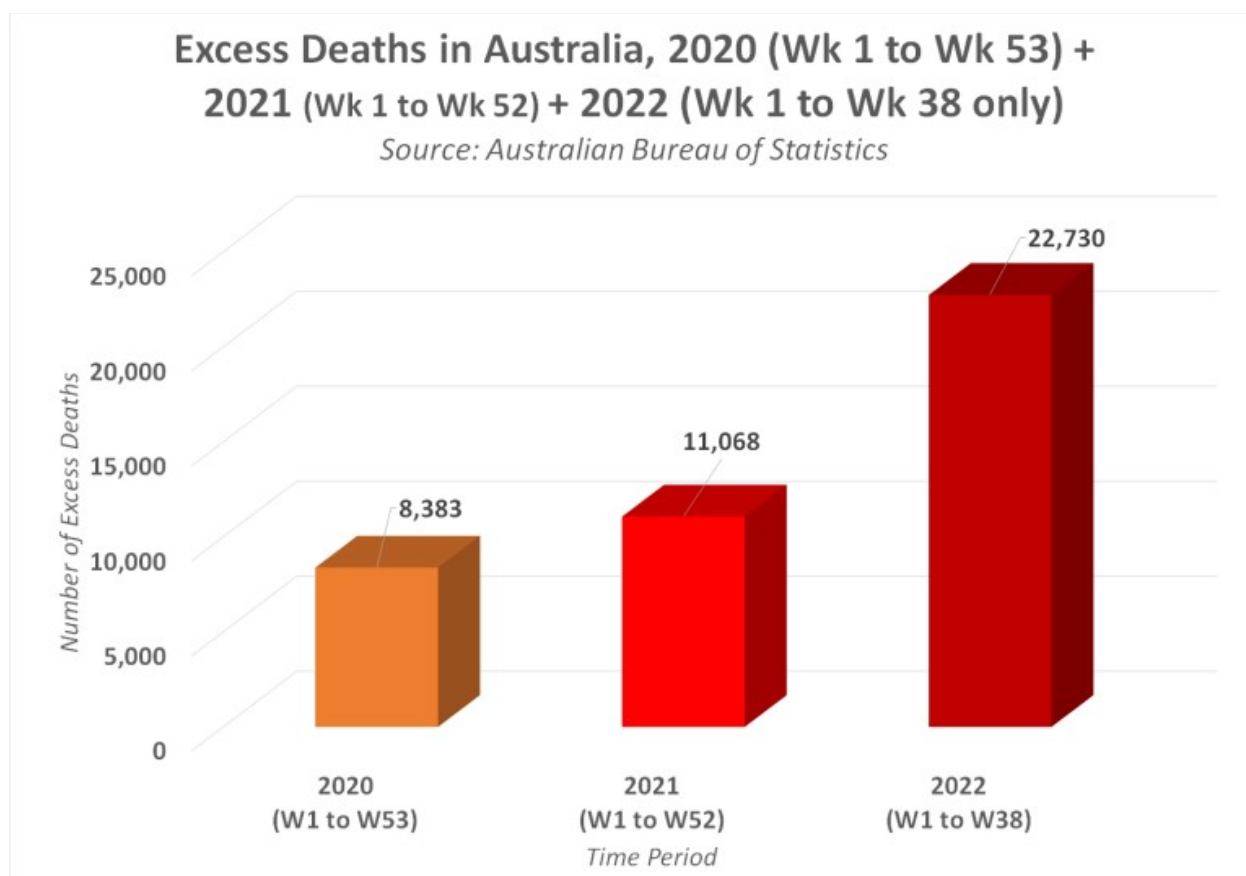
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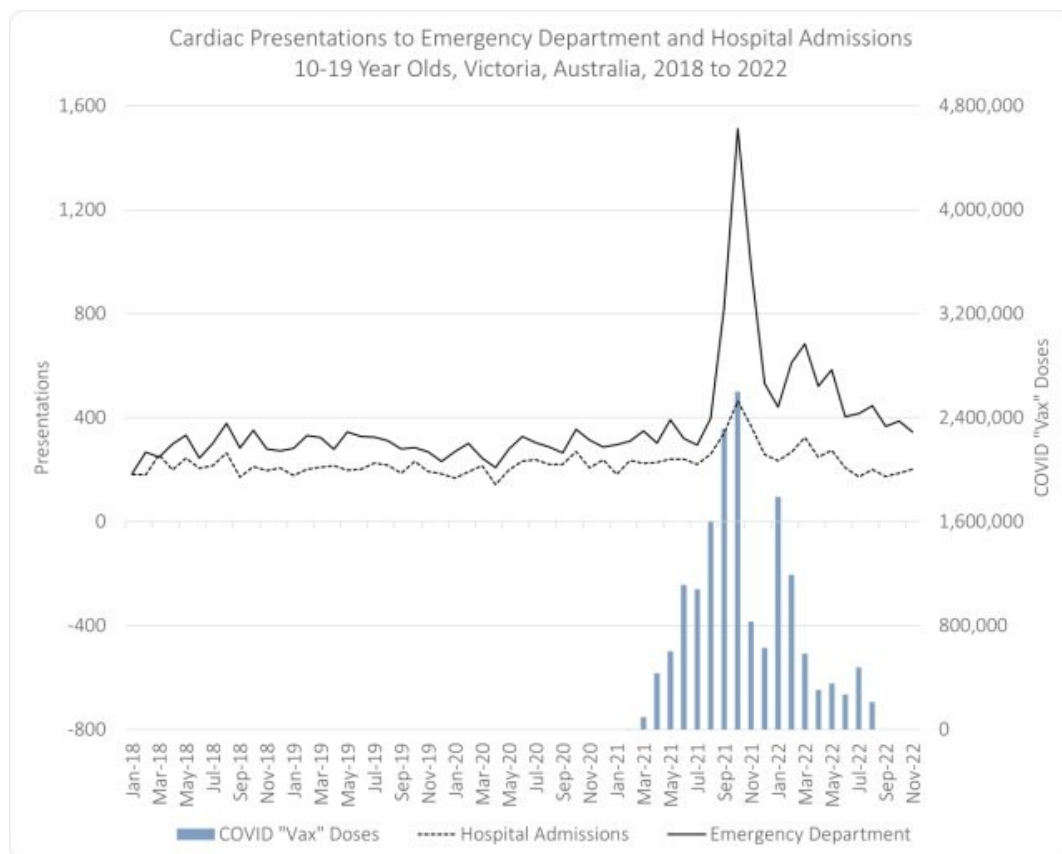
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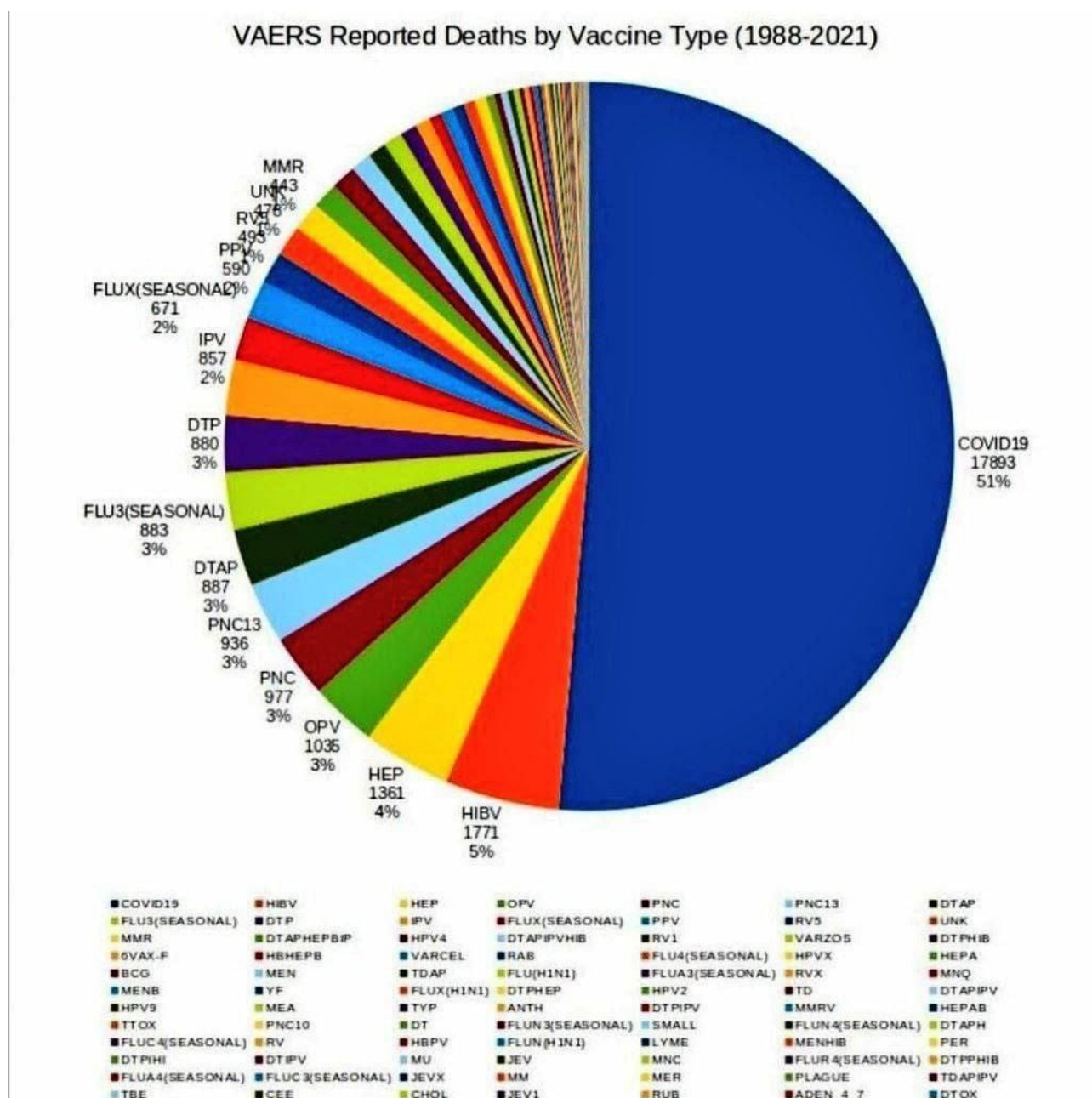
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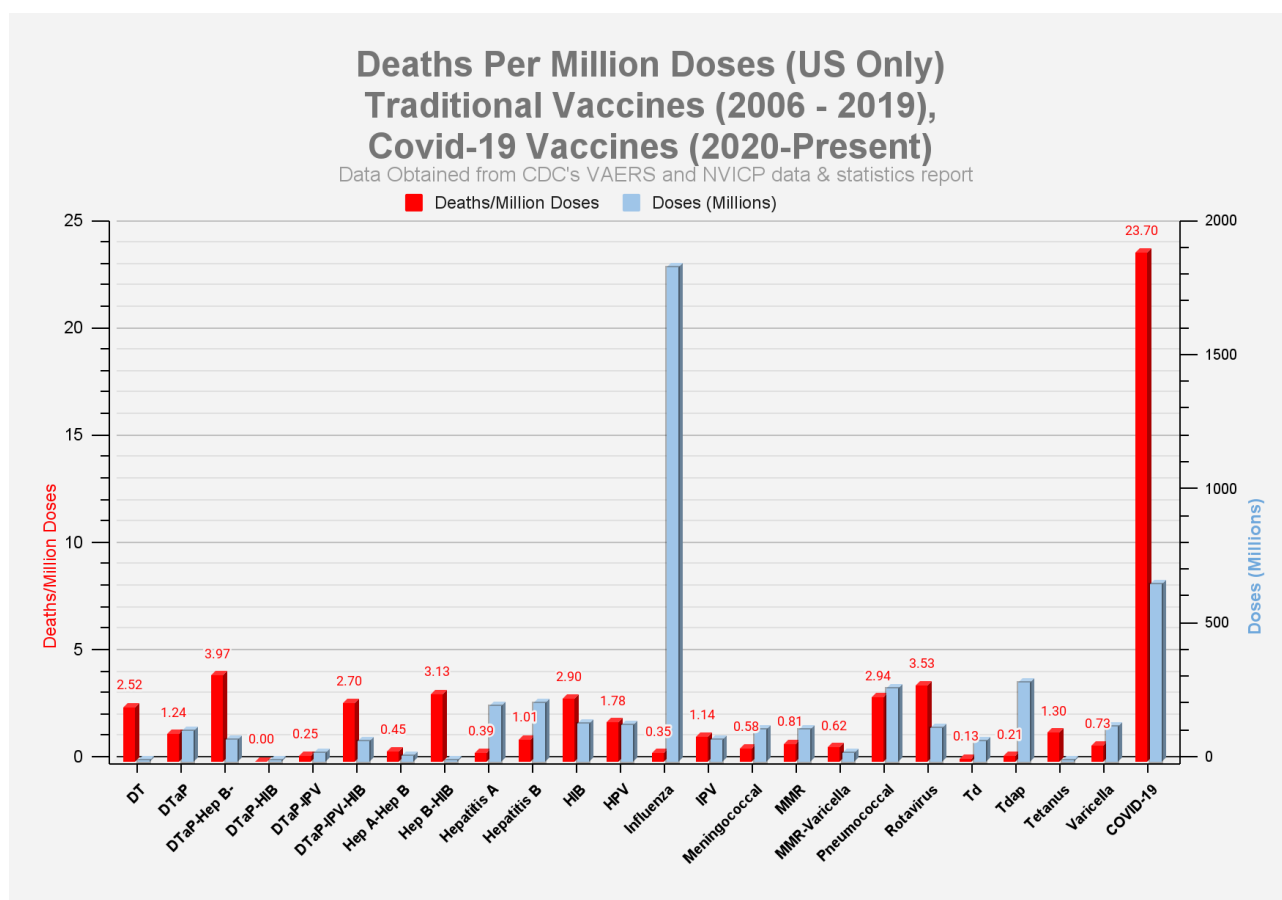
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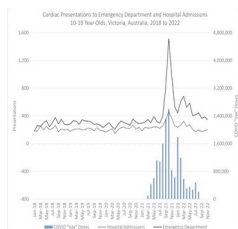
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**DOCUMENTO COMPLETO**

Referencia:
12/001/3/5848/2022
IDOC

Fecha de ingreso: 05/09/2022 10:04
Lugar de Ingreso: División Jurídico Notarial

Datos del documento

Titulares: DIVISIÓN SERVICIOS JURÍDICOS
Resumen: Acceso a la información publica- Fernando Vega Torrens
Cantidad de Actuaciones: 11

Campos del tipo de documento

Procedencia: 12/001/1.511
Nómina Procedencia:
Oficio:



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación: 03/11/2022 10:49
Usuario Creación: ANA LUCIA SANGUINETTI
Dependencia: 12/001/1.5 Dirección General
Finalizada Por: Ana Lucia Sanguinetti
Adjuntos: 1
Acceso 5848.pdf

Firmado Por: ANA LUCÍA SANGUINETTI ROBAUDO
Fecha Firma: 03/11/2022 10:50

Montevideo, 3 de Noviembre de 2022

Ref. N° 12/001/3/5848/2022.-

Mediante acceso a la información pública se solicita:

“TEMA PCR. CONSIDERANDOS:

Vuestro Ministerio a autorizado y ha condicionado la movilidad de ciudadanos en función del Test RT PCR, el cual viene altamente cuestionado desde las Publicaciones que Christian Drosten realizó a 24 horas del alerta que emitió China en 2020.

PREGUNTAS.

- 1) Deseo saber si los Test por Ustedes validados tienen la posibilidad de distinguir entre un Virus Activo de un Virus Inactivo.*
- 2) Deseo saber si los Test por ustedes validados pueden determinar el grado de infecciosidad del paciente.*
- 3) Deseo saber si a vuestro Ministerio le consta que algún trabajo científico en el mundo, haya podido verificar la existencia del Virus Sars Cov2 infectando a personal o animal sano a partir de células infectadas con dicho virus.*
- 4) Deseo consultar si vuestro Ministerio esta al tanto de algún trabajo científico que hayan podido documentar poder infectar células humanas de pulmón a partir hisopados de personas asintomáticos pero con un PCR positivo.*
- 5) Por último y no menos importante consultar si vuestro Ministerio está al tanto que el nivel de fiabilidad del resultado está en función de la cantidad de ciclos o ampliaciones necesarias para obtener la fluorescencia o CT de corte”.*

Consultada la Dirección General de la Salud, se informa por parte de la División de Epidemiología:

- 1) Deseo saber si los Test por Ustedes validados tienen la posibilidad de distinguir entre un Virus Activo de un Virus Inactivo.

El Departamento de Laboratorio de Salud Pública no validó test para distinguir entre Virus activo de un Virus inactivo.

- 2) Deseo saber si los Test por ustedes validados pueden determinar el grado de infecciosidad del paciente.

El Departamento de Laboratorios de Salud Pública no validó estudios para determinar el grado de infecciosidad del paciente.

- 3) Deseo saber si a vuestro Ministerio le consta que algún trabajo científico en el mundo , haya podido verificar la existencia del Virus Sars Cov2 infectando a personal o animal sano a partir de células infectadas con dicho virus.

El Departamento de Laboratorios de Salud Pública no tiene conocimiento de trabajo científico que comunique lo que se consulta.

- 4) Deseo consultar si vuestro Ministerio esta al tanto de algún trabajo científico que hayan podido documentar poder infectar células humanas de pulmón a partir hisopados de personas asintomáticos pero con un PCR positivo.

El Departamento de Laboratorios de Salud Pública no tiene conocimiento de trabajo científico que comunique lo que se consulta.

- 5) Por último y no menos importante consultar si vuestro Ministerio está al tanto que el nivel de fiabilidad del resultado está en función de la cantidad de ciclos o ampliaciones necesarias para obtener la fluorescencia o CT de corte.

Desde el punto de vista del laboratorio se utilizan el número los ciclos en que aparece la positividad para cada reactivo utilizado para definir si el material genético del virus se detectó en la muestra.

En virtud de los motivos expuestos, se sugiere hacer lugar a lo solicitado en los términos del presente informe.-



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación: 04/11/2022 10:40
Usuario Creación: MIRIAN OLID
Dependencia: 12/001/1.51 Dpto. De Secretaría Y Acuerdos
Finalizada Por: Gustavo Cardoso, Mirian Olid
Adjuntos: 1
001-3-5848-2022 respuesta ACCESO A LA INFORMACIÓN fernando vega torrens.pdf

Firmado Por: MIRIAN GRICEL OLID PRESA
Fecha Firma: 04/11/2022 10:41

Firmado Por: GUSTAVO CARDOSO MUÑOZ
Fecha Firma: 07/11/2022 11:19

Ministerio de Salud Pública

Dirección General de Secretaría

VISTO: la solicitud de información pública efectuada por el Sr. Fernando Vega Torrens, titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381 de 17 de octubre de 2008;

RESULTANDO: que el peticionante solicita información vinculada a los test RT - PCR validados por el Ministerio de salud Pública, a saber: i) si distinguen entre un virus activo y un virus inactivo; si determinan el grado de infecciosidad del paciente y si se ha podido verificar la existencia del Virus Sars Cov2 infectando a personal o animal sano a partir de células infectadas con dicho virus; ii) si el Ministerio de Salud Pública está al tanto de algún trabajo científico que hayan podido documentar acerca de infectar células humanas de pulmón a partir hisopados de personas asintomáticos pero con un PCR positivo; y iii) si el nivel de fiabilidad del resultado está en función de la cantidad de ciclos o ampliaciones necesarias para obtener la fluorescencia o CT de corte;

CONSIDERANDO: I) que corresponde hacer lugar a lo solicitado;

II) que de acuerdo a lo dispuesto por el Artículo 16 de la citada disposición legal, el acto que resuelva la petición debe emanar del jerarca máximo del Inciso o quien posea facultades delegadas al efecto;

ATENTO: a lo precedentemente expuesto y a lo establecido por Resolución Ministerial N° 38/991 de 22 de enero de 1991;

EL DIRECTOR GENERAL DE SECRETARÍA

en ejercicio de las atribuciones delegadas

RESUELVE:

- 1º) Autorízase el acceso a la información en referencia a la solicitud efectuada por el **Sr. Fernando Vega Torrens**, titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381 de 17 de octubre de 2008.

- 2º) Notifíquese a la parte interesada a través de Secretaría de la Dirección General de Secretaría. Pase al Departamento de Comunicaciones para su publicación en la página web institucional. Cumplido, archívese.

Ref. N° 001-3-5848-2022

VC

Documento: 12/001/3/5848/2022 Actuación: 11

30

Se otorgó N° de Resolución DIGESE N° 804-2022.



DOCUMENTO COMPLETO

Referencia:
12/001/3/2697/2023
IDOC

Fecha de ingreso: 05/05/2023 12:04
Lugar de Ingreso: División Jurídico Notarial

Datos del documento

Titulares: DIRECCIÓN SERVICIOS JURÍDICOS
Resumen: Acceso a la información pública - Fernando Vega Torrens
Cantidad de Actuaciones: 8

Campos del tipo de documento

Procedencia: 12/001/1.511
Nómina Procedencia: -
Oficio: -



Ministerio
de Salud Pública

DIRECCIÓN GENERAL DE LA SALUD

Montevideo, 17 de mayo de 2023

Sra. Directora General de Salud,

Dra. Adriana Alfonso,

Ref: acceso de información 3/2697/2023

Se solicita:

- 1) Saber si el Ministerio de Salud Pública Obliga a las prestadoras de salud a que Obliguen a los ciudadanos a utilizar tapabocas?
- 2) Saber si el MSP Obliga a los ciudadanos al uso del tapabocas y en caso positivo en qué circunstancias?
- 3) Saber si el MSP solo sugiere y son los prestadores de salud los que obligan el uso del tapabocas a sus pacientes.
- 4) Consultar si vuestro Ministerio dispone de evidencia científica que pueda justificar una mínima evidencia superior al 10% en eficacia entre grupos de ensayo con y sin tapabocas.

Respuesta 1, 2 y 3:

El Ministerio de Salud Pública establece en el comunicado del 9 de junio de 2022 los casos en que se debe usar obligatoriamente el tapabocas. (disponible en: <https://www.gub.uy/ministerio-saludpublica/comunicacion/noticias/uso-mascarilla-facial-obligatorio-altamenterecomendado>)

Respuesta 4: Aún no existe evidencia científica publicada. La experiencia no publicada de los profesionales de salud expresa que en los ámbitos hospitalarios el uso de mascarilla disminuye el contagio de enf. de transmisión respiratoria.

Dra. Ima León

Unidad de Información



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación: 23/05/2023 8:15
Usuario Creación: ANA LUCIA SANGUINETTI
Dependencia: 12/001/1.5 Dirección General
Finalizada Por: Ana Lucia Sanguinetti
Adjuntos: 1
Acceso 3-2697-2023.pdf

Firmado Por: ANA LUCÍA SANGUINETTI ROBAUDO
Fecha Firma: 23/05/2023 8:15

Montevideo, 23 de Mayo de 2023

Ref. N° 12/001/3/2697/2023.-

Mediante acceso a la información pública se solicita:

“1) Quisiera saber si el Ministerio de Salud Pública Obliga a las prestadoras de salud a que Obliguen a los ciudadanos a utilizar tapabocas? 2) Deseo saber si el MSP Obliga a los ciudadanos al uso del tapabocas y en caso positivo en que circunstancias ? 3) Deseo saber si el MSP solo sugiere y son los prestadores de salud los que obligan el uso del tapabocas a sus pacientes. 4) Por último deseo consultar si vuestro Ministerio dispone de evidencia científica que pueda justificar una mínima evidencia superior al 10% en eficacia entre grupos de ensayo con y sin tapabocas.”

Consultada la Unidad de Información, se elabora informe que luce en los presentes obrados y se sugiere notificar, a fojas 8.-

Al respecto, venidos los presentes obrados a la suscrita, corresponde informar, no obstante la información recibida, lo siguiente:

Corresponde destacar, en primer lugar, que por mandato del artículo 13 de la Ley N° 18.381, las solicitudes de acceso a la información pública deben contener *“La descripción clara de la información requerida y cualquier dato que facilite su localización”*, lo cual en el caso del escrito presentado por el interesado, presenta un pliego de preguntas que exceden el objeto del instrumento normativo aplicable.

A su vez, como destaca el artículo 14 de la norma antes mencionada, *“Esta ley tampoco faculta a los peticionarios a exigir a los organismos que efectúen evaluaciones o análisis de la información que posean...”*, por lo cual tampoco ésta cartera de Estado está obligada a generar información.

Finalmente corresponde concluir que la Ley N° 18.381 reglamenta un canal para solicitar información concreta, no para obligar a la Administración a que elabore análisis o informes a medida. No es un mecanismo de solicitud de opiniones, explicaciones o justificaciones ni tampoco de elaboración de informes situaciones hipotéticas.-

En virtud de lo expuesto, y no obstante lo manifestado, se sugiere hacer lugar parcial a lo solicitado al amparo del artículo 14 de la Ley N°18.381 y en los términos del presente informe.-



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación: 25/05/2023 12:57
Usuario Creación: MARIA DEL HUERTO CORRADO
Dependencia: 12/001/1.51 Dpto. De Secretaría Y Acuerdos
Finalizada Por: Gustavo Cardoso, Maria del Huerto Corrado
Adjuntos: 1
001-3-2697-2023 parcial ACCESO A INFORMACIÓN SOLICITADO fernando vega torrens.pdf

Firmado Por: MARÍA del HUERTO CORRADO SCARCELA
Fecha Firma: 25/05/2023 12:57

Firmado Por: GUSTAVO CARDOSO MUÑOZ
Fecha Firma: 25/05/2023 13:46

Ministerio de Salud Pública
Dirección General de Secretaría

VISTO: la solicitud de información pública efectuada por el Sr. Fernando Vega Torrens, titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381, de 17 de octubre de 2008;

RESULTANDO: que el peticionante solicita acceder a la siguiente información:

i) si el Ministerio de Salud Pública obliga a las prestadoras de salud a que obliguen a los ciudadanos a utilizar tapabocas y a los ciudadanos al uso del tapabocas y en caso positivo, en qué circunstancias; ii) si el Ministerio de Salud Pública sólo sugiere y son los prestadores de salud los que obligan el uso del tapabocas a sus pacientes; y iii) si se dispone de evidencia científica que pueda justificar una mínima evidencia superior al 10% en eficacia entre grupos de ensayo con y sin tapabocas;

CONSIDERANDO: I) que en mérito de lo informado por la Asesoría Legal de la Dirección General de Secretaría, por mandato del artículo 13 de la Ley N° 18.381, las solicitudes de acceso a la información pública deben contener “la descripción clara de la información requerida y cualquier dato que facilite su localización”, lo cual en el caso del escrito presentado por el interesado, presenta un pliego de preguntas que exceden el objeto del instrumento normativo aplicable. A su vez, como destaca el artículo 14 de la norma antes mencionada, “Esta ley tampoco faculta a los peticionarios a exigir a los organismos que efectúen evaluaciones o análisis de la información que posean...”, por lo cual tampoco esta cartera de Estado está obligada a generar información. Finalmente corresponde concluir que la Ley N° 18.381 reglamenta un canal para solicitar información concreta, no para obligar a la Administración a que elabore análisis o informes a medida. No es un mecanismo de solicitud de opiniones, explicaciones o justificaciones ni tampoco de elaboración de informes situaciones hipotéticas, por lo que corresponde acceder a lo solicitado en forma parcial;

II) que de acuerdo a lo dispuesto por el artículo 16 de la citada disposición legal, el acto que resuelva la petición debe emanar del jerarca máximo del Inciso o quien posea facultades delegadas al efecto;

ATENTO: a lo precedentemente expuesto y a lo establecido por Resolución Ministerial N° 38/991 de 22 de enero de 1991;

EL DIRECTOR GENERAL DE SECRETARÍA

en ejercicio de las atribuciones delegadas

RESUELVE:

- 1º) Autorízase el acceso a la información en forma parcial, en referencia a la solicitud efectuada por el Sr. Fernando Vega Torrens, titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381, de 17 de octubre de 2008.
- 2º) Notifíquese a la parte interesada a través de Secretaría de la Dirección General de Secretaría. Pase al Departamento de Comunicaciones para su publicación en la página web institucional. Cumplido, archívese.

Ref. N° 001-3-2697-2023

VC

Documento: 12/001/3/2697/2023 Actuación: 8

20

Se otorgó N° de Res. DIGESE 391-2023

**DOCUMENTO COMPLETO**

Referencia:
12/001/3/3163/2021
IDOC

Fecha de ingreso: 11/05/2021 11:18
Lugar de Ingreso: División Jurídico Notarial

Datos del documento

Titulares: MSP
Resumen: Acceso a la información pública - Fernando Vega Torrens
Cantidad de Actuaciones: 10

Campos del tipo de documento

Procedencia: 12/001/1.511
Nómina Procedencia:
Oficio:

Documento: 12/001/3/3163/2021 Actuación: 1

2

Pase a DIGESA a efectos de informar lo solicitado

----- Mensaje reenviado -----

De: "Atencion al usuario" <atencionalusuario@msp.gub.uy>Para: digese@msp.gub.uy

Enviados: Martes , 11 de Mayo 2021 9:16:12

Asunto: Solicitud de acceso a la informacion

Fernando Vega Torrens ([webform_submission:values:correo_electronico:raw]) ha enviado la siguiente consulta:

Solicitud de acceso

Información personal

Nombre completo:

Fernando Vega Torrens

Documento de identidad:

26299673

Dirección:

GENERAL LUNA 1390

Teléfono:

099611205

Correo electrónico:

[<mailto:fernando@fulltime.uy> | fernando@fulltime.uy]

Datos de la solicitud

Información solicitada:

Deseo consultar si el MSP, tiene o cuenta con información chequeada de quién tiene el virus Sars-CoV2 cultivado, aislado, purificado , y correctamente secuenciado.

En caso de ser una institución Uruguaya necesitamos toda la documentación para buscar la replicabilidad en otro laboratorio y comenzar los estudios adecuados, en caso de ser en el exterior agradecemos se nos brinde la información y en caso que no se tenga dicha información agradeceríamos que además de informarnos se dé difusión pública al tema.

El genetista Argentino Dr. Luis Marcelo Martinez me informa que realizado monitoreos en publicaciones de EEUU y Europa no ha encontrado publicaciones en este sentido.

Desde ya muchas gracias,

Formato de respuesta

Formato de respuesta:

Mail con archivos adjuntos

Cláusula de consentimiento informado

Términos de la cláusula

Términos de la cláusula:

Acepto los términos



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación: 07/06/2021 14:50
Usuario Creación: MARIA DEL HUERTO CORRADO
Dependencia: 12/001/1.51 Dpto. De Secretaría Y Acuerdos
Finalizada Por: Gustavo Cardoso, Maria del Huerto Corrado
Adjuntos: 1
001-3-3163-2021 prorroga acceso a la información FERNANDO VEGA TORRENS.pdf

Firmado Por: MARÍA del HUERTO CORRADO SCARCELA
Fecha Firma: 07/06/2021 14:53

Firmado Por: GUSTAVO CARDOSO MUÑOZ
Fecha Firma: 07/06/2021 17:37

Ministerio de Salud Pública

Dirección General de Secretaría

VISTO: la solicitud de información pública efectuada por el Sr. Fernando Vega Torrens titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381 de 17 de octubre de 2008;

RESULTANDO: que el peticionante solicita información sobre: si el MSP cuenta con información chequeada de quién tiene el virus Sars- CoV2 cultivado, aislado, purificado y correctamente secuenciado;

CONSIDERANDO: I) que se ha entendido necesario solicitar una prórroga para recabar la información respectiva;

II) que corresponde en consecuencia prorrogar el plazo que alude el Artículo 15 de la Ley N° 18.381, a regir a partir del vencimiento del original;

ATENTO: a lo precedentemente expuesto y a lo establecido por Resolución Ministerial N° 38/991 de 22 de enero de 1991;

LA DIRECCIÓN GENERAL DE SECRETARÍA

en ejercicio de las atribuciones delegadas

RESUELVE:

- 1º) Prorrógase el plazo que refiere el Artículo 15 de la Ley N° 18.381 de 17 de octubre de 2008, en referencia a la solicitud efectuada por el Sr. Fernando Vega Torrens, titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381 de 17 de octubre de 2008, por el máximo legal a partir del vencimiento del plazo original.
- 2º) Notifíquese a la parte interesada a través de Secretaría de la Dirección General de Secretaría. Cumplido, pase a la Dirección General de la Salud.

Ref. N° 001-3-3163-2021

VF

Se otorgó N° de Res. DIGESE 382-2021

A DIRECCIÓN GENERAL DE SECRETARÍA

En función de lo solicitado mediante acceso a la información pública, se informa que, de acuerdo a lo informado por la Dirección del Departamento de Laboratorios del MSP, no se tiene conocimiento de la existencia de lo solicitado en nuestro país.

Se eleva sugiriendo dar respuesta a lo consultado, en los términos del presente informe.



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación: 21/06/2021 14:00
Usuario Creación: MARIA DEL HUERTO CORRADO
Dependencia: 12/001/1.51 Dpto. De Secretaría Y Acuerdos
Finalizada Por: Gustavo Cardoso, Maria del Huerto Corrado
Adjuntos: 1
001-3-3163-2021 RESPUESTA acceso a la información FERNANDO VEGA TORRENS.pdf

Firmado Por: MARÍA del HUERTO CORRADO SCARCELA
Fecha Firma: 21/06/2021 14:00

Firmado Por: GUSTAVO CARDOSO MUÑOZ
Fecha Firma: 21/06/2021 16:06

Ministerio de Salud Pública

Dirección General de Secretaría

VISTO: la solicitud de información pública efectuada por el Sr. Fernando Vega Torrens titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381 de 17 de octubre de 2008;

RESULTANDO: que el peticionante solicita información sobre: si el MSP cuenta con información de quién tiene el virus Sars- CoV2 cultivado, aislado, purificado y correctamente secuenciado;

CONSIDERANDO: que de acuerdo a lo dispuesto por el Artículo 16 de la citada disposición legal, el acto que resuelva la petición debe emanar del jerarca máximo del Inciso o quien posea facultades delegadas al efecto;

ATENTO: a lo precedentemente expuesto y a lo establecido por Resolución Ministerial N° 38/991 de 22 de enero de 1991;

LA DIRECCIÓN GENERAL DE SECRETARÍA

en ejercicio de las atribuciones delegadas

RESUELVE:

- 1º) Autorízase el acceso a la información en referencia a la solicitud efectuada por el Sr. Fernando Vega Torrens titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381 de 17 de octubre de 2008.
- 2º) Notifíquese a la parte interesada a través de Secretaría de la Dirección General de Secretaría. Pase al Departamento de Comunicaciones para su publicación en la página web Institucional. Cumplido, archívese.

Documento: 12/001/3/3163/2021 Actuación: 10

SE OTORGÓ RESOLUCIÓN DIGESE Nº 427 - 2021

**DOCUMENTO COMPLETO**

Referencia:
12/001/3/764/2024
IDOC

Fecha de ingreso: 06/02/2024 9:07
Lugar de Ingreso: División Jurídico Notarial

Datos del documento

Titulares: DIVISIÓN SERVICIOS JURÍDICOS
Resumen: Acceso a la información pública - Fernando Vega Torrens.
Trámite # 8976405.
Cantidad de Actuaciones: 14

Campos del tipo de documento

Procedencia: 12/001/1.511
Nómina Procedencia:
Oficio:



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación: 06/02/2024 9:08
Usuario Creación: LAURA CAROLINA BIDONDO LÓPEZ
Dependencia: 12/001/1.511 División Jurídico Notarial
Finalizada Por: Laura Carolina Bidondo López
Adjuntos: 0

Firmado Por: LAURA CAROLINA BIDONDO LÓPEZ
Fecha Firma: 06/02/2024 9:09

Habiendose ingresado a la planilla, pase a la DIGESE a efectos de informar lo solicitado.

----- Mensaje reenviado -----

De: "Ministerio de Salud Pública" <msp_tramites@tramitesenlinea.gub.uy>

Para: "Direccion General de Secretaria" <digese@msp.gub.uy>

Enviados: [Sábado, 3 de Febrero](#) 2024 15:19:19

Asunto: Solicitud de acceso a la Información Pública - Trámite # 8976405

Se ha ingresado una nueva solicitud:

Información personal

Nombre completo: Fernando Vega Torrens

Documento de identidad: 26299673

Dirección: GENERAL LUNA 1386

Teléfono: 099611205

Correo electrónico: fernando@fulltime.uy

Datos de la solicitud

Información solicitada: Atención Dra. Karina Rando.

Por la presente deseo hacer un acceso a la información pública con el siguiente objetivo.

1) Se me informe cantidad de inoculaciones compradas a partir de Octubre del 2023 a la firma PFIZER contra el supuesto SarsCoV2, desglosando por lotes, y vencimientos,, vale decir Cantidad, detalle del Lote, Vencimientos de los lotes.

2) se me informe que destino tuvieron las inoculaciones vencidas hasta el momento y el detalle de cantidad , lote y vencimiento de dichas inoculaciones vencidas.

Simplemente aprovecho la ocasión para informarle que en Nueva Zelanda se han publicado, información sobre lotes que llegan a tener un 21% de Letalidad en sus inyectados, el Diputado César Vega a informado a la cámara de diputados dicha información, quizá le sea de utilidad si el objetivo final del MSP, es SALVAR VIDAS, también es cierto que puede "hacer" como el diputado Alvaro Perrone de su partido político , que solicitó desestimar todo y pasar a tratar "temas más importantes" Desde ya le deseo muy buenas tardes y mucha salud, para ver y vivir todo lo que viene a partir de las verdades que llevaran a la que se haga justicia y todo el fraude termine para siempre.

Uruguay de Uruguayos libres, soberanos y bien cuestionadores.

fernando vega torrens

099 611 205

Formato de respuesta: Mail con archivos adjuntos



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación:	09/02/2024 8:52
Usuario Creación:	IVANA DELGADO VILAR
Dependencia:	12/001/1.5 Dirección General
Finalizada Por:	Ivana Delgado Vilar
Adjuntos:	0
Firmado Por:	IVANA ABIGAIL DELGADO VILAR
Fecha Firma:	09/02/2024 8:52

Documento: 12/001/3/764/2024 Actuación: 9



Montevideo, 20 de marzo 2024

Sra. Directora General de Salud,
Dra. Adriana Alfonso,

En referencia a la solicitud de acceso a la información 3/764/2024 que pide:

1. *Se me informe cantidad de inoculaciones compradas a partir de Octubre del 2023 a la firma PFIZER contra el supuesto SarsCoV2, desglosando por lotes, y vencimientos, vale decir Cantidad, detalle del Lote, Vencimientos de los lotes.*

Respuesta 1: La Unidad de Inmunizaciones informa que no se han comprado vacunas de COVID-19 al laboratorio Pfizer desde la fecha solicitada. Las vacunas que se están utilizando actualmente corresponden a las establecidas en los acuerdos iniciales mantenidos con el proveedor al inicio de la pandemia. La vacuna disponible es la vacuna actualizada para variante de SARS-CoV-2 OMICRON XBB 1.5

Los lotes disponibles son:

LABORATORIO FABRICANTE	NOMBRE DE LA VACUNA	LOTE	CANTIDAD DE DOSIS	VENCIMIENTO*
Pfizer	Comirnaty Omicron XBB.1.5, presentación adulto	HJ9510	296.640	28/2/2025
Pfizer	Comirnaty Omicron XBB.1.5, presentación pediátrica	HJ4781	25.920	31/7/2024

*Los lotes pueden estar sujetos a extensión de su vida útil. Para lograr la extensión de las fechas de vencimiento el laboratorio fabricante, (en este caso Pfizer), deberá presentar ante el Departamento de Medicamentos del MSP nuevos estudios de estabilidad y los certificados de aprobación de las autoridades internacionales regulatorias (FDA y EMA).



Ministerio
de Salud Pública

DIRECCIÓN GENERAL DE LA SALUD

2. *Se me informe que destino tuvieron las inoculaciones vencidas hasta el momento y el detalle de cantidad, lote y vencimiento de dichas inoculaciones vencidas.*

Respuesta 2: De acuerdo a lo informado por la Dirección General de Secretaria, se informa que las vacunas vencidas, al igual que todo medicamento, son sometidos a un proceso de destrucción según los protocolos vigentes. Se detalla información de vacunas retiradas por vencimiento:

Serie/Lote	Cant. stock	Vencimiento
FX5823	49140	31/1/2024
FX5823	67665	31/1/2024
FX5823	33150	31/1/2024
FP1176	4220	30/9/2023

Unidad de Información



Montevideo, 13 de marzo 2024.

Director General de Secretaría

Ref. N.º 12/001/3/764/2024.-

Mediante solicitud de Acceso a la Información Pública, el Sr. Fernando Vega Torrens, solicita la siguiente información al Ministerio de Salud Pública:

1) Se me informe cantidad de inoculaciones compradas a partir de Octubre del 2023 a la firma PFIZER contra el supuesto SarsCoV2, desglosando por lotes, y vencimientos,, vale decir Cantidad, detalle del Lote, Vencimientos de los lotes.

2) se me informe que destino tuvieron las inoculaciones vencidas hasta el momento y el detalle de cantidad , lote y vencimiento de dichas inoculaciones vencidas.

Consultada la Direccion General de la Salud (DIGESA), cuyo informe luce adjunto a estos obrados fs. 23 y 24,se sugiere proporcionar la información ut supra referida en los términos que se detallan a continuación.

Considerando que la solicitud se formuló conforme al procedimiento establecido en la norma (Ley 18.381 - art. 13 y ss.), y no se encuentra declarada como reservada o confidencial.

Se recomienda hacer lugar al pedido de Acceso a la Información Pública de forma total, notificando al interesado las fojas 23 - 24 y la correspondiente resolución.



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación: 09/04/2024 15:44
Usuario Creación: MARIA DEL HUERTO CORRADO
Dependencia: 12/001/1.51 Dpto. De Secretaría Y Acuerdos
Finalizada Por: Gustavo Cardoso, Maria del Huerto Corrado
Adjuntos: 1
001-3-764-2024 RESPUESTA ACCESO A LA INFORMACIÓN vega torrens fernando.pdf

Firmado Por: MARÍA del HUERTO CORRADO SCARCELA
Fecha Firma: 09/04/2024 15:45

Firmado Por: GUSTAVO CARDOSO MUÑOZ
Fecha Firma: 09/04/2024 15:59

Ministerio de Salud Pública

Dirección General de Secretaría

VISTO: la solicitud de información pública efectuada por el Sr. Fernando Vega Torrens, titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381 de 17 de octubre de 2008;

RESULTANDO: que el peticionante solicita la siguiente información: i) cantidad de inoculaciones compradas a partir de octubre del 2023 a la firma PFIZER contra SarsCoV2, desglosando por lotes, y vencimientos de los mismos; y ii) qué destino tuvieron las inoculaciones vencidas hasta el momento detallando cantidad, lote y vencimiento de dichas inoculaciones;

CONSIDERANDO: I) que corresponde hacer lugar a lo peticionado;

II) que de acuerdo a lo dispuesto por el Artículo 16 de la citada disposición legal, el acto que resuelva la petición debe emanar del jerarca máximo del Inciso o quien posea facultades delegadas al efecto;

ATENTO: a lo precedentemente expuesto y a lo establecido por Resolución Ministerial N° 38/991 de 22 de enero de 1991;

EL DIRECTOR GENERAL DE SECRETARÍA

en ejercicio de las atribuciones delegadas

RESUELVE:

- 1º) Autorízase el acceso a la información en referencia a la solicitud efectuada por el Sr. Fernando Vega Torrens, titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381, de 17 de octubre de 2008.
- 2º) Notifíquese a la parte interesada a través de Secretaría de la Dirección General de Secretaría. Pase al Departamento de Comunicaciones para su publicación en la página web institucional. Cumplido, archívese.

Ref. N° 001-3-764-2024

MO

Se otorgó el N^º de Res. DIGESE 378-2024

**DOCUMENTO COMPLETO**

Referencia:
12/001/3/2100/2024
IDOC

Fecha de ingreso: 11/04/2024 10:41
Lugar de ingreso: División Jurídico Notarial

Datos del documento

Titulares: FERNANDO VEGA TORRENS
Resumen: Fernando Vega Torrens - Solicitud de acceso a la Información Pública - Trámite # 9042080
Cantidad de Actuaciones: 6

Campos del tipo de documento

Procedencia: 12/001/1.511
Nómina Procedencia: -
Oficio: -



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación: 11/04/2024 10:44
Usuario Creación: EDUARDO GONZALEZ
Dependencia: 12/001/1.511 División Jurídico Notarial
Finalizada Por: Eduardo Gonzalez
Adjuntos: 0

Firmado Por: EDUARDO JOSÉ GONZÁLEZ CRESPO
Fecha Firma: 11/04/2024 10:46

Documento: 12/001/3/2100/2024 Actuación: 1

2

A DIRECCIÓN GENERAL DE SECRETARÍA

Habiéndose registrado en la planilla correspondiente, pase a efectos de informar lo solicitado.-

----- Mensaje reenviado -----

De: "Ministerio de Salud Pública" <msp_tramites@tramitesenlinea.gub.uy>

Para: "Direccion General de Secretaria" <digese@msp.gub.uy>

Enviados: Miércoles, 10 de Abril 2024 18:40:56

Asunto: Solicitud de acceso a la Información Pública - Trámite # 9042080

Se ha ingresado una nueva solicitud:

Información personal

Nombre completo: Fernando Vega Torrens

Documento de identidad: 26299673

Dirección: GENERAL LUNA 1390

Teléfono: 099611205

Correo electrónico: fernando@fulltime.uy

Datos de la solicitud

Información solicitada: Atencion Ministro de Salud Pública

Dra. Karina Rando

[10/04/2024](#)

En el acceso 12/001/3/191/2024 actuación 3 vuestro Ministerio informa, el

[18 de Enero](#) del 2024

Se informa que en el acceso 3/3295/2023

tenian los siguientes lotes próximos a vencer

SINOVAC -lote [2021060831](#) vencimiento [10/06/2023](#) 452.720 dosis.

SINOVAC - lote [2021060811](#) vencimiento [09/09/2023](#) 97.280 dosis

Pfizer (pediátrica) - lote FP1176 vencimiento [30/09/2023](#) - 43.600 dosis.

Vale decir que ustedes informaron tener próximas a vencer o vencidas un total de 593.150 dosis

Yo pregunté en el 12/001/3/764/2024 se me informe sobre destino de INOCULACIONES VENCIDAS. Se me informa que fueron destruidas conforme a protocolo,

LOTE FX5823 VENCIMIENTO [31/01/2024](#) cantidad 149.955 dosis, y

LOTE FP1176 Vencimiento [30/09/2023](#) 4.220 dosis.

totalizando una destruccion de 154.175 dosis desde el comienzo de la PLANDEMIA.

Dicho esto y si no caigo en error de interpretacion deseo consultar.

1) Donde están.. las 438.975 dosis que faltan destruir ?

Desde ya muchas gracias,

Fernando Vega Torrens

099 611 205

Documento: 12/001/3/2100/2024 Actuación: 2

5

Acorde a lo solicitado se informa que las vacunas de SINOVAC y Pfizer se encuentran en proceso de destrucción.



Montevideo, 30 de abril 2024.

Director General de Secretaría

Ref. N.º 12/001/3/2100/2024.-

Mediante solicitud de Acceso a la Información Pública, el Sr. Fernando Vega Torrens, solicita la siguiente información al Ministerio de Salud Pública:

En el acceso 12/001/3/191/2024 actuación 3 vuestro Ministerio informa, el 18 de Enero del 2024

Se informa que en el acceso 3/3295/2023 tenían los siguientes lotes próximos a vencer
SINOVAC -lote 2021060831 vencimiento 10/06/2023 452.720 dosis.

SINOVAC - lote 2021060811 vencimiento 09/09/2023 97.280 dosis

Pfizer (pediátrica) - lote FP1176 vencimiento 30/09/2023 - 43.600 dosis.

Vale decir que ustedes informaron tener próximas a vencer o vencidas un total de 593.150 dosis

Yo pregunté en el 12/001/3/764/2024 se me informe sobre destino de INOCULACIONES VENCIDAS. Se me informa que fueron destruidas conforme a protocolo,

LOTE FX5823 VENCIMIENTO 31/01/2024 cantidad 149.955 dosis, y

LOTE FP1176 Vencimiento 30/09/2023 4.220 dosis.

totalizando una destruccion de 154.175 dosis desde el comienzo de la PLANDEMIA.

Dicho esto y si no caigo en error de interpretacion deseo consultar.

1) Donde están.. las 438.975 dosis que faltan destruir ?

Referente a esta interrogante, es necesario hacer referencia al Decreto reglamentario de la Ley 18.381, el decreto N.º 232/010, particularmente a su artículo 17, literal E, el cual define a "información" como "todo archivo, registro o dato contenido en cualquier medio, documento o registro impreso, óptico, electrónico, magnético, químico, físico, o biológico

que se encuentre en poder de los sujetos obligados”, la interrogante referida ut supra, no describe una solicitud de información concreta, independientemente de ello, esta asesora sugiere que se proporcione lo informado por la Dirección General de Secretaría, en tanto se manifiesta que a la fecha 23 de abril del corriente año *“se informa que las vacunas de SINOVAC y Pfizer se encuentran en proceso de destrucción.”*

Por lo expuesto, se recomienda hacer lugar a la solicitud de Acceso a la Información Pública de forma total, notificando al interesado la foja 5 y la correspondiente resolución en los términos del presente informe.



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación: 06/05/2024 13:12
Usuario Creación: MARIA DEL HUERTO CORRADO
Dependencia: 12/001/1.51 Dpto. De Secretaría Y Acuerdos
Finalizada Por: Gustavo Cardoso, Maria del Huerto Corrado
Adjuntos: 1
001-3-2100-2024 RESPUESTA ACCESO A LA INFORMACIÓN vega torrens fernando.pdf

Firmado Por: MARÍA del HUERTO CORRADO SCARCELA
Fecha Firma: 06/05/2024 13:13

Firmado Por: GUSTAVO CARDOSO MUÑOZ
Fecha Firma: 06/05/2024 14:17

Ministerio de Salud Pública

Dirección General de Secretaría

VISTO: la solicitud de información pública efectuada por el Sr. Fernando Vega Torrens, titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381 de 17 de octubre de 2008;

RESULTANDO: que el peticionante solicita acceder a la cantidad de inoculaciones contra SarsCoV2 vencidas que fueron destruidas desde el comienzo de la pandemia a la fecha;

CONSIDERANDO: I) que corresponde hacer lugar a lo peticionado;

II) que de acuerdo a lo dispuesto por el Artículo 16 de la citada disposición legal, el acto que resuelva la petición debe emanar del jerarca máximo del Inciso o quien posea facultades delegadas al efecto;

ATENTO: a lo precedentemente expuesto y a lo establecido por Resolución Ministerial N° 38/991 de 22 de enero de 1991;

EL DIRECTOR GENERAL DE SECRETARÍA

en ejercicio de las atribuciones delegadas

RESUELVE:

- 1º) Autorízase el acceso a la información en referencia a la solicitud efectuada por el Sr. Fernando Vega Torrens, titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381, de 17 de octubre de 2008.
- 2º) Notifíquese a la parte interesada a través de Secretaría de la Dirección General de Secretaría. Pase al Departamento de Comunicaciones para su publicación en la página web institucional. Cumplido, archívese.

Ref. N° 001-3-2100-2024

VC

Se otorgó el N^a de Res. DIGESE 523 - 2024

**DOCUMENTO COMPLETO**

Referencia:
12/001/3/4561/2021
IDOC

Fecha de ingreso: 07/07/2021 17:37
Lugar de Ingreso: División Jurídico Notarial

Datos del documento

Titulares: MSP
Resumen: Acceso a la información pública - Fernando Vega Torrens
Cantidad de Actuaciones: 9

Campos del tipo de documento

Procedencia: 12/001/1.511
Nómina Procedencia:
Oficio: MSP

Montevideo, 5 de agosto de 2021

A DIRECCIÓN GENERAL DE SECRETARÍA

Ref. N° 3/4561/2021.-

Mediante solicitud de acceso a la información pública, Fernando Vega Torrens solicita:

- 1) ¿Por qué motivo en el consentimiento informado no figuran los riesgos de corto, mediano y largo plazo?
- 2) ¿Por qué motivo en el consentimiento informado no figuran los posibles efectos adversos graves que el fabricante Pfizer publica en la FDA?
- 3) ¿Por qué motivo no hay ningún profesional de la salud que se haga responsable de indicar o no la vacuna asumiendo para sí las responsabilidades legales sobre ulteriores complicaciones al paciente?
- 4) ¿En qué publicación científica se basa el MPS para recomendar la vacunación en menores de 16 años cuando la propia OMS lo desaconseja en su publicación del 21 de Abril del presente año?
- 5) Quisiera saber si es posible realizar un monitoreo en forma urgente de fertilidad para los jóvenes inoculados contra el SARS-CoV2.

En relación a las cinco preguntas, y como ya se le ha aclarado al interesado en anteriores expedientes, la Ley N° 18.381 establece un procedimiento para solicitar información pública en poder de organismos públicos, lo cual no es equiparable al pedido de informes parlamentario previsto en el artículo 118 de la Constitución. La Ley N° 18.381 reglamenta un canal para solicitar información concreta, no para obligar a la Administración a que elabore análisis o informes técnicos a medida. No es un mecanismo de solicitud de opiniones, explicaciones, justificaciones o debates. Como destaca el artículo 14 de la Ley N° 18.381 *“Esta ley tampoco faculta a los peticionarios a exigir a los organismos que efectúen evaluaciones o análisis de la información que posean...”* Tampoco corresponde al Ministerio de Salud Pública generar citas, ni de estudios, ni de bibliografía. El Ministerio de Salud Pública dicta actos administrativos, recomendaciones e informes técnicos públicos, a cuyo contenido corresponde remitirse, no siendo la Ley N° 18.381 una vía para solicitar ampliación de los mismos. Si el interesado no comparte una decisión en particular o desea realizar una solicitud

fuera de lo previsto en la Ley N° 18.381, cuenta con los canales constitucionales adecuados para ello.

- 6) ¿Cuál es el porcentaje de efectos adversos graves que Pfizer declara en su ensayo previo, Fase3, de Diciembre del 2020?

De acuerdo a lo informado por la División Epidemiología:

	Vacuna n=21.621 individuos	Placebo n=21.631 individuos
Grave	240 (1.1%)	139 (0.6%)
Graves con riesgo vital	21 (0.1%)	24 (0.1%)

Todos los eventos adversos graves ocurrieron en frecuencia similar tanto en el grupo vacunal como placebo.

- 7) ¿Cuál es el NNT número necesario a tratar de Pfizer en su ensayo de Fase 3?

De acuerdo a lo informado por la División Epidemiología: dado que es una vacuna, el término correcto es NNV (número necesario a vacunar), según los datos publicados en el New England Journal of Medicine en el estudio de fase 3 es 1/119.

- 8) Quisiera saber cuál es la eficacia de Reducción de Riesgo Absoluta de Pfizer considerando los resultados de la manga de Placebo.

De acuerdo a lo informado por la División Epidemiología: La reducción de riesgo absoluto o aRR fue de 0,84%.

Corresponde de cualquier forma aclarar, en relación a las tres últimas preguntas, que se trata de la información que tiene el Ministerio en su poder, con relación a un tercero.

Se eleva sugiriendo brindar acceso parcial, en los términos del presente informe.



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación: 05/08/2021 17:44
Usuario Creación: MARÍA JOSE BELEDO
Dependencia: 12/001/1.51 Dpto. De Secretaría Y Acuerdos
Finalizada Por: Gustavo Cardoso, María Jose Beledo
Adjuntos: 1
001-3-4561-2021 RESPUESTA PARCIAL ACCESO A LA INFORMACIÓN SR. FERNANDO VEGA - MJB.pdf

Firmado Por: MARÍA JOSÉ BELEDO GONZALEZ
Fecha Firma: 05/08/2021 17:46

Firmado Por: GUSTAVO CARDOSO MUÑOZ
Fecha Firma: 06/08/2021 12:09

Ministerio de Salud Pública

Dirección General de Secretaría

VISTO: la solicitud de información pública efectuada por el Sr. Fernando Vega Torrens, titular de la cedula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381 de 17 de octubre de 2008;

RESULTANDO: que el peticionante solicita información respecto a: i) motivo por el cual en el consentimiento informado no figuran los riesgos de corto, mediano y largo plazo; ii) motivo por el cual en el consentimiento informado no figuran los posibles efectos adversos graves que el fabricante Pfizer publica en la FDA; iii) motivo por el cual no hay ningún profesional de la salud que se haga responsable de indicar o no la vacuna, asumiendo para sí las responsabilidades legales sobre ulteriores complicaciones al paciente; iv) en que publicación científica se basa el Ministerio de Salud Pública para recomendar la vacunación en menores de 16 años; v) si es posible realizar, en forma urgente, un monitoreo de fertilidad para los jóvenes inoculados contra el SARS-CoV2; vi) cual es el porcentaje de efectos adversos graves que Pfizer declara en su ensayo previo, Fase 3, de diciembre de 2020; vii) cual es el NNT número necesario a tratar de Pfizer en su ensayo de Fase 3; viii) cuál es la eficacia de Reducción de Riesgo Absoluta de Pfizer considerando los resultados de la manga de Placebo;

CONSIDERANDO: I) que en merito a lo informado por la División Servicios Jurídicos, corresponde acceder a lo peticionado con excepción de aquella información que no se ajusta a los requisitos normativos, la Ley 18.381 establece un procedimiento para solicitar información pública en poder de organismos públicos, reglamenta un canal para solicitar información concreta, no para obligar a la Administración a que elabore análisis o informes técnicos a medida. No es un mecanismo de solicitud de opiniones, explicaciones, justificaciones o debates, como destaca el artículo 14 de la mencionada norma, estableciendo que “esta Ley tampoco faculta a los peticionantes a exigir a los organismos que efectúen evaluaciones o análisis de la información

que poseen, salvo aquellos que por sus cometidos institucionales deban producir”;

II) que de acuerdo a lo dispuesto por el Artículo 16 de la citada disposición legal, el acto que resuelva la petición debe emanar del jerarca máximo del Inciso o quien posea facultades delegadas al efecto;

ATENTO: a lo precedentemente expuesto y a lo establecido por Resolución Ministerial N° 38/991 de 22 de enero de 1991;

LA DIRECCIÓN GENERAL DE SECRETARÍA

en ejercicio de las atribuciones delegadas

RESUELVE:

- 1º) Autorízase el acceso a la información en forma parcial, en referencia a la solicitud efectuada por el Sr. Fernando Vega Torrens, titular de la cedula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381 de 17 de octubre de 2008.
- 2º) Notifíquese a la parte interesada a través de Secretaría de la Dirección General de Secretaría. Pase al Departamento de Comunicaciones para su publicación en la página web Institucional Cumplido, archívese.

Ref. N° 001-3-4561-2021

MJB

se otorgó el N° de Res DIGESE 625-2021

**DOCUMENTO COMPLETO**

Referencia:
12/001/3/5848/2022
IDOC

Fecha de ingreso: 05/09/2022 10:04
Lugar de Ingreso: División Jurídico Notarial

Datos del documento

Titulares: DIVISIÓN SERVICIOS JURÍDICOS
Resumen: Acceso a la información publica- Fernando Vega Torrens
Cantidad de Actuaciones: 11

Campos del tipo de documento

Procedencia: 12/001/1.511
Nómina Procedencia:
Oficio:



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación: 03/11/2022 10:49
Usuario Creación: ANA LUCIA SANGUINETTI
Dependencia: 12/001/1.5 Dirección General
Finalizada Por: Ana Lucia Sanguinetti
Adjuntos: 1
Acceso 5848.pdf

Firmado Por: ANA LUCÍA SANGUINETTI ROBAUDO
Fecha Firma: 03/11/2022 10:50

Montevideo, 3 de Noviembre de 2022

Ref. N° 12/001/3/5848/2022.-

Mediante acceso a la información pública se solicita:

“TEMA PCR. CONSIDERANDOS:

Vuestro Ministerio a autorizado y ha condicionado la movilidad de ciudadanos en función del Test RT PCR, el cual viene altamente cuestionado desde las Publicaciones que Christian Drosten realizó a 24 horas del alerta que emitió China en 2020.

PREGUNTAS.

- 1) Deseo saber si los Test por Ustedes validados tienen la posibilidad de distinguir entre un Virus Activo de un Virus Inactivo.*
- 2) Deseo saber si los Test por ustedes validados pueden determinar el grado de infecciosidad del paciente.*
- 3) Deseo saber si a vuestro Ministerio le consta que algún trabajo científico en el mundo, haya podido verificar la existencia del Virus Sars Cov2 infectando a personal o animal sano a partir de células infectadas con dicho virus.*
- 4) Deseo consultar si vuestro Ministerio esta al tanto de algún trabajo científico que hayan podido documentar poder infectar células humanas de pulmón a partir hisopados de personas asintomáticos pero con un PCR positivo.*
- 5) Por último y no menos importante consultar si vuestro Ministerio está al tanto que el nivel de fiabilidad del resultado está en función de la cantidad de ciclos o ampliaciones necesarias para obtener la fluorescencia o CT de corte”.*

Consultada la Dirección General de la Salud, se informa por parte de la División de Epidemiología:

- 1) Deseo saber si los Test por Ustedes validados tienen la posibilidad de distinguir entre un Virus Activo de un Virus Inactivo.

El Departamento de Laboratorio de Salud Pública no validó test para distinguir entre Virus activo de un Virus inactivo.

- 2) Deseo saber si los Test por ustedes validados pueden determinar el grado de infecciosidad del paciente.

El Departamento de Laboratorios de Salud Pública no validó estudios para determinar el grado de infecciosidad del paciente.

- 3) Deseo saber si a vuestro Ministerio le consta que algún trabajo científico en el mundo , haya podido verificar la existencia del Virus Sars Cov2 infectando a personal o animal sano a partir de células infectadas con dicho virus.

El Departamento de Laboratorios de Salud Pública no tiene conocimiento de trabajo científico que comunique lo que se consulta.

- 4) Deseo consultar si vuestro Ministerio esta al tanto de algún trabajo científico que hayan podido documentar poder infectar células humanas de pulmón a partir hisopados de personas asintomáticos pero con un PCR positivo.

El Departamento de Laboratorios de Salud Pública no tiene conocimiento de trabajo científico que comunique lo que se consulta.

- 5) Por último y no menos importante consultar si vuestro Ministerio está al tanto que el nivel de fiabilidad del resultado está en función de la cantidad de ciclos o ampliaciones necesarias para obtener la fluorescencia o CT de corte.

Desde el punto de vista del laboratorio se utilizan el número los ciclos en que aparece la positividad para cada reactivo utilizado para definir si el material genético del virus se detectó en la muestra.

En virtud de los motivos expuestos, se sugiere hacer lugar a lo solicitado en los términos del presente informe.-



DOCUMENTO COMPLETO

IDOC

Actuación

Fecha Creación: 04/11/2022 10:40
Usuario Creación: MIRIAN OLID
Dependencia: 12/001/1.51 Dpto. De Secretaría Y Acuerdos
Finalizada Por: Gustavo Cardoso, Mirian Olid
Adjuntos: 1
001-3-5848-2022 respuesta ACCESO A LA INFORMACIÓN fernando vega torrens.pdf

Firmado Por: MIRIAN GRICEL OLID PRESA
Fecha Firma: 04/11/2022 10:41

Firmado Por: GUSTAVO CARDOSO MUÑOZ
Fecha Firma: 07/11/2022 11:19

Ministerio de Salud Pública

Dirección General de Secretaría

VISTO: la solicitud de información pública efectuada por el Sr. Fernando Vega Torrens, titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381 de 17 de octubre de 2008;

RESULTANDO: que el peticionante solicita información vinculada a los test RT - PCR validados por el Ministerio de salud Pública, a saber: i) si distinguen entre un virus activo y un virus inactivo; si determinan el grado de infecciosidad del paciente y si se ha podido verificar la existencia del Virus Sars Cov2 infectando a personal o animal sano a partir de células infectadas con dicho virus; ii) si el Ministerio de Salud Pública está al tanto de algún trabajo científico que hayan podido documentar acerca de infectar células humanas de pulmón a partir hisopados de personas asintomáticos pero con un PCR positivo; y iii) si el nivel de fiabilidad del resultado está en función de la cantidad de ciclos o ampliaciones necesarias para obtener la fluorescencia o CT de corte;

CONSIDERANDO: I) que corresponde hacer lugar a lo solicitado;

II) que de acuerdo a lo dispuesto por el Artículo 16 de la citada disposición legal, el acto que resuelva la petición debe emanar del jerarca máximo del Inciso o quien posea facultades delegadas al efecto;

ATENTO: a lo precedentemente expuesto y a lo establecido por Resolución Ministerial N° 38/991 de 22 de enero de 1991;

EL DIRECTOR GENERAL DE SECRETARÍA

en ejercicio de las atribuciones delegadas

RESUELVE:

- 1º) Autorízase el acceso a la información en referencia a la solicitud efectuada por el **Sr. Fernando Vega Torrens**, titular de la cédula de identidad N° 2.629.967-3, al amparo de lo dispuesto por la Ley N° 18.381 de 17 de octubre de 2008.

- 2º) Notifíquese a la parte interesada a través de Secretaría de la Dirección General de Secretaría. Pase al Departamento de Comunicaciones para su publicación en la página web institucional. Cumplido, archívese.

Ref. N° 001-3-5848-2022

VC

Documento: 12/001/3/5848/2022 Actuación: 11

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Se otorgó N° de Resolución DIGESE N° 804-2022.

Informe: Análisis sobre viales de las denominadas “vacunas” contra la enfermedad COVID-19, utilizando microscopía electrónica de barrido acoplada a EDS (Espectroscopía de Rayos X de Energía Dispersiva).

2022

AUTORAS: Dra. MARCELA SANGORRÍN ¹ y Lic. LORENA DIBLASI ²

1- Dra. En Ciencias Biológicas, Investigadora Independiente de CONICET, Profesora asociada de la Universidad Nacional del Comahue. PROBIEN (Instituto de Investigación y Desarrollo en Ingeniería de Procesos, Biotecnología y Energías Alternativas) - CONICET-UNCO.

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MATERIALES Y METODOS

Se analizaron 7 viales de las denominadas “vacunas” contra la enfermedad COVID-19, utilizando microscopía electrónica de barrido acoplada a EDS, la MARCA, LOTE y FECHA DE VENCIMIENTO de los mismos, se describen en el siguiente cuadro:

MARCA	LOTE	FECHA DE VENCIMIENTO
Pfizer/BioNTech	FN0087	1/03/2022
Pfizer/BioNTech	FK8892	1/03/2022
CanSino. Convidecia	NCOV202109013VT	24/9/2022
CanSino. Convidecia	NCOV202105008V	5/4/2022
Covilo. CNBG BIO	202108B2715	26/08/2023
Covilo. CNBG BIO	202108B2692	25/8/2023
AstraZeneca	AB23413	11/2021

Se compararon contra un patrón de Óxido de Grafeno, Marca: Sigma-Aldrich, Código: 763713-250MG, Lote: MKCF4166. Se adjunta Certificado de Análisis de Origen (ANEXO 1).

Preparación de las muestras:

Las muestras de las distintas “vacunas” fueron tomadas con agujas 25G y jeringas de 3 ml, ambas estériles.

Se colocaron 10 uL de cada muestra sobre portaobjetos metálicos tipo stub (los portaobjetos se limpiaron por sonicación con alcohol isopropílico y luego con gas inerte) y se dejaron secar a temperatura ambiente tapados para evitar contaminación ambiental. Luego las muestras fueron metalizadas con oro para poder ser observadas al microscopio electrónico de barrido.

Para preparar la muestra del estándar de óxido de grafeno se tomó una escama (flake), se la pulverizó y se preparó una suspensión con agua ultrapura estéril. Para la preparación de la muestra del estándar a ser observada bajo MEB se procedió de la misma manera que para las demás muestras.

Observación de las muestras

Se utilizó un Microscopio Electrónico de Barrido (MEB), Marca Zeiss, Modelo EVO 15 dotado con dos detectores de electrones secundarios (SE), un detector de electrones retrodispersados (BSE), un detector de cátodoluminiscencia (CL) y un espectrómetro de energía dispersiva (EDS),

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localizado en el Instituto de Investigación en Paleobiología y Geología (Consejo Nacional de Investigaciones Científicas y Técnicas - Universidad Nacional de Río Negro).

Se analizaron las muestras de las distintas marcas de “vacunas”, se determinó la composición semi-cuantitativa de las partículas presentes en cada muestra. Se detectaron partículas extrañas con diferente morfología, de tamaño y cantidad que superan el límite dictado por la Farmacopea Argentina en el capítulo 650 “partículas para inyectables” y la USP (Farmacopea de los Estados Unidos) en el capítulo 788 “particulate matter in injections”.

Sobre esas partículas extrañas se tomaron microfotografías (denominadas como IMAGEN en cada informe), se eligieron zonas de cada partícula para determinar su composición semi-cuantitativa (denominadas como ESPECTROS en cada informe). Se realizó un INFORME por cada partícula. En total se analizaron de la marca: Pfizer, 8 imágenes y 27 espectros (ANEXO 2), CanSino, 6 imágenes y 15 espectros (ANEXO 3), COVILO, 18 imágenes y 61 espectros (ANEXO 4), AstraZeneca, 16 imágenes y 38 espectros (ANEXO 5).

RESULTADOS

Se detectaron los siguientes elementos químicos NO DECLARADOS EN LA COMPOSICIÓN de cada marca: **Cobre, Bromo, Titanio, Silicio, Aluminio, Flúor, Hierro, Cromo, Manganeso y Cesio**. Se adjuntan los 48 informes (ANEXO 2-5).

En la Tabla 1 se muestran, para cada marca, los resultados del total de partículas analizadas por SEM-EDS que contenían los diferentes elementos químicos no declarados:

Tabla 1. Elementos químicos detectados en las partículas analizadas de las cuatro marcas de “vacunas” COVID-19.

Elemento químico detectado	Cantidad de partículas			
	Pfizer	CanSino	COVILO	AstraZeneca
Cobre	12	1	10	32
Bromo		1	31	
Titanio	2	3		3
Silicio	12	12		
Aluminio	11	5	40	6
Flúor	9	5	20	
Hierro	7	4		3
Cromo	1			
Manganeso	1			
Cesio				1

Los porcentajes de estos elementos oscilaron entre el 0,01 y 66,58 %. Ver ANEXOS 6-9 Tablas Excel “SEM-EDS-Resultados”.

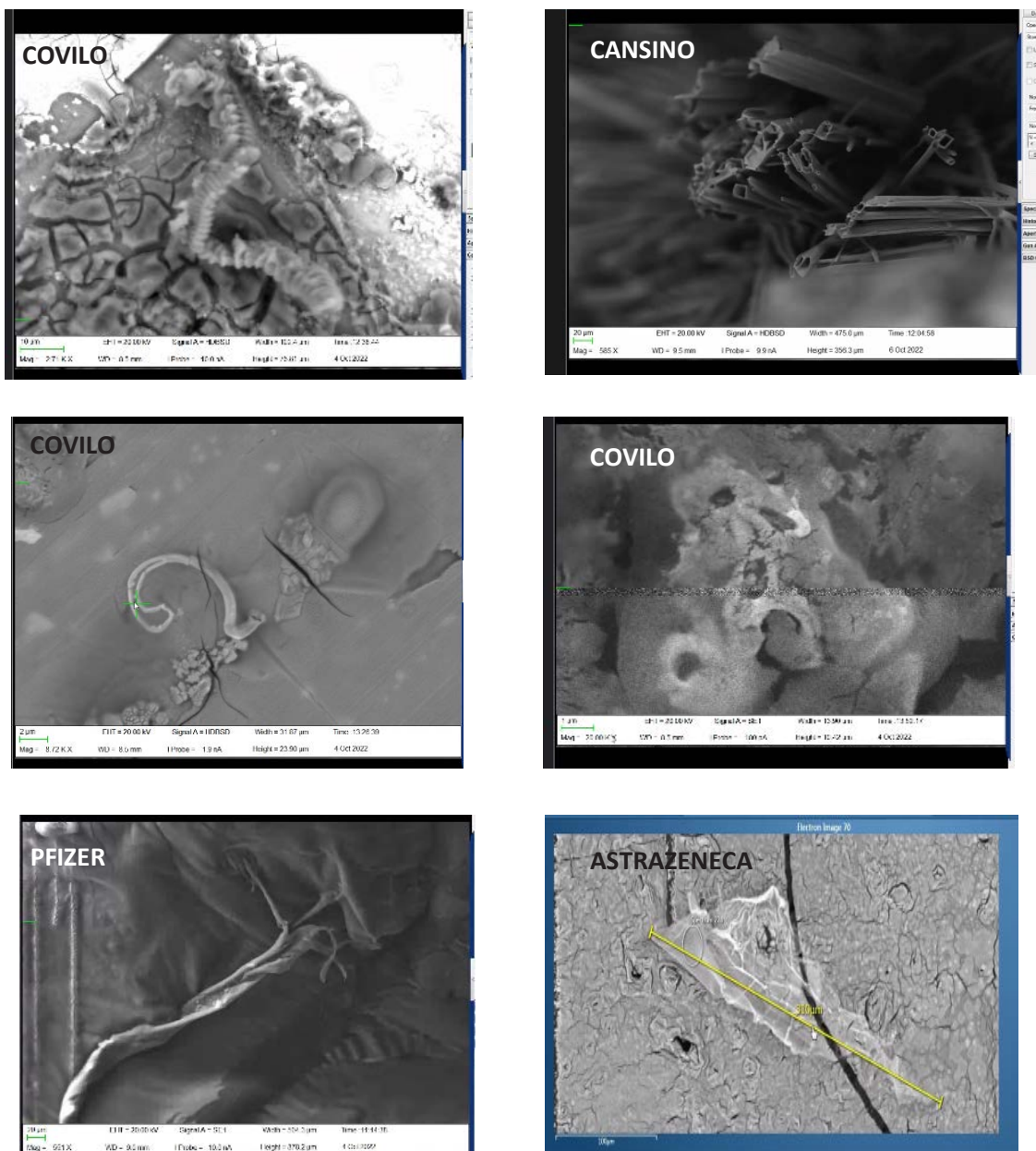
Se encontraron partículas de diversos tamaños. Los tamaños oscilaron entre 30-1500 um.

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Se encontraron partículas con diversa morfología en algunos casos coincidieron con las de óxido de grafeno (por ejemplo cintas y láminas u hojas), en otras muestras se vieron figuras con geometría cuadrada y barras con alto contenido de elementos metálicos y algunas muy extrañas que coinciden con hallazgos de investigadores independientes de otros países (pulpos?, gusanos?, etc.), en la figura 1 se muestran algunos ejemplos de las decenas de microfotografías que adjuntamos en los informes oficiales del Instituto de Investigación en Paleobiología y Geología.

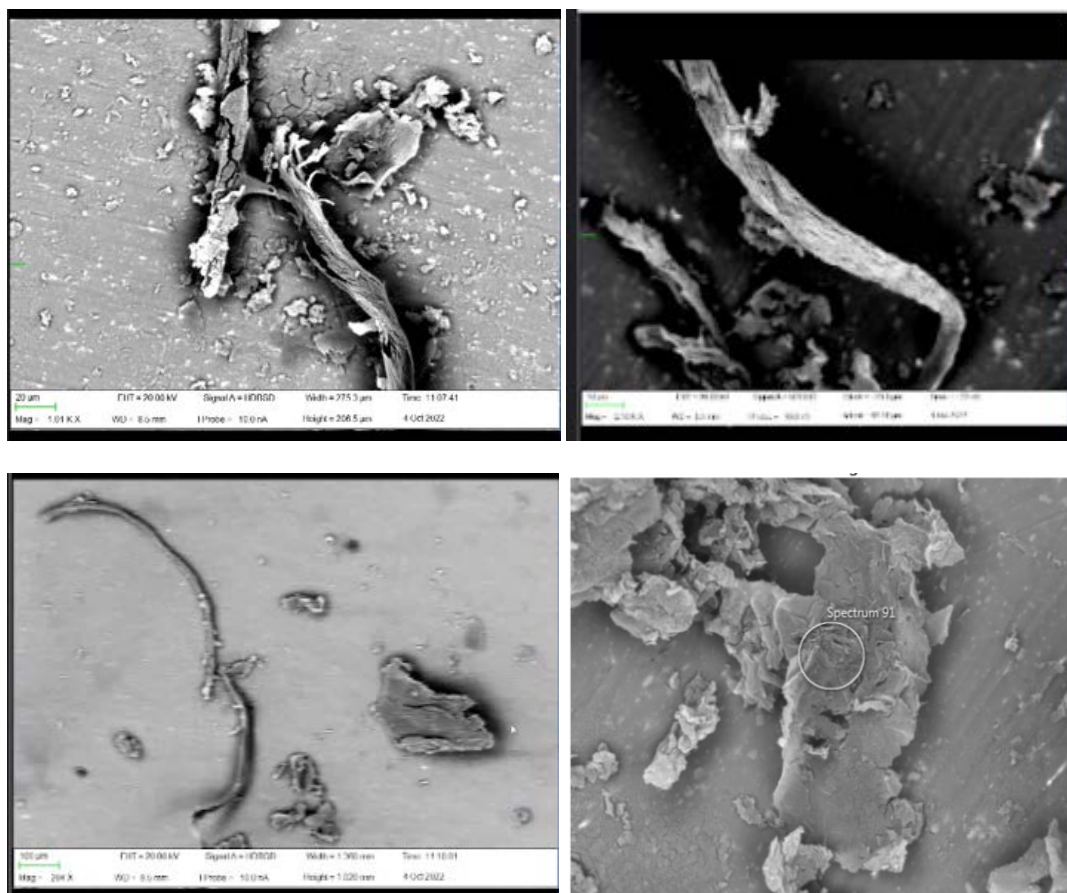
Figura 1: Imágenes de SEM de diferentes muestras de “vacunas” COVID-19



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Figura 2: Imágenes en SEM-EDS del patrón de óxido de grafeno marca SIGMA-ALDRICH.



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Las cuatro marcas de “vacunas” analizadas presentaron partículas cuya composición contiene elementos químicos NO DECLARADOS en la fórmula. Las fórmulas declaradas se muestran en la respuesta de INAME-ANMAT, con fecha 11 de Junio de 2022, al pedido de informe solicitado por la Dra. María Eugenia Maldonado, número de nota: NO-2022-54293428-APN-ANMAT#MS y expediente: EX-2022-50699694-APN-ANMAT#MS:

SINOPHARM (COVILO):

Principio activo: antígenos del virus SARS-CoV-2 inactivado, en una cantidad de 6,5 U/dosis.

Adyuvante: hidróxido de aluminio en cantidad de 0,225 mg/dosis.

Excipientes: fosfato de hidrógeno disódico 1,4 mg/dosis; fosfato de dihidrógeno de sodio 0,1373 mg/dosis; cloruro de sodio 4,25 mg/dosis.

CONVIDECIA/ CanSino:

Principio activo: contiene $\geq 4 \times 10^{10}$ partículas virales de Adenovirus tipo 5 humano recombinante que es incapaz de replicar y el cual expresa la proteína S del SARS-CoV-2.

Excipientes: Manitol, sacarosa, cloruro de sodio, cloruro de magnesio, polisorbato 80, glicerina, N-(2-hidroxietil) piperazina-N-(ácido 2-etanosulfónico) (HEPES) y agua estéril para inyección como disolvente.

Esta vacuna NO contiene conservantes ni adyuvantes.

COMIRNATY/ Pfizer-BioNTech:

El principio activo es vacuna de ARNm frente a COVID-19. Tras la dilución, el vial contiene 6 dosis de 0,3 ml con 30 microgramos de ARNm cada una. Los demás componentes son:

- ((4-hidroxibutil)azanodiil)bis(hexano-6,1-diil)bis(2-hexildecanoato) (ALC-0315)
- 2-[[polietilenglicol]-2000]-N,N-ditetradecilacetamida (ALC-0159)
- 1,2-diestearoil-sn-glicero-3-fosfocolina (DSPC)
- colesterol
- cloruro de potasio, dihidrogenofosfato de potasio, cloruro de sodio, fosfato de disodio dihidrato, sacarosa
- agua para preparaciones inyectables

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ASTRAZENECA: composición en sitio web de EMA:

https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-astrazeneca-product-information-approved-chmp-29-january-2021-pending-endorsement_en.pdf

Estos son viales multidosis que contienen 8 dosis o 10 dosis de 0,5 ml por vial (ver sección 6.5). Una dosis (0,5 ml) contiene: Adenovirus de chimpancé que codifica la glicoproteína Spike del SARS-CoV-2 (ChAdOx1-S)*, no menos de $2,5 \times 10^8$ unidades infecciosas (Inf.U) *Producido en riñón embrionario humano genéticamente modificado (HEK) 293 células y por tecnología de ADN recombinante. Este producto contiene organismos genéticamente modificados (OGM). Excipiente con efecto conocido Cada dosis (0,5 ml) contiene aproximadamente 2 mg de etanol

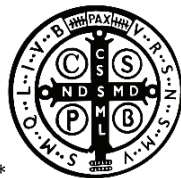
Lista de excipientes: L-Histidina, clorhidrato monohidrato, Cloruro de magnesio hexahidratado, Polisorbato 80 (E 433), Etanol, Sacarosa, Cloruro de sodio, EDTA (dihidrato), Agua para inyectables.

Ninguna de las marcas analizadas cumpliría con los límites establecidos para cantidad y tamaño de partículas en inyectables, según capítulo 788 de la USP donde se indica: “Para productos donde el volumen del vial es menor a 25 mL, se realiza un pool de las unidades para alcanzar los 25 mL, se analiza ese volumen y luego se referencia a una unidad, por cada unidad no puede haber más de 6000 partículas de 10 μm y más de 600 partículas de 25 μm .”

En todos los casos las muestras analizadas fueron de un volumen de aproximadamente 10 μL , y se encontraron múltiples partículas de distintos tamaños, que oscilaron entre 30 y 1500 μm . Si se extrapola la cantidad de partículas encontradas en 10 μL (1 mL, mililitro = 1000 μL , microlitros), al volumen de una unidad, por ejemplo 2 mL, se observaron en 10 μL más de 10 partículas entonces en 2 mL habría 2000 partículas de tamaño mayor a 25 μm . Estos productos NO pasarían este control de calidad de rutina para un producto inyectable, ya que no cumplen con la cantidad de partículas y tamaño permitidos por las diferentes farmacopeas.

Además los elementos químicos encontrados: **Cobre, Bromo, Titanio, Silicio, Aluminio, Flúor, Hierro, Cromo, Manganeso y Cesio** no están declarados en la composición, se encontraron asociados a partículas de diferente morfología y tamaño, la mayoría de estos elementos son tóxicos para el ser humano. Al no estar declarados estos componentes no se puede confiar en el **control de calidad** correspondiente. Cabe preguntarse qué técnicas analíticas emplearon para el análisis y aprobación de cada lote, para la confección de los diferentes Certificados de Análisis de Origen (COAs), sumado a que no existen monografías en las diferentes farmacopeas para estos nuevos productos biológicos.

DETECCIÓN DE GRAFENO EN VACUNAS COVID19 POR ESPECTROSCOPIA MICRO-RAMAN



INFORME TÉCNICO

Almería, España, 2 de noviembre de 2021

Prof. Dr. Pablo Campra Madrid
PROFESOR TITULAR DE UNIVERSIDAD
Doctor en Ciencias Químicas
Licenciado en Ciencias Biológicas

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RESUMEN

El objetivo del siguiente trabajo ha sido realizar un muestreo de señales espectrales de vibración RAMAN que, asociadas a imágenes de microscopia óptica acoplada a los espectros, permita determinar la presencia de derivados de grafeno en muestras de vacunas COVID19 comercializadas bajo cuatro marcas diferentes.

Se han analizado más de 110 objetos visibles al microscopio óptico con apariencia compatible con estructuras de grafeno, de los cuales se seleccionaron para el presente informe un total de 28 objetos por su compatibilidad con la presencia de grafeno o derivados en las muestras, teniendo en cuenta la correspondencia entre sus imágenes y señales espectrales con los obtenidos de una muestra patrón y de la literatura científica.

De estos 28 objetos, en 8 de ellos **la identidad del material con óxido de grafeno es concluyente** por la elevada correlación espectral con el patrón.

Los restantes 20 objetos presentan una **compatibilidad muy elevada con estructuras de grafeno**, teniendo en cuenta conjuntamente tanto sus espectros como su imagen óptica.

La investigación continúa abierta y se pone a disposición de la comunidad científica para su discusión y replicación y optimización.

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DESCARGO DE RESPONSABILIDAD

La presente investigación ha sido realizada exclusivamente por el Dr. Pablo Campra, sin ningún tipo de retribución por parte de entidad privada o pública alguna, ni implicación o conformidad a sus resultados y conclusiones por parte de la institución donde está afiliado.

La caracterización de los objetos relacionados corresponde en exclusiva a las muestras analizadas. No es posible sin un muestreo significativo conocer si estos resultados son generalizables a otras muestras de similares marcas comerciales.

El Dr. Pablo Campra sólo se responsabiliza de las afirmaciones redactadas en este archivo firmado electrónicamente, no siendo responsable de las opiniones o conclusiones que del mismo pudieran extraerse en su divulgación en medios y redes sociales no expresadas en el presente documento, cuya versión original autenticada y firmada electrónicamente puede consultarse en la plataforma *Researchgate*: [https://www.researchgate.net/publication/355684360 Deteccion de grafeno en vacunas COVID19 por espectroscopia Micro-RAMAN](https://www.researchgate.net/publication/355684360_Deteccion_de_grafeno_en_vacunas_COVID19_por_espectroscopia_Micro-RAMAN)

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1. METODOLOGÍA ANALÍTICA

1.1. Fundamento de la técnica micro-Raman

Debido a las características de la muestra y en particular a la dispersión de objetos con apariencia grafénica de tamaño micrométrico en una matriz compleja de composición indeterminada, la aplicación directa de métodos espectroscópicos no permite caracterizar los objetos problema sin una previa localización o fraccionamiento de la muestra original. Por ello se seleccionó la microscopía acoplada a espectroscopía RAMAN (micro-RAMAN) como técnica eficaz para una prospección exhaustiva de los objetos micrométricos visibles al microscopio óptico.

La espectroscopia de infrarrojo RAMAN es una técnica rápida, no destructiva, que permite la verificación de la estructura del material mediante la identificación de modos vibracionales y fonones generados tras la excitación con láser monocromático, generando dispersión inelástica que se manifiesta en picos de emisión infrarroja característicos de la estructura reticular del grafeno y derivados. La microscopía óptica acoplada permite enfocar el láser de excitación a objetos concretos y puntos localizados en los objetos y reforzar el grado de confianza en la identificación de la naturaleza del material, y complementariamente obtener información de grosor, defectos, conductividad térmica y geometría de borde de las mallas cristalinas de grafeno.

Modos vibracionales RAMAN de grupos funcionales frecuentes

O-P-O 813 cm^{-1}

C-C 800 (600-1300) cm^{-1}

C-O-C 800-970 cm^{-1} Raman media

C-(NO₂) 1340-1380 cm^{-1} Raman fuerte; 1530-1590 cm^{-1} (asimétrica) Raman medio

C=C vibraciones en anillos aromáticos (ej Grafeno, grafito) (Otto, 1984)

1580-1600 cm^{-1} : Señal Raman fuerte

1450, 1500 cm^{-1} : señal Raman media

-CH₂- 1465 cm^{-1} doblamiento en plano H-C-H (*scissoring*)

C=N 1610-1680 cm^{-1} (bases nitrogenadas)

C=O carbonilo 1640, 1680-1820 cm^{-1}

C-H 3000 cm^{-1}

O-H 3100-3650 cm^{-1}

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1.2. Equipo para espectroscopía micro-Raman



ESPECTROMETRO LASER RAMAN JASCO NRS-5100

MICROSCOPIO Raman confocal con espectrógrafo, incluye:

- variedad de aumentos y distancias de trabajo de x5 a x100
- hasta 8 láseres que van desde el UV hasta el NIR
- SRI (imagen de resolución espacial) para ver simultáneamente la imagen de muestra y el punto láser.
- DSF (Filtración espacial dual) que optimiza el enfoque confocal de la imagen producida por la lente del objetivo para reducir la aberración y mejorar la resolución espacial y reducir los efectos de la fluorescencia de la matriz.

Los espectros fueron analizados con software *SPECTRA MANAGER*, versión 2. JASCO Corporation.

Previamente se calibró el equipo con patrón de silicio a 520 cm⁻¹.

Parámetros de espectroscopía micro-RAMAN aplicados

Data array type Linear data array
 Horizontal axis Raman Shift [cm⁻¹]
 Vertical axis Int.
 Start 1200 cm⁻¹
 End 1800 cm⁻¹
 Data interval 1 cm⁻¹
 Data points 601
 [Measurement Information]
 Model Name NRS-5100
 Exposure 30 sec
 Accumulation 3
 Center wavenumber 1470.59 cm⁻¹
 Z position 27041.5 μm

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Binning Upper 143
Binning Lower 202
Valid Channel 1 - 1024
CCD DV420_OE
Laser wavelength 532.09 nm
Monochromator Single
Grating 1800 l/mm
Slit 100 x 1000 μm
Aperture d-4000 μm
Notch filter 532.0 nm
Resolution 3.69 cm^{-1} , $0.96\text{ cm}^{-1}/\text{pixel}$
Objective lens MPLFLN 100 x
BS/DMBS 30/70
1/2 plate Not fitted
Polarization Not fitted
Laser power 4.0 mW
Attenuator Open
CCD temperature $-60.0\text{ }^{\circ}\text{C}$
Shift -3.00 cm^{-1}

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1.3. Espectroscopía micro-Raman de grafito y grafeno

BANDAS RAMAN CARACTERÍSTICAS DE GRAFITO, GRAFENO y DERIVADOS

- G y 2D: estructura cristalina del grafeno y grafito.
- D: defectos en la malla cristalina

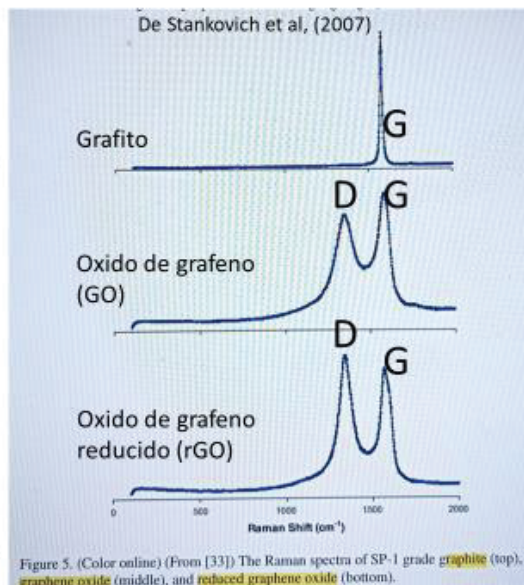
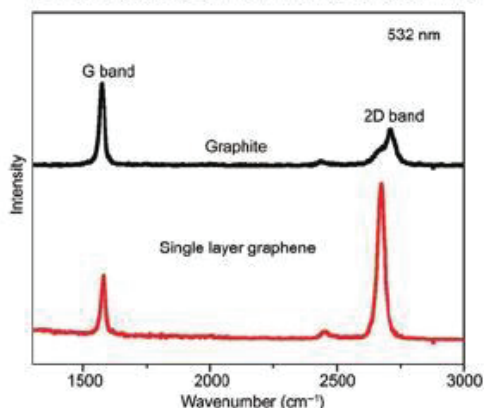


Figure 5. (Color online) (From [33]) The Raman spectra of SP-1 grade graphite (top), graphene oxide (middle), and reduced graphene oxide (bottom).

1. BANDAS DE ESTRUCTURA NANOCRISTALINA

-**Banda G ($\sim 1580-1600 \text{ cm}^{-1}$):** Indica una vibración permitida del fonón (vibración elemental de la red) en el plano del anillo aromático (hibridación sp^2), característica de la estructura cristalina del grafito y grafeno. Presenta un desplazamiento al rojo o *red shift* (menor frecuencia en cm^{-1}), así como mayor intensidad con mayor número de capas. Al contrario, la mayor energía en grafeno dopado se manifiesta como *blue shift* (mayor frecuencia en cm^{-1}), a lo largo del rango $1580-1600 \text{ cm}^{-1}$ (Ferrari et al, 2007). En grafito G se presentan más afilado y estrecho que en grafeno.

-**Banda 2D ($\sim 2690 \text{ cm}^{-1}$) (o G'):** Indica orden de apilamiento. Depende del número de capas, no depende del grado de defectos, pero su frecuencia es cercana al doble de la del pico D. Su posición oscila según el tipo de dopado. La presencia de grafeno monocapa (SLG) se ha asociado a la presencia de un pico 2D aislado y afilado, aumentando su anchura con el número de capas (Ni et al., 2008).

- La ratio de I_{2D}/I_G es proporcional al número de capas de la malla gráfica

- En grafito G y 2D se presentan más afilados y estrechos que en grafeno.

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2. BANDAS ACTIVADAS POR DEFECTOS en la estructura gráfica.

Se generan por dispersión elástica (misma energía) de transportadores de carga y por el confinamiento del fonón (anomalía de *Kohn* en la dispersión del fonón).

En **óxidos de grafeno (GO)** el desorden procede de la inserción de grupos hidroxilo (-OH) y epóxido (-O-).

-Banda D (~1340 cm⁻¹). Manifiesta la densidad de defectos en la malla cristalina por funcionalización, dopaje o anomalías estructurales generan agujeros o nuevos centros sp³ (C-C). La intensidad de la banda D disminuye con el alineamiento de capas en la estructura gráfica

-Banda D' (~1620 cm⁻¹). Sigue un comportamiento de doble resonancia por defectos en la malla. En ocasiones llega a fundirse con la banda G por *blueshift* de ésta.

-Banda D+G (~2940 cm⁻¹)

PARÁMETROS QUE INTRODUCEN VARIABILIDAD DE FRECUENCIA (cm⁻¹), INTENSIDAD Y PERFIL DE LAS BANDAS RAMAN

Estos indicadores de variabilidad no han sido objeto de estudio detallado en el presente informe, pero deben de tenerse en cuenta para la asignación de bandas a modos vibracionales.

- Grado y tipo de **desorden** (dopaje, roturas, etc.). El desorden aumenta la anchura de los picos G, D, y 2D, la disminuir el tiempo de vida del fonón (vibración molecular)
- La banda G no muestra diferencias de intensidad por desorden, pero sí varía la relación (I_D/I_G).
- **Compresión y estiramiento** de la malla por **dopaje**. Puede haber *blueshifts* (>cm) en todas las bandas (hasta 15 cm⁻¹ en G y 25 cm⁻¹ en 2D) y estrechamientos de banda (hasta 10 cm⁻¹)
ej "*back gates*" por dopado con óxidos mediante deposición
- Por **doblamiento** de lámina también aumenta la banda 2D, sin cambios en G, pero con *blueshifts* de entre 4-12 cm⁻¹
- Nivel de apilamiento o **número de capas**
- **Funcionalización** (introducción de grupos funcionales) de las mallas genera la aparición de nuevos picos Raman: 746 cm⁻¹ (C-S *stretching*), 524, 1062, 1102, 1130 cm⁻¹ (*skeletal vibrations*, CCCC *trans* y *gauche*), 1294 (*twisting*), **1440, 1461 (C-H deformation, scissoring)**, 2848 and 2884 cm⁻¹ (C-H *stretching*).
- En un mismo objeto puede haber variaciones espectrales según el ángulo de incidencia y las capas afectadas. Los bordes mostraran más desorden que el núcleo cristalino (Ni et al, 2008)
- *Blueshifts* dependientes del **sustrato** de crecimiento del grafeno (ej SiC) (Chen et al, 2008)
- Intensidad variable de los picos en el mismo objeto según el **punto de focalización del láser**, por variabilidad estructural respecto al ángulo de incidencia respecto a la malla cristalina (Barros et al, 2005)

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1.4. MUESTRAS ANALIZADAS Y OBJETOS CARACTERIZADOS (VER ANEXOS 1 Y 2)**1.5. PROCESAMIENTO DE MUESTRAS**

1. Las muestras se obtuvieron a partir de viales sellados de las vacunas mRNA COVID19 reseñadas en el anexo 1. Todos los viales estaban sellados en el momento de su procesamiento, excepto MOD y JAN, que no presentaban cierre de aluminio.

2. Se extrajeron mediante micro-jeringa diferentes alícuotas por vial de 10 ul cada una y se depositaron en portaobjetos de microscopia óptica, dejándose secar en campana aséptica de flujo laminar a temperatura ambiente. Seguidamente se custodiaron en estuche portaobjetos cerrado y en frío hasta análisis Raman.

3. Se realizaron inspecciones visuales exhaustivas al microscopio óptico (OLIMPUS CX43) para búsqueda de objetos compatibles con estructuras gráficas o grafeno. Aumentos de X100 a x60.

Criterios de selección de objetos:

1. Localización en los restos de la gota o en zona exterior de arrastre por secado
2. Aspecto visual: objetos translucidos bidimensionales o cuerpos opacos oscuros.
4. Obtención de espectros RAMAN de los objetos seleccionados
5. Procesamiento de los datos espectrales

La relación y claves de los objetos caracterizados en el presente informe se expone en el anexo 2.

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3. RESULTADOS Y DISCUSION

(Ver imágenes y espectros de los objetos seleccionados en ANEXO 3: RESULTADOS)

La técnica de micro-Raman aplicada ha resultado ser muy efectiva para la caracterización rápida de un número elevado de objetos microscópicos en la detección de micro-estructuras de grafeno dispersas en muestras complejas. En comparación con la espectroscopía macro-Raman directa de dispersiones acuosas, la combinación con la microscopía tiene la ventaja de poder asociar señales espectrales a objetos visibles al microscopio óptico, lo que permite focalizar la prospección hacia objetos concretos con apariencia grafénica, reforzando su caracterización espectroscópica. En este trabajo, la selección preliminar de objetos se ha centrado en dos tipologías, láminas translúcidas y objetos carbonáceos opacos, por su semejanza visual con formas similares observables en patrones sometidos a ultrasonidos o en dispersiones de óxido de grafeno (ver anexo Resultados). La diferencia entre ambas tipologías no se debe a su composición química, derivada del grafito, sino tan solo al grado de exfoliación del material gráfitico de partida y al número de capas superpuestas, pudiéndose establecer 10 capas como el límite para considerar que un material ya es grafito (3D) (Ramos-Fernandez, 2017).

Una vez seleccionados un total de 110 objetos con posible apariencia grafénica, localizados mayoritariamente en el borde de las gotas de las muestras tras su deshidratación, el interior o exterior en la zona de arrastre por secado a temperatura ambiente de la fase acuosa original. Del total de estos objetos, se han seleccionado un total de 28 objetos por su mayor grado de compatibilidad espectral con materiales grafénicos reportados en literatura. Las imágenes y espectros RAMAN de estos objetos se muestran en el anexo 3 de resultados del presente informe. Es de interés notar que a temperatura ambiente las muestras no llegan a secarse por completo, quedando siempre un resto gelatinoso, cuyo límite puede observarse en algunas fotografías mostradas. Se ignora por el momento la composición de dicho medio por no haber sido objeto del presente estudio, así como la de otras tipologías de objetos de tamaño micrométrico que pudieron observarse recurrentemente en las muestras a bajo aumento (40-600X). Los espectros Raman de algunos de estos objetos se obtuvieron, pero no se presentan en este estudio por no mostrar semejanza visual con grafeno o grafito.

Una limitación en la obtención de patrones espectrales definidos ha sido la intensidad de la fluorescencia que emitían muchos objetos observados. En numerosas láminas translúcidas con apariencia grafénica, no fue posible obtener espectros Raman libres de ruido por fluorescencia, por lo que la técnica no permitió la obtención de señales RAMAN específicas con picos bien definidos. **Por ello en estos objetos no puede afirmarse ni descartarse la presencia de estructuras de grafeno.** Otra limitación de la técnica micro-RAMAN es la baja calidad de la imagen óptica del equipo, que impide detectar con frecuencia láminas semejantes a grafeno de alta transparencia, que pueden observarse sin embargo en microscopios ópticos con ajuste adecuado del condensador. Para estos objetos una alternativa sería emplear otras técnicas

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complementarias de microscopía acoplada con espectroscopía, como XPS con buena óptica o difracción de electrones por TEM.

Teniendo en cuenta estos criterios de selección, se han distribuido en 2 grupos los 28 objetos encontrados con posible identidad grafénica, según el grado de correlación con el espectro RAMAN del patrón de óxido de grafeno reducido empleado (rGO, TMDICSA). En el **GRUPO 1** se han incluido **8 objetos cuyos patrones espectrales son similares al espectro del patrón rGO, y por tanto puede afirmarse con certeza la presencia de óxido de grafeno (nº 1-8)**. Esta correspondencia espectral puede considerarse **inequívoca**, y se caracteriza por 2 picos dominantes en el rango escaneado (entre 1200-1800 cm⁻¹), picos denominados G (~1584 cm⁻¹) y D (~1344 cm⁻¹), característicos de óxidos de grafeno. Esta caracterización por correspondencia espectral entre las señales de las muestras problema y del patrón rGO viene reforzada por la apariencia microscópica de estos objetos, todos ellos con apariencia opaca carbonácea similar a la de los objetos patrón, como puede verse en las fotografías del anexo de Resultados. Por tanto, **podemos afirmar con un elevado nivel de confianza que la identificación de material grafénico en todas las muestras analizadas del Grupo 1 ES CONCLUYENTE**, y con alta probabilidad se trata de óxidos de grafeno. Estos objetos del grupo 1 presentaron un tamaño micrométrico en rangos de decenas de micras (mostrado en las fotografías de algunos de ellos por una línea azul).

En el segundo grupo (**GRUPO 2, nº 9-28**), se han detectado **señales RAMAN compatibles con la presencia de estructuras de grafeno** o grafíticas en 20 objetos, al presentar máximos vibracionales RAMAN en torno a la banda G (1585-1600 cm⁻¹), compatibles con el pico G de la estructura cristalina de la malla cristalina de grafito o grafeno. Este modo vibracional se genera por la vibración permitida del fonón en el plano del anillo aromático (sp²). Su desplazamiento hacia mayores frecuencias en algunos objetos, tendiendo hacia 1600 cm⁻¹ (*blue shift*) puede deberse a muy diversas modificaciones referidas extensamente en la literatura, como, por ejemplo, número de capas de grafeno o dopaje con grupos funcionales o metales pesados entre otros (Ferrari et al, 2007). Visualmente los objetos del grupo 2 pueden presentar los dos tipos de apariencias que se observan en el patrón, tanto como objetos micrométricos opacos con apariencia carbonácea (nº 9, 11, 16, 21, 22, 23, 24, 25, 26, 27 y 28) como láminas translúcidas con apariencia grafénica (nº 10, 12, 13, 14, 18, 19 y 20).

En los espectros de este grupo 2, los máximos del pico G se acompañan de otros picos dominantes de asignación no determinada en este trabajo. Un subgrupo (2.1.) está formado por objetos cuyos espectros presentan los dos 2 picos dominantes situados en rangos de banda que podrían asignarse a los dos modos vibracionales del óxido de grafeno, G (rango 1569-1599 cm⁻¹) y D (rango 1342-1376 cm⁻¹) (objetos nº 11, 14, 15, 16, 17, 20, 21, 22, 23, 24, 25 y 26). Considerando conjuntamente las imágenes microscópicas y las señales RAMAN, **la asignación de los espectros de este grupo a estructuras grafénicas puede hacerse con un elevado nivel de confianza**, si bien están por determinar las modificaciones estructurales de la malla que generan señales espectrales

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que no son idénticas a la del patrón empleado de referencia (rGO), y causan variabilidad en la frecuencia y perfil de estos picos respecto al estándar utilizado.

Un segundo subgrupo (2.2) de objetos de este Grupo 2 (nº 9, 10, 12, 13, 18, 19, 25, 27, 28) se consideran compatibles con la presencia de estructuras grafénicas por la presencia de máximos en la banda G, si bien sería necesario el empleo de algoritmos de análisis espectral más detallado, ya que no se observan con claridad picos que pudieran asignarse al modo vibracional D, en torno a 1344 cm^{-1} en el patrón rGO. Ello no es sin embargo condición *sine qua non* para la presencia de estructuras de grafeno., por lo que se han seleccionado estos objetos para el presente informe al mostrar máximos vibracionales compatibles en el entorno de la banda G (rango $1569\text{-}1600\text{ cm}^{-1}$). Existe aún un debate abierto sobre la interpretación de esta banda D y su localización y perfil variable (Ferrari y Robertson, 2004). Como se expuso en la introducción metodológica, la intensidad del pico D, en general citado en torno de 1355 cm^{-1} , así como la relación de intensidad con el pico G (I_D/I_G) es indicativa del grado de desorden en la malla grafénica, introducido por diferentes agentes como dopado, introducción de muy diversos grupos funcionales o roturas en la continuidad de la malla. En materiales gráfiticos ordenados este pico está ausente. En algunos espectros de este subgrupo 2.2. aparecen otros picos con mayores frecuencias (*blueshift*), cuya asignación al modo vibracional D es posible, aunque esta asignación está aún por determinar mediante el procesamiento con algoritmos de análisis que excede el ámbito del presente trabajo. Por tanto, de momento para estos espectros sólo podemos afirmar que la ausencia o el desplazamiento (*shift*) del pico D respecto a la localización del patrón rGO precisa aun de una interpretación estructural según los modelos disponibles. Según la literatura, tanto las variaciones en el *shift* de los picos G y D, como su anchura e intensidad variable, así como la presencia de otros picos presentes en estos espectros podrían deberse a las diversas modificaciones aún por determinar que pueden encontrarse en estos materiales gráfiticos, incluyendo grado de desorden, oxidación, dopaje, funcionalización y roturas estructurales. Estas modificaciones exceden el ámbito de estudio del presente informe.

Complementariamente al rango $1200\text{-}1800\text{ cm}^{-1}$, para algunos objetos se amplió el espectro hasta 2800 cm^{-1} (nº 3, 8 y 11), se detectándose en algunos objetos de este grupo un pico 2D de baja intensidad y amplitud de frecuencia, estando ausente en otros objetos escaneados (datos no mostrados). Sin embargo, tanto en el patrón rGO como en muestreos aleatorios de objetos con máximos de pico G la intensidad de este pico ha resultado siempre muy reducida en comparación con los picos G y D de los espectros, asociados a vibraciones de los carbonos sp^2 de los anillos aromáticos. Ello puede deberse a que, en óxidos de grafeno, la intensidad relativa del pico 2D ($\sim 2700\text{ cm}^{-1}$) respecto a los picos G y D aparece muy disminuida. Por ello en este estudio de prospección se ha prescindido en general de analizar el pico 2D por razones de mayor eficacia y empleo de recursos en el escaneo del mayor número posible de objetos en tiempo limitado. En futuros trabajos sería de interés su examen en todos los objetos, estimando con ello la ratio de intensidades $I_{2D}/2I_G$ en aquellos objetos donde se manifieste mínimamente este

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modo vibracional, lo que permite hacer estimaciones sobre el número de capas de la estructura.

Los objetos mostrados en este estudio representan una porción minoritaria respecto al total de objetos micrométricos visibles a bajo aumento en microscopía óptica de campo claro (100X). Estos objetos fueron escaneados y no se presentan en este estudio por no manifestar espectros compatibles con grafeno al carecer del pico G. Es de gran interés destacar que la mayoría de estos objetos, o quizás por solapamiento de señal con el medio hidrogel donde se encuentran embebidos algunos de ellos, presentan máximos RAMAN en la banda de $1439\text{--}1457\text{ cm}^{-1}$. Igualmente, entre los objetos del grupo 2.2, es frecuente la aparición de un pico prominente en dicha banda, en torno a 1450 cm^{-1} , en combinación con los picos G y D (nº 11, 12, 14, 15, 16, 17, 20, 21, 23, 24, 25, 26 y 28). **La asignación de esta banda en torno de 1450 cm^{-1} está pendiente de realizar, por no corresponder con picos frecuentes en grafeno, pero consideramos es de gran importancia para el conocimiento de la composición de las muestras por su frecuente aparición.** Como hipótesis de trabajo, esta banda suele asignarse a los grupos orgánicos metileno $\text{--CH}_2\text{--}$ por doblado del par de hidrógenos- (*scissoring* o *vending*). Sin embargo, también se refiere como una banda de intensidad moderada asociable a los anillos aromáticos, por lo que podría asociarse asimismo a grafeno (Ferrari y Robertson, 2004). Otra posible asignación de esta banda sería la de un modo vibracional superpuesto de algún compuesto diferente al grafeno, con mayor probabilidad, o incluso del **medio hidrogel** remanente tras el secado. Recordemos que en todas las muestras tras la deshidratación a temperatura ambiente siempre queda un remanente viscoso. Este remanente pudiera en muchos casos estar manifestando vibraciones RAMAN solapadas con los objetos que permanecen embebidos en él, no así en los que aparecen fuera del gel en los límites de la zona de arrastre por secado. En este sentido, es posible que este modo vibracional del medio aparezca solapado con los picos G y D del grafeno los espectros del subgrupo 2.1. Está fuera del ámbito de este trabajo la caracterización de este medio, así como de todos los componentes de la muestra. No obstante, existen algunas sustancias capaces de formar esta matriz hidrogel cuyas señales RAMAN muestran modos vibracionales prominentes en torno de esta banda, como por ejemplo alcohol polivinílico (PVA), metilacrilamida, o el polímero PQT-12 (Mik Andersen, <https://corona2inspect.blogspot.com/> pers. comm). Se da el caso además de que algunas de estas sustancias se han combinado con grafeno en diseños experimentales que pueden consultarse en la literatura científica, por ejemplo sinapsis artificiales para el PQT-12 (Chen and Huang, 2020), gelatinas para regeneración neuronal combinando metilacrilamida con grafeno (Zhu et al, 2016) o fibras de *electrospun* de PVA/GO (Tan et al, 2016). **Por el momento todas estas hipótesis sobre la asignación de este pico en el entorno de 1450 cm^{-1} siguen abiertas.**

En conclusión, de un total de 110 objetos escaneados **se han hallado señales inequívocas de la presencia de óxido de grafeno en 8 objetos, y señales compatibles con la presencia de estructuras gráficas o de grafeno en otros 20 objetos.** El resto de objetos no ha mostrado señales compatibles con grafeno, con espectros en ocasiones

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dominados por exceso de ruido causado por excesiva intensidad de fluorescencia, por lo que no podemos definir su asignación por el momento.

Como continuación de esta línea de trabajo, y si bien nuestro análisis micro-RAMAN ha mostrado señales concluyentes de la presencia de objetos con estructura grafénica, para consolidar la certeza en la identificación y profundizar en la caracterización estructural sería conveniente la realización de análisis complementarios mediante técnicas acopladas de microscopía y espectroscopía como la espectroscopia XPS, o difracción TEM.

Para la presente investigación se han obtenido la mayoría de las muestras a partir de viales sellados. Asimismo, durante la extracción de las muestras y su traslado a portaobjetos para la microscopia Raman, se trabajó en condiciones de asepsia bajo campana de flujo laminar. No obstante, la posibilidad de procesos de contaminación de las muestras durante su fabricación, distribución y procesamiento, así como la generalización de estos hallazgos a muestras comparables, deben valorarse mediante muestreos rutinarios y más amplios de lotes similares de estos productos.

Si bien los resultados de este muestreo son concluyentes en cuanto a **la presencia de estructuras grafénicas en las muestras analizadas**, esta investigación se considera abierta para su continuación y se pone a disposición de la comunidad científica para su replicación y optimización, considerando necesaria su continuación con un estudio espectral más detallado y exhaustivo, basado en un muestreo estadísticamente significativo de viales similares, y la aplicación de técnicas complementarias que permitan confirmar, rebatir, matizar o generalizar las conclusiones de este informe. Las muestras analizadas están adecuadamente custodiadas y a disposición de futuras colaboraciones científicas.

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CONCLUSIONES

Se ha realizado un muestreo aleatorio de viales de vacunas COVID19 mediante técnica acoplada micro-RAMAN para caracterizar objetos microscópicos con apariencia grafénica mediante señales espectroscópicas características de la estructura molecular.

La técnica micro-RAMAN permite reforzar el nivel de confianza en la identificación del material mediante el acoplamiento de imágenes y análisis espectral como evidencias observacionales que deben considerarse conjuntamente.

Se han detectado objetos cuyas señales RAMAN por similitud con el patrón inequívocamente corresponden con OXIDO DE GRAFENO REDUCIDO.

Otro grupo de objetos presentan señales espectrales variables compatibles con derivados de grafeno, por la presencia mayoritaria de señales RAMAN específicas (banda G) asignado a la estructura aromática de dicho material, en conjunción con su apariencia visible.

La investigación sigue abierta para su continuación, contraste y replicación. Ulteriores análisis con la técnica descrita u otras complementarias basadas en muestreos significativos permitirían evaluar con significación estadística adecuada el nivel de presencia de materiales grafénicos en estos fármacos, así como su caracterización química y estructural detallada.

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ANEXO 1**VACUNAS COVID19 ARNm objeto de análisis micro-RAMAN**

PFIZER 1 (RD1). Lote EY3014. Sellada

PFIZER 2 (WBR). Lote Nº FD8271. Sellada

PFIZER 3 (ROS). Lote Nº F69428. Sellada

PFIZER 4 (ARM). Lote Nº FE4721. Sellada

ASTRAZENECA (AZ MIT). Lote Nº ABW0411. Sellada

MODERNA (MOD). Lote Nº 3002183. No sellada

JANSSEN (JAN). Lote Nº No disponible. No sellada.

MUESTRAS PATRÓN DE GRAFENO

Patrón de oxido de grafeno reducido (rGO) (™Sigma Aldrich. Ref 805424)

Patrón de suspensión de OXIDO DE GRAFENO (™The Graphene Box)

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ANEXO 2**OBJETOS CARACTERIZADOS COMPATIBLES CON ESTRUCTURAS DE GRAFENO****GRUPO 1**

- 1 PFIZER 2 WBR UP GO2
- 2 PFIZER 3 Ros 2hy GO1
- 3 PFIZER 3 Ros 2hy GO1b
- 4 PFIZER 3 Ros 2hy b GO2
- 5 AZ MIT UP CARB1
- 6 AZ MIT UP CARB4
- 7 AZ MIT DOWN CARB2
- 8 MOD grumo1

GRUPO 2

- 9 PFIZER 2 WBR GO1
- 10 PFIZER 2 WBR GO6a
- 11 PFIZER 2 WBR 2 GO7
- 12 PFIZER 2 WBR UP GO1
- 13 PFIZER 2 WBR UP GO3b
- 14 PFIZER 2 WBR UP GO4
- 15 PFIZER 2 WBR DOWN GO2
- 16 PFIZER 2 WBR DOWN GO3
- 17 PFIZER 2 WBR DOWN GO5
- 18 PFIZER 3 ROS OBJ 1
- 19 PFIZER 3 ROS 2 OBJ 1
- 20 PFIZER 3 ROS 2 OBJ 2
- 21 PFIZER 4 Pdown grumo1
- 22 PFIZER 4 Pdown grumo2
- 23 PFIZER 4 Pdown grumo3
- 24 ASTRAZENECA AZ MIT UP CARB5
- 25 ASTRAZENECA AZ MIT UP CARB6
- 26 JANSSEN JAN GO1
- 27 JANSSEN JAN GO3
- 28 JANSSEN JAN GO4

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ANEXO 3. RESULTADOS

Este anexo puede consultarse en el link

https://www.researchgate.net/publication/355684360_Deteccion_de_grafeno_en_vacunasa_COVID19_por_espectroscopia_Micro-RAMAN

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Detección de grafeno en vacunas COVID19 por espectroscopía micro-RAMAN



INFORME TÉCNICO

ANEXO 3. RESULTADOS

Almería, España 2 de Noviembre 2021

Prof. Dr. Pablo Campra Madrid
PROFESOR TITULAR DE UNIVERSIDAD
Doctor en Ciencias Químicas
Licenciado en Ciencias Biológicas

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VIALES ANALIZADOS por microRAMAN

VACUNAS COVID19 ARNm

PFIZER 1 (RD1). Lote EY3014. Sellada
PFIZER 2 (WBR). Lote N° FD8271. Sellada
PFIZER 3 (ROS). Lote N° F69428. Sellada
PFIZER 4 (ARM). Lote N° FE4721. Sellada
ASTRAZENECA (AZ MIT). Lote N° ABW0411. Sellada
MODERNA (MOD). Lote N° 3002183. No sellada
JANSSEN (JAN). Lote N° No disponible. No sellada.

MUESTRAS PATRÓN DE GRAFENO

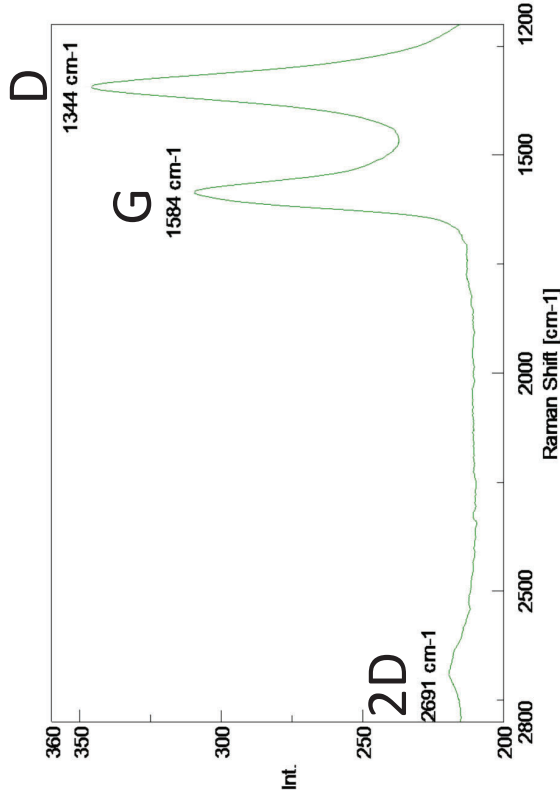
Patrón de óxido de grafeno reducido (rGO) (™Sigma Aldrich. Ref 805424)
Patrón de suspensión de ÓXIDO DE GRAFENO (™The Graphene Box)

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Espectro RAMAN del patrón de referencia
OXIDO DE GRAFENO reducido (DICSATM)

- En el patrón rGO el equipo registra la presencia de 3 picos característicos:
 - Banda G a 1584 cm⁻¹
 - Banda D a 1344 cm⁻¹
 - Banda 2D a 2691 cm⁻¹
- En óxidos de grafeno la intensidad de 2D es normalmente pequeña respecto a G y D.
- Grado de desorden: $I_D/I_G = 346/309 = 1,12$
- Nivel de apilamiento: $I_{2D}/I_G = 219/309 = 0,70$
- Previamente se calibró el equipo con patrón de silicio a 520 cm⁻¹



$$I_D/I_G = 1,12$$

3

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4

2.1. GRUPO 1

OBJETOS CON SEÑAL RAMAN SIMILAR
AL PATRÓN DE OXIDO DE GRAFENO
REDUCIDO

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5

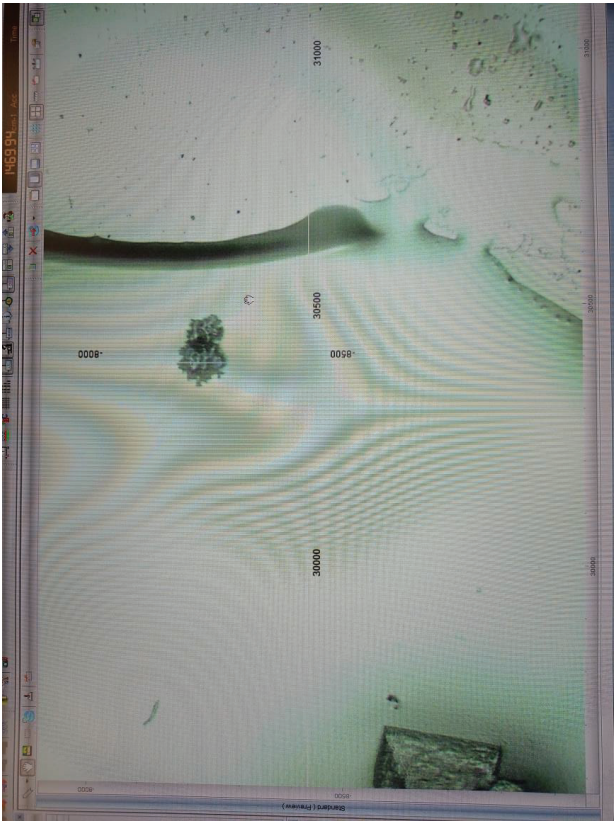
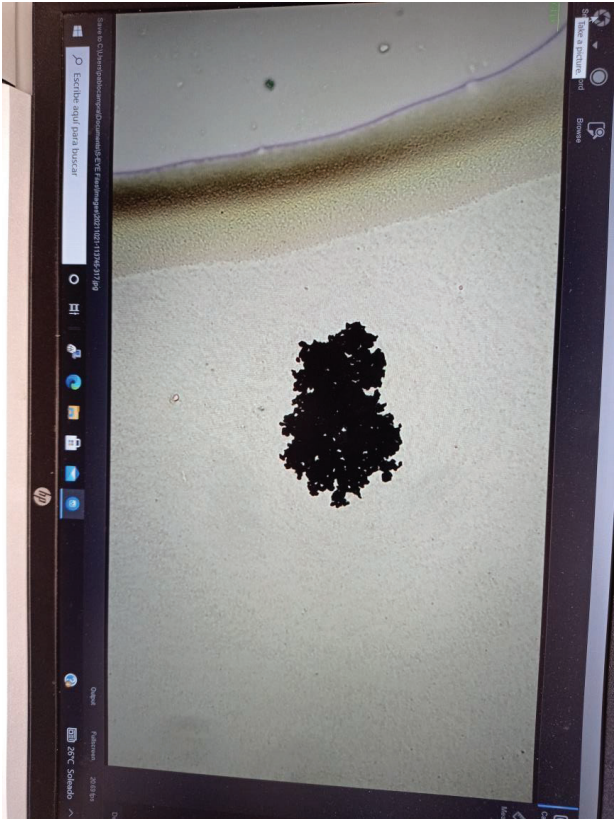
OBJETOS ANALIZADOS
GRUPO 1

- 1. PFIZER 2 WBR UP GO2
- 2. PFIZER 3 ROS 2hy GO1b
- 3. PFIZER 3 ROS 2hy b GO2
- 4. PFIZER 3 ROS2 HY GO1
- 5. AZ MIT UP CARB 1
- 6. AZ MIT UP CARB4
- 7. AZ MIT DOWN CARB2
- 8. MOD grumo1

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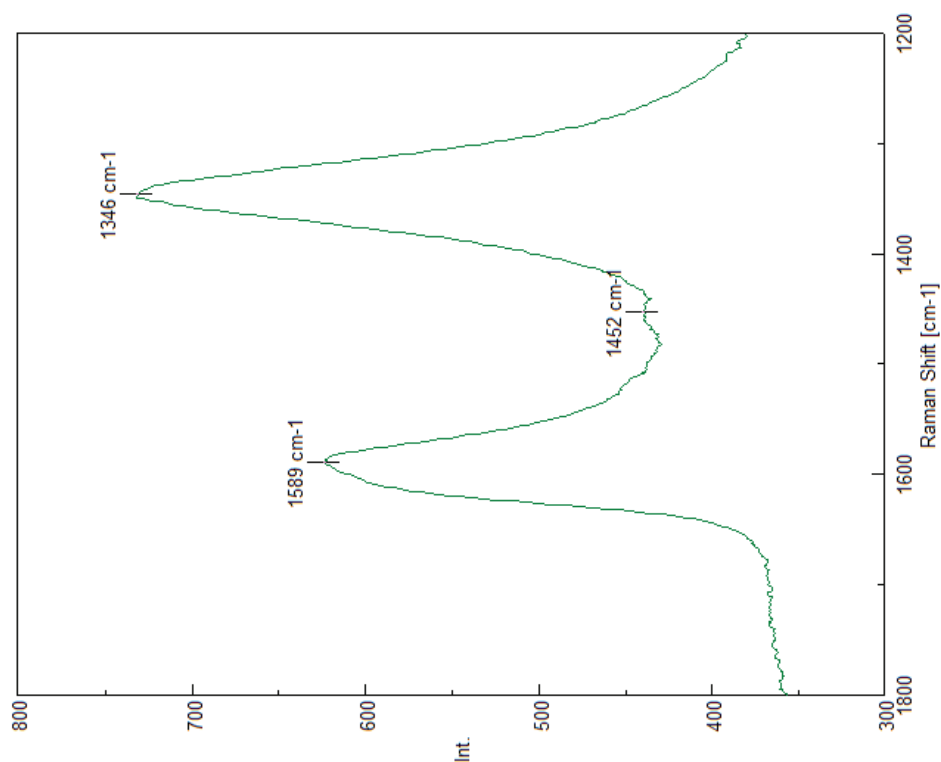
1. PFIZER 2 WBR UP GO2



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1. PFIZER 2
WBR UP GO2

$$I_D/I_G = 1,18$$



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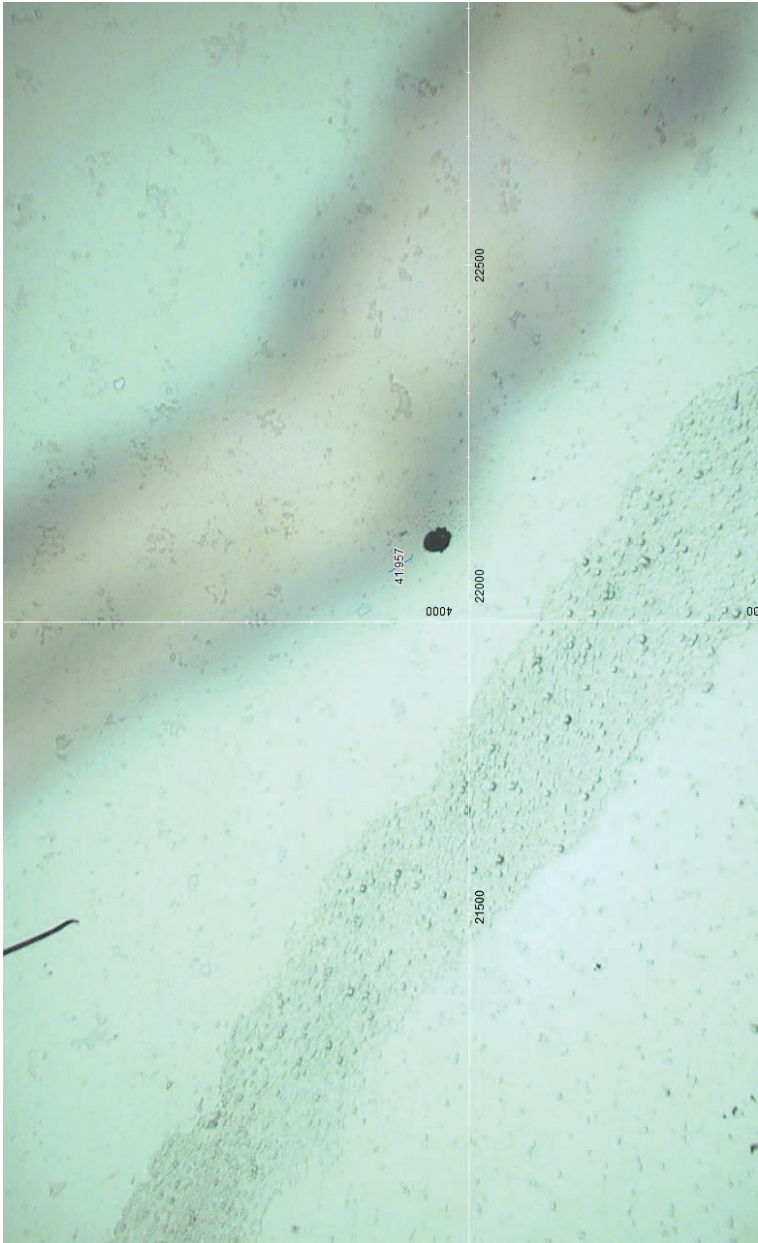
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2. PFIZER 3
ROS 2 HY GO1

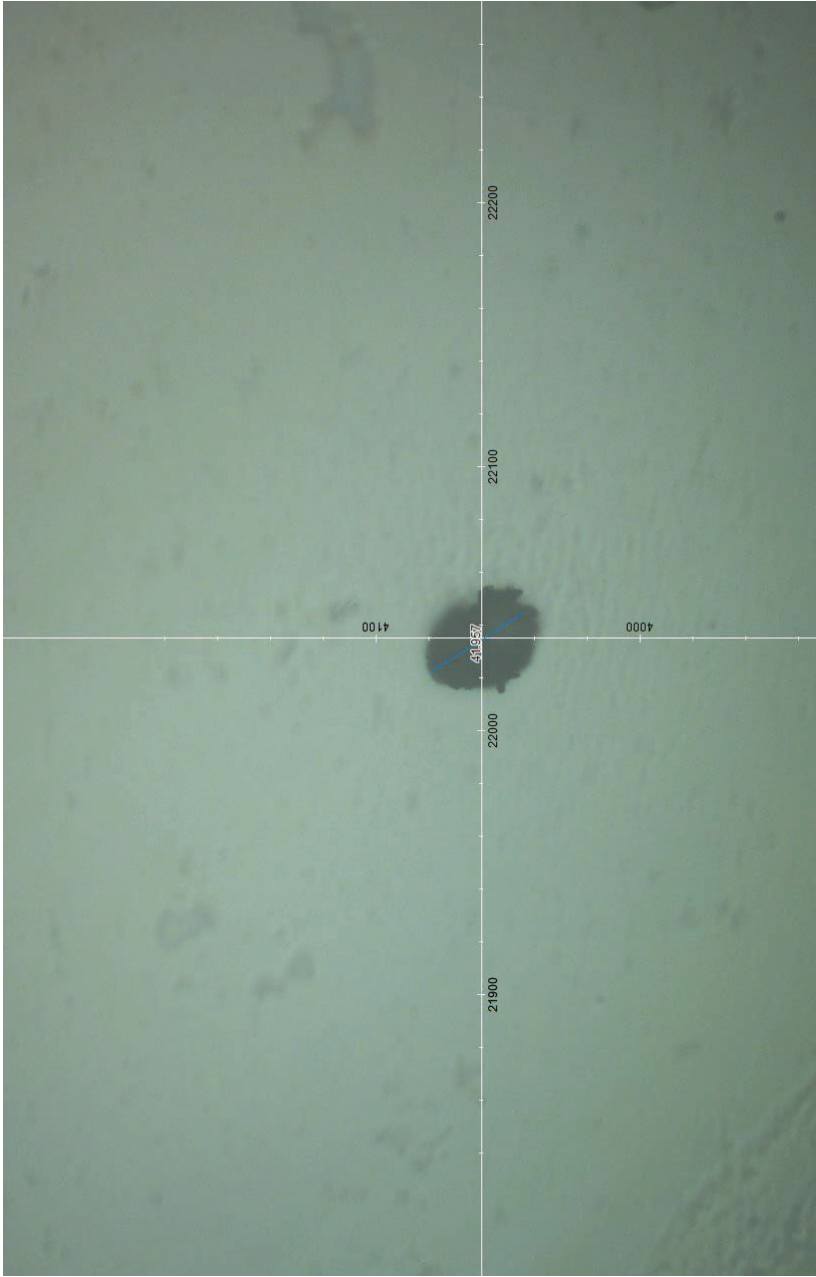


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2. PFIZER 3
ROS 2 HY GO1



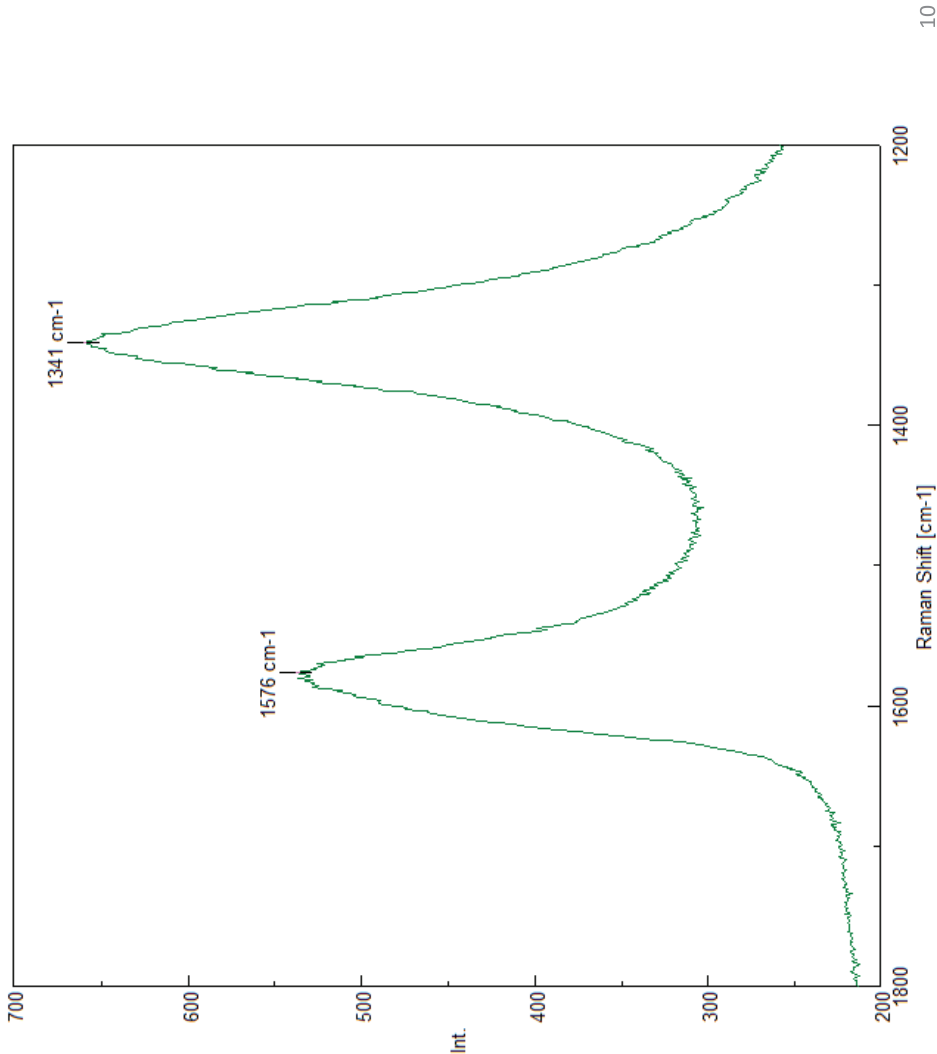
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2. PFIZER 3
ROS2 HY GO1

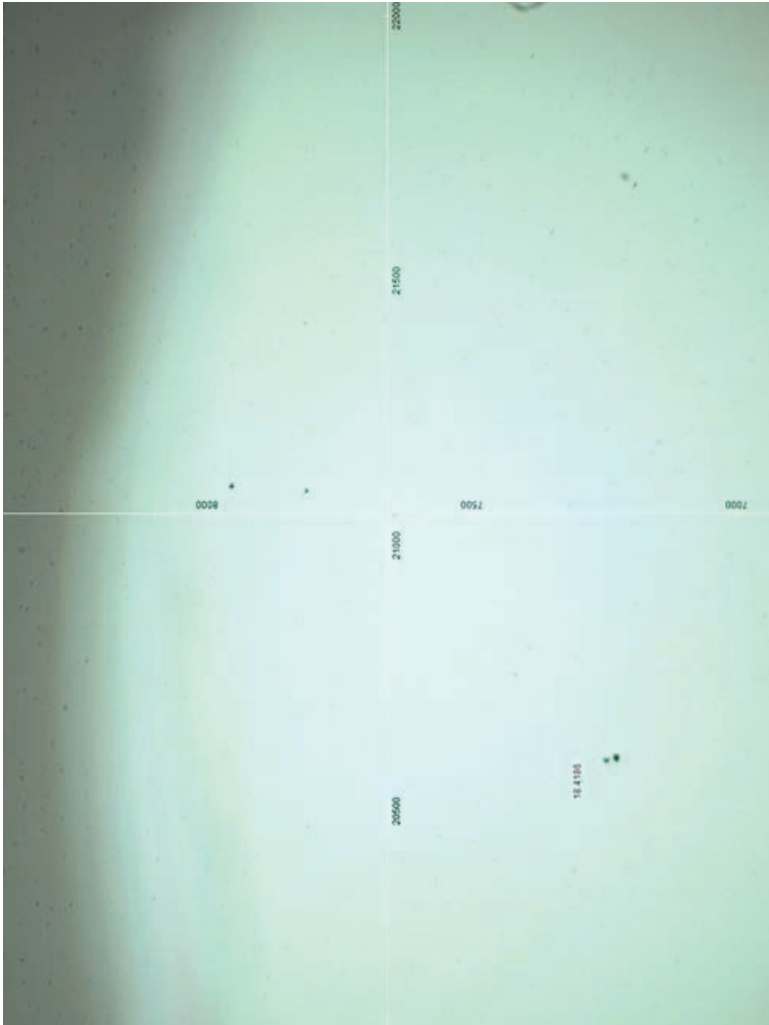
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3. PFIZER 3
Ros 2hy GO1b

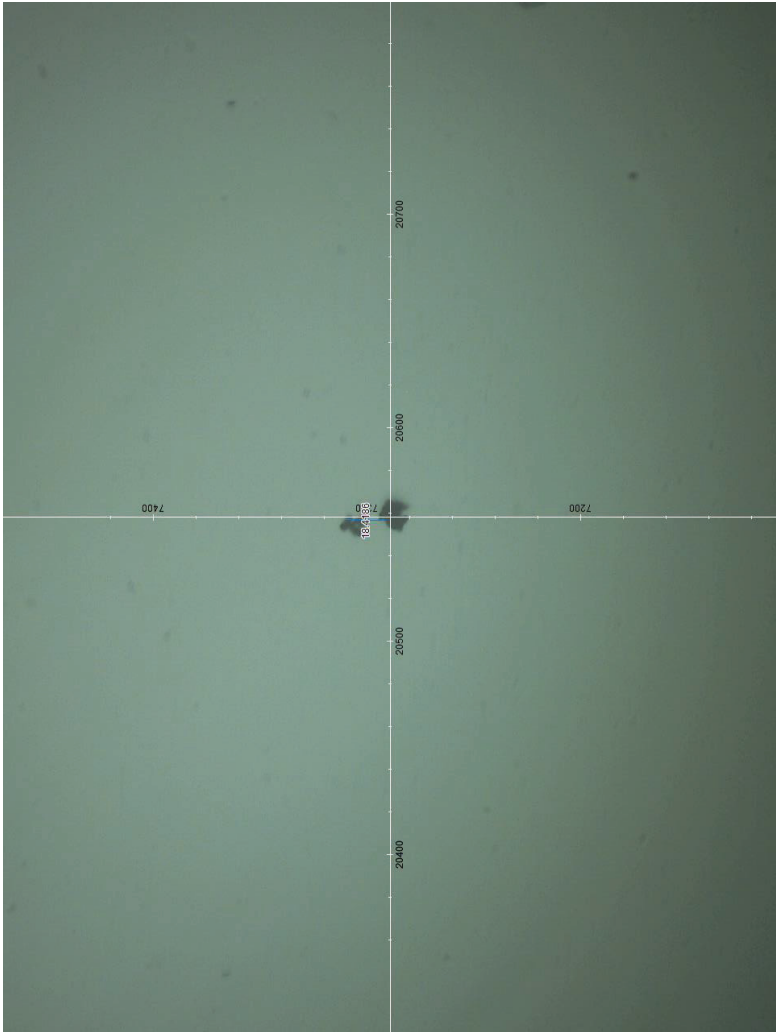


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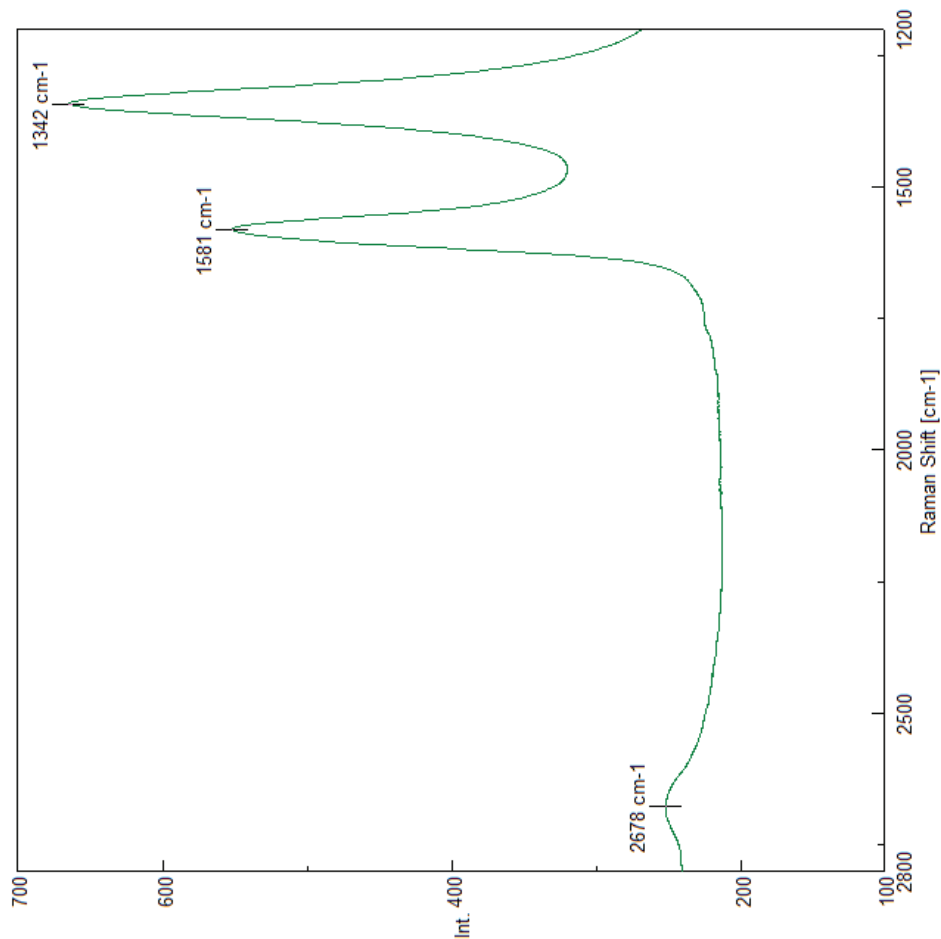
3. PFIZER 3 Ros 2hy G01b



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3. PFIZER 3
Ros 2hy GO1b

$$I_D/I_G = 1,22$$

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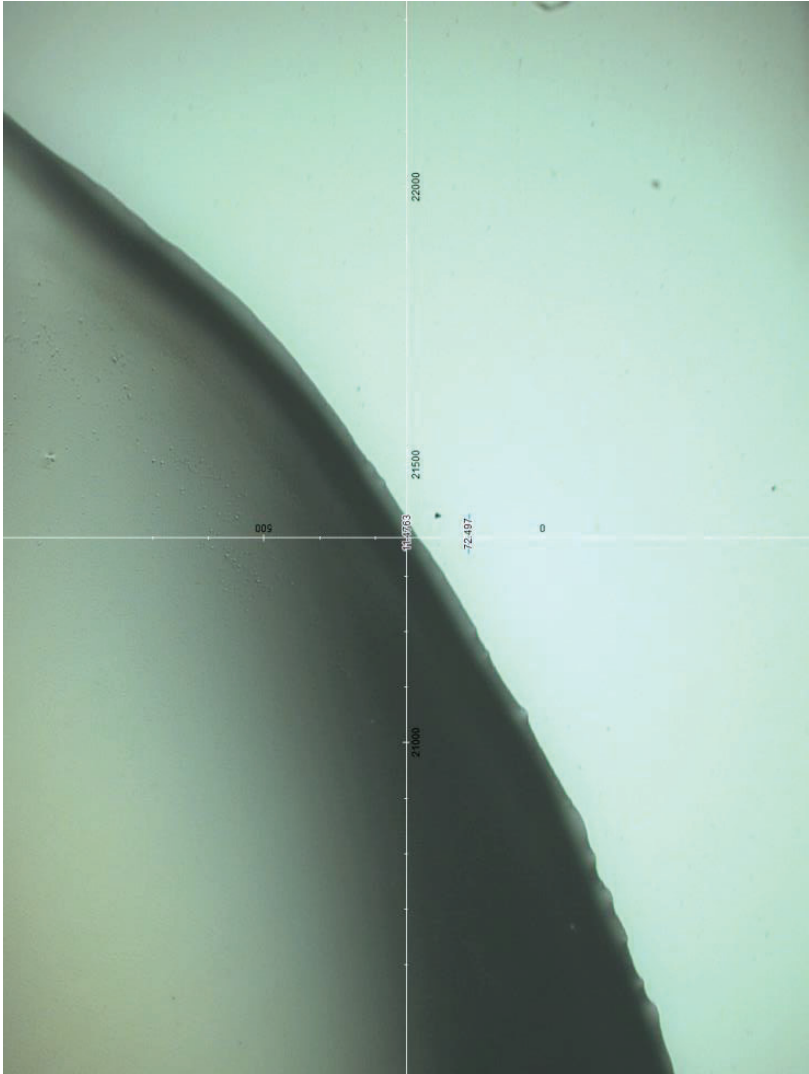
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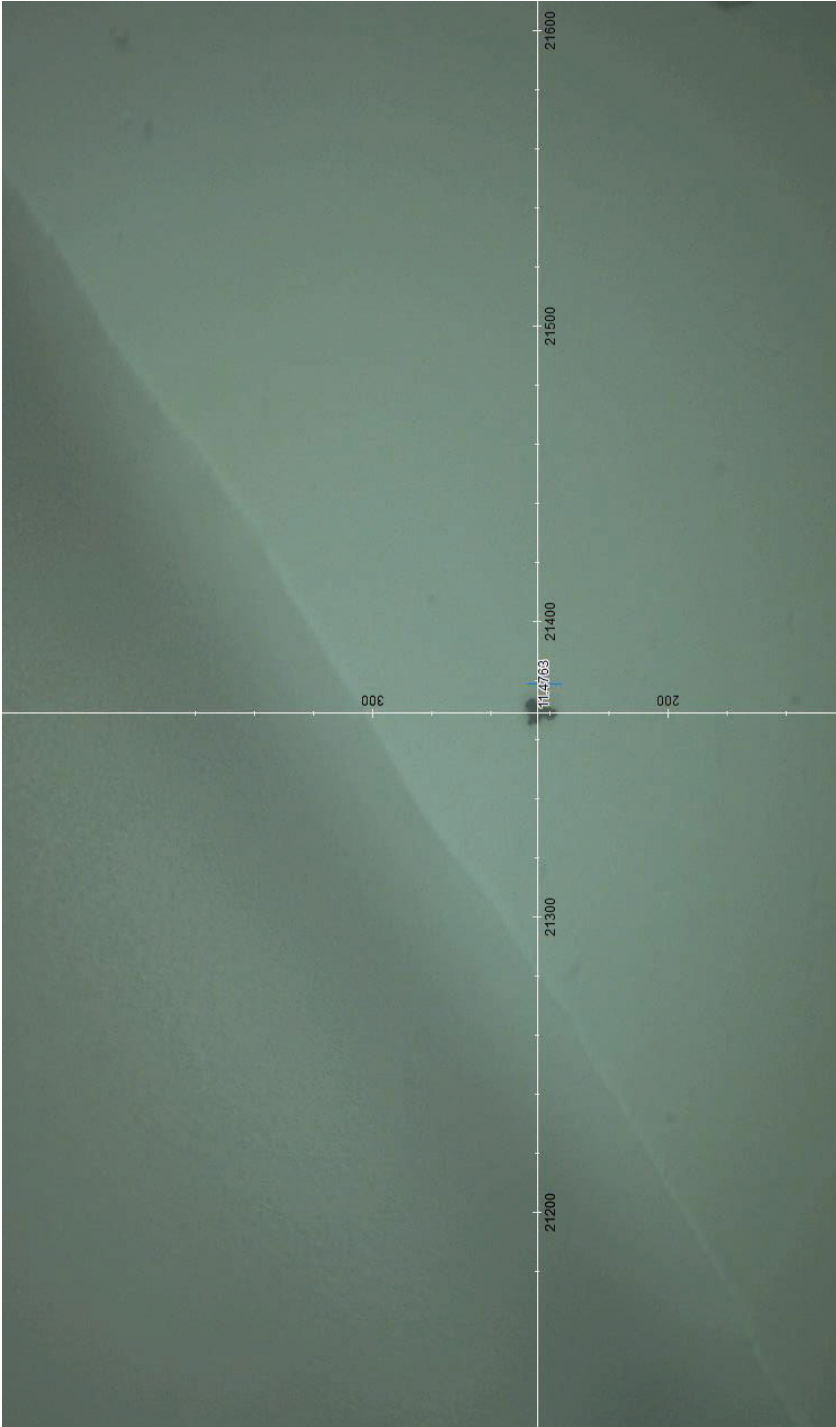
4. PFIZER 3
Ros 2hy b GO2



14

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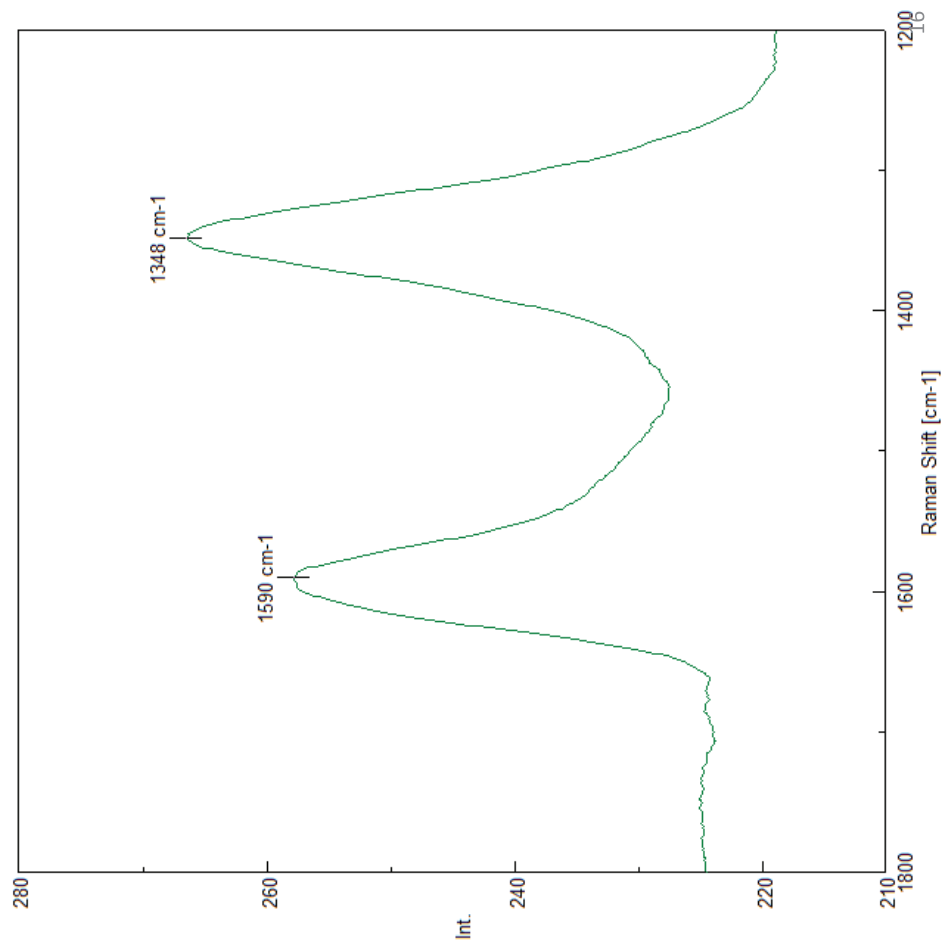
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Ros 2hy b G02



15

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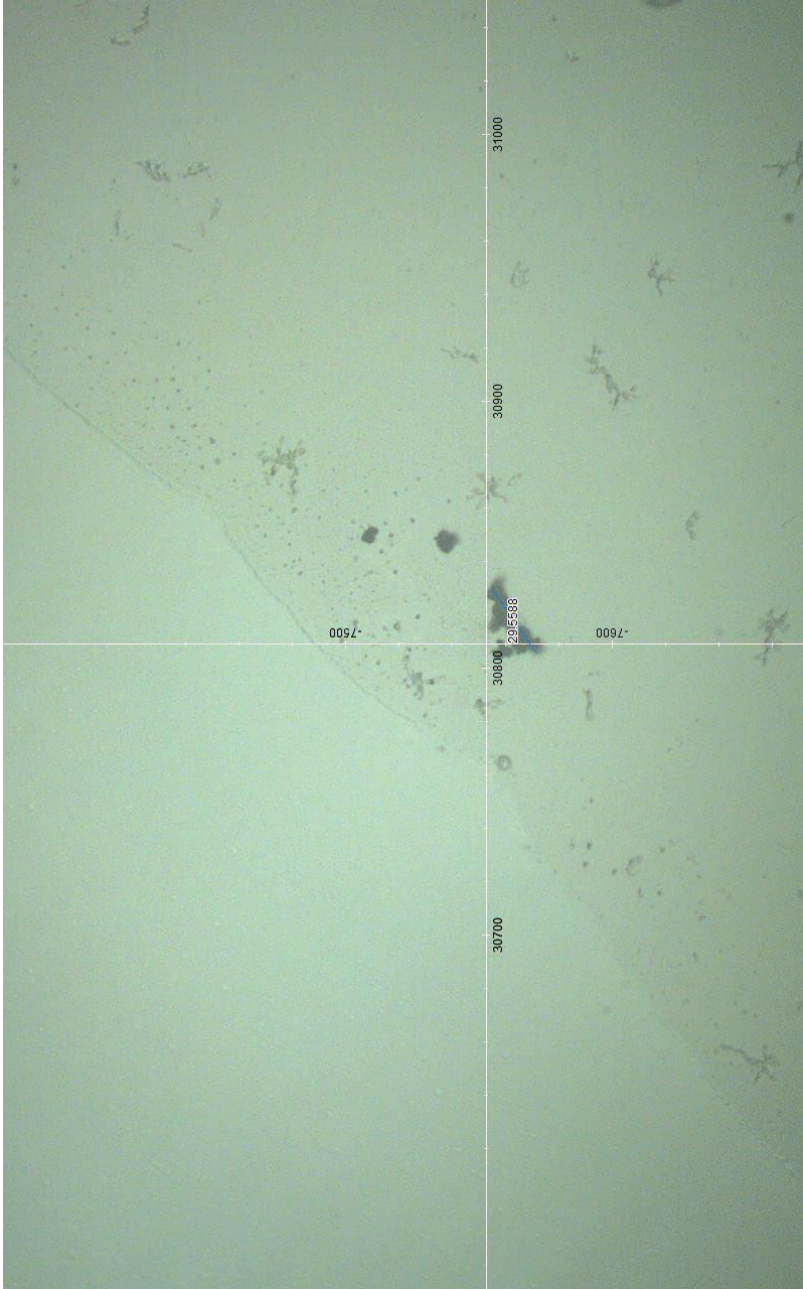


4. PFIZER 3
Ros 2hy b GO2

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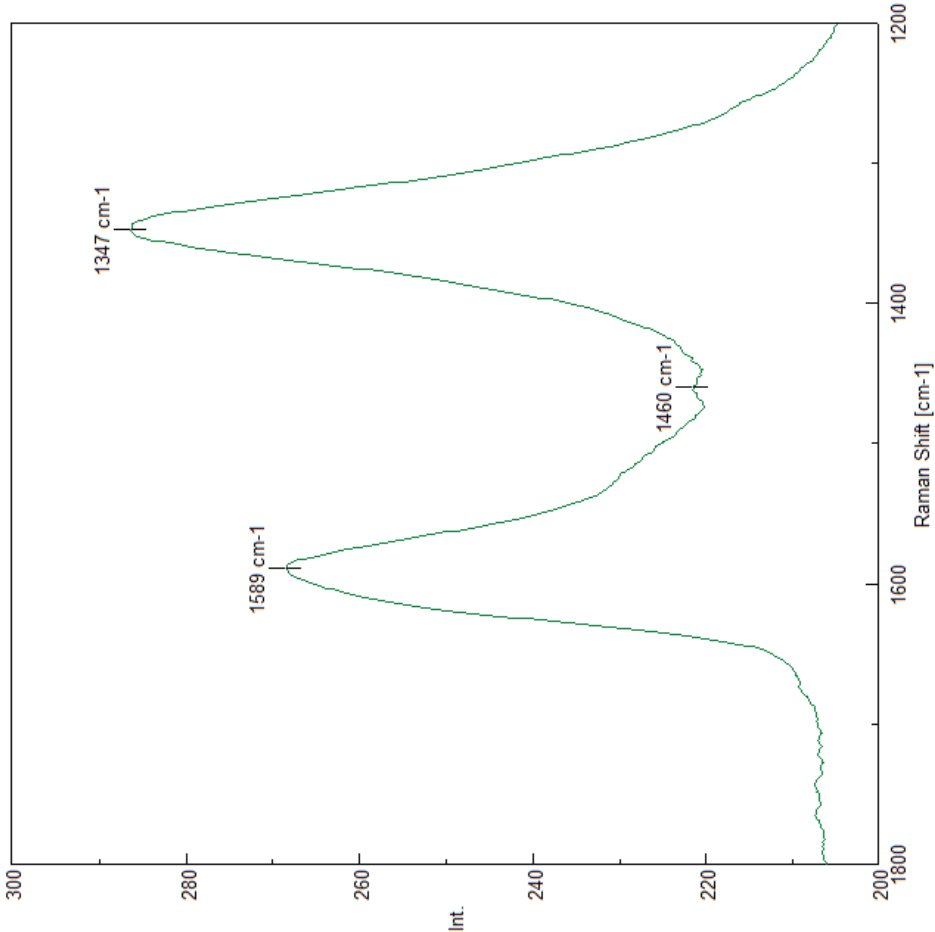
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5. ASTRAZENECA
AZ MIT UP CARB1



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18

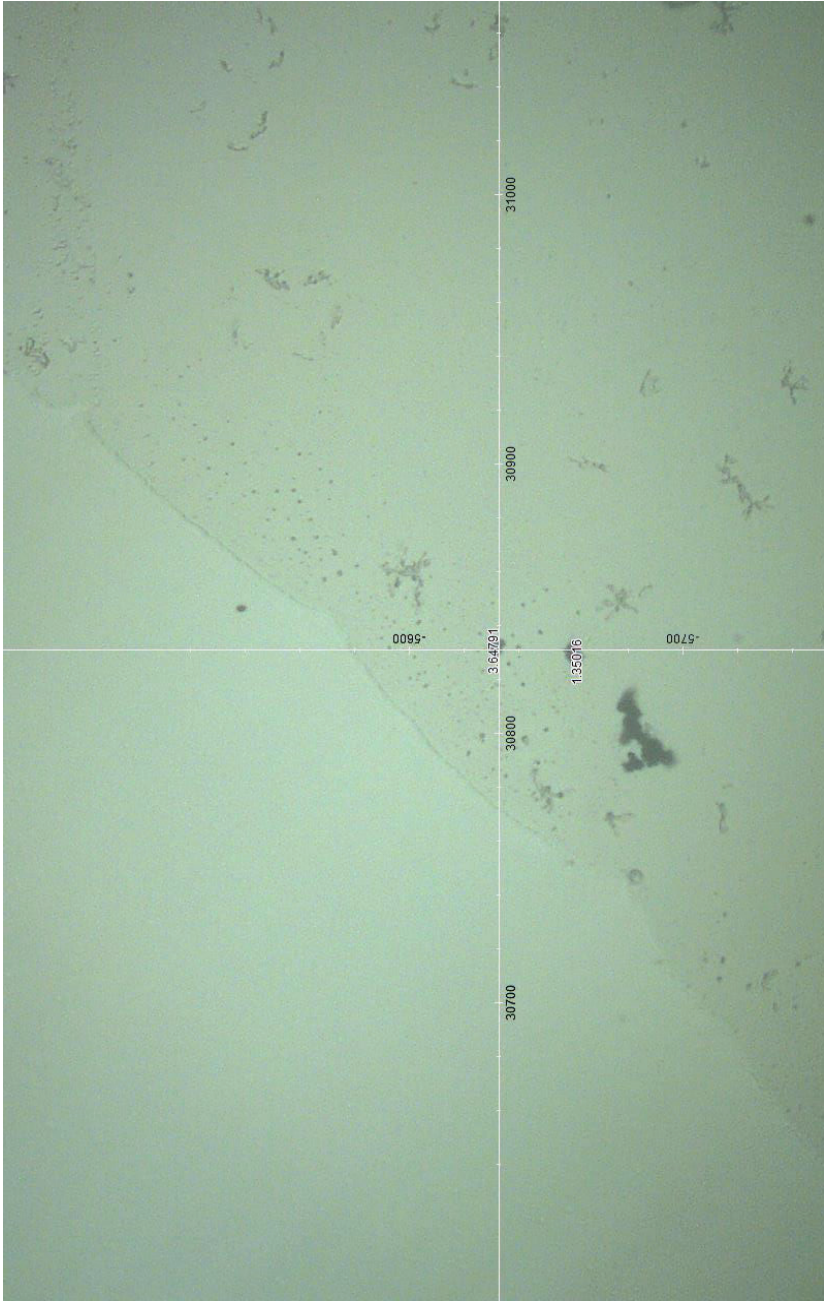
5. ASTRAZENECA
AZ MIT UP CARB1

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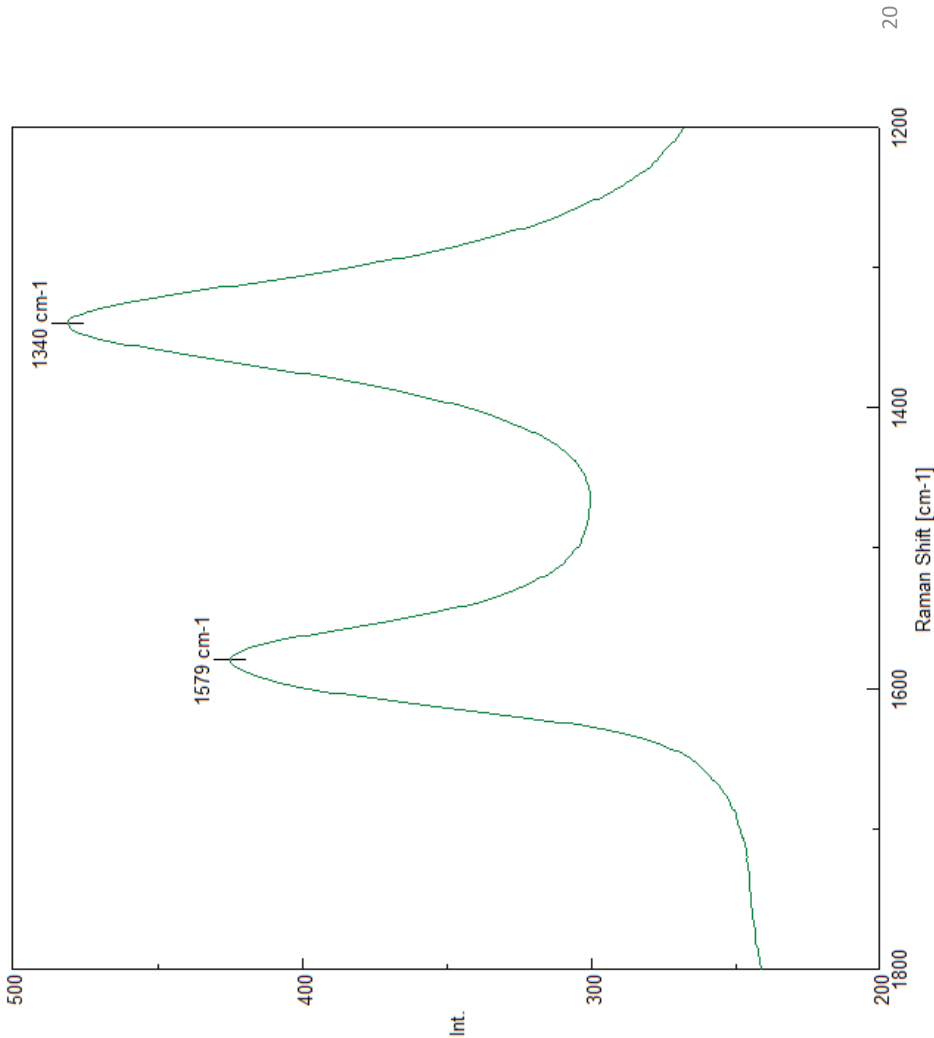
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6. ASTRAZENECA
AZ MIT UP CARB4



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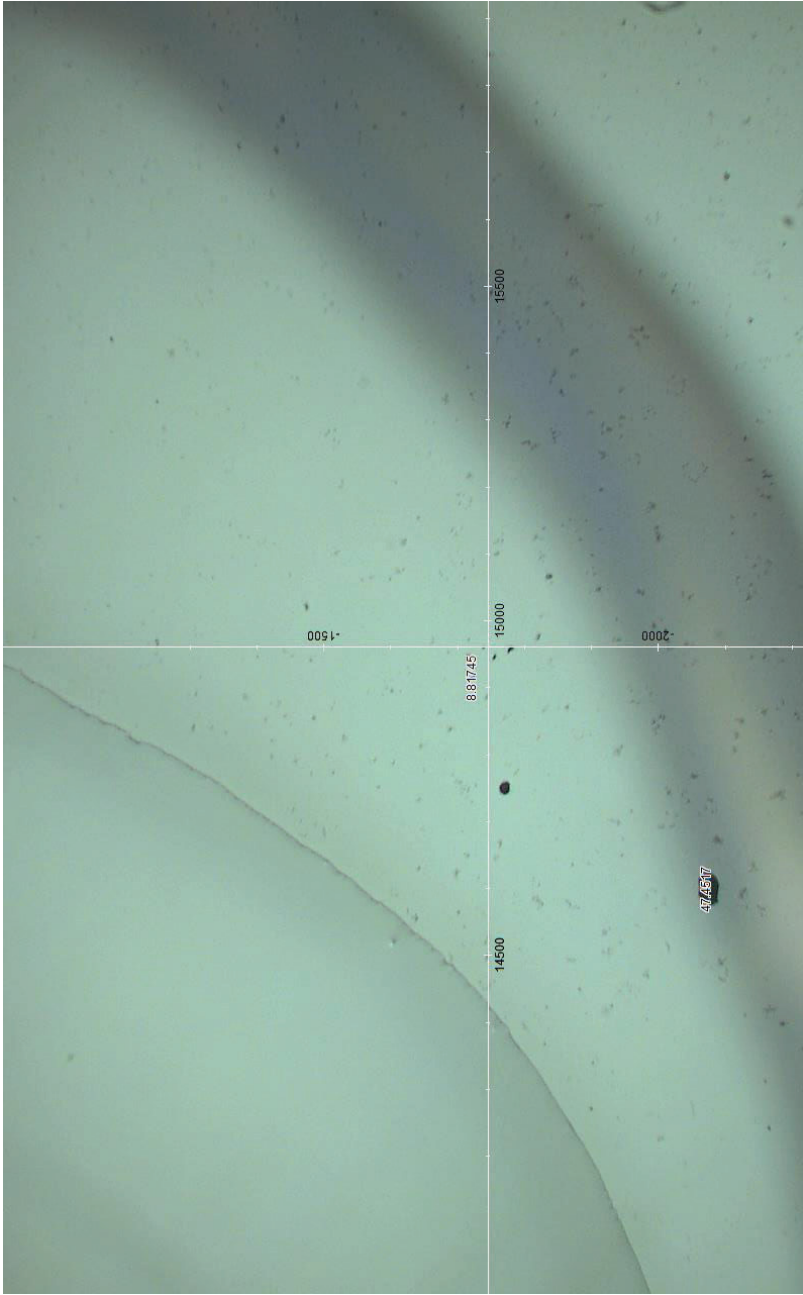
6. ASTRAZENECA
AZ MIT UP CARB4

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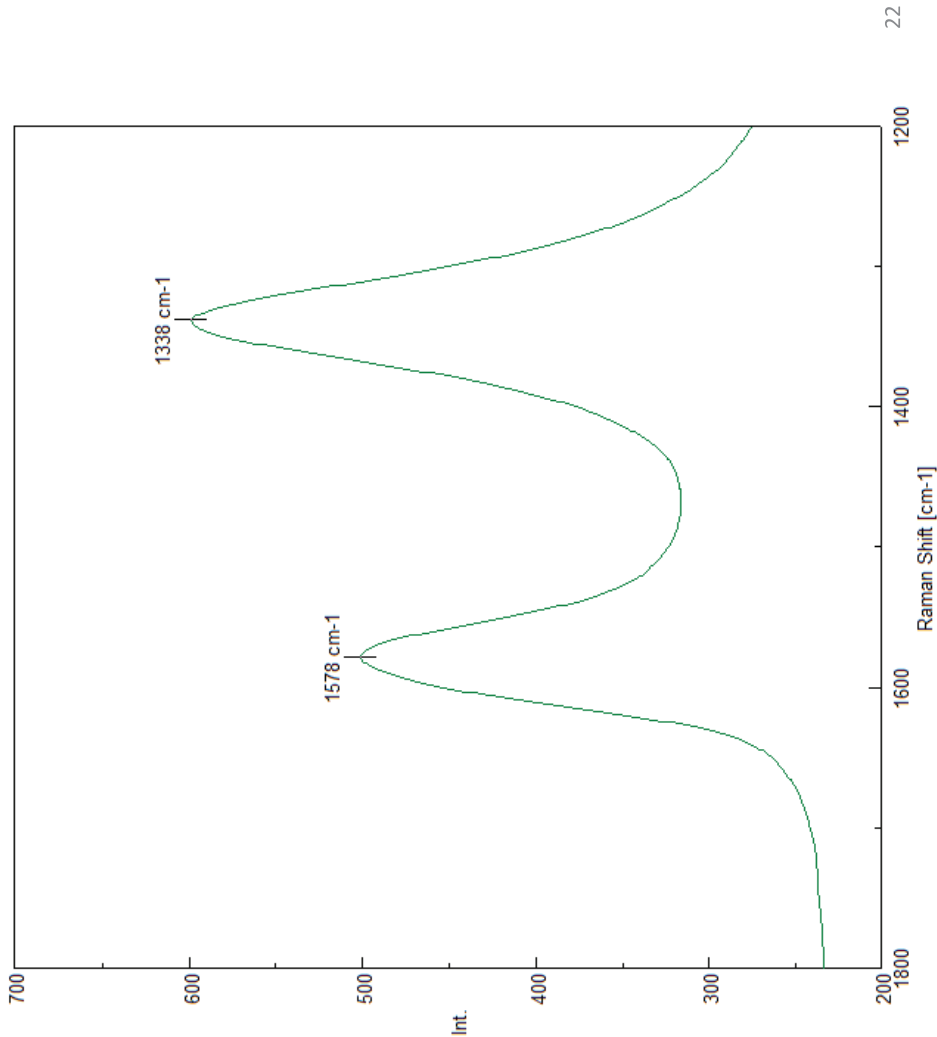
7. ASTRAZENECA
AZ MIT DOWN 2 CARB2



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7. ASTRAZENECA
AZ MIT DOWN CARB2



$$I_D/I_G = 1,18$$

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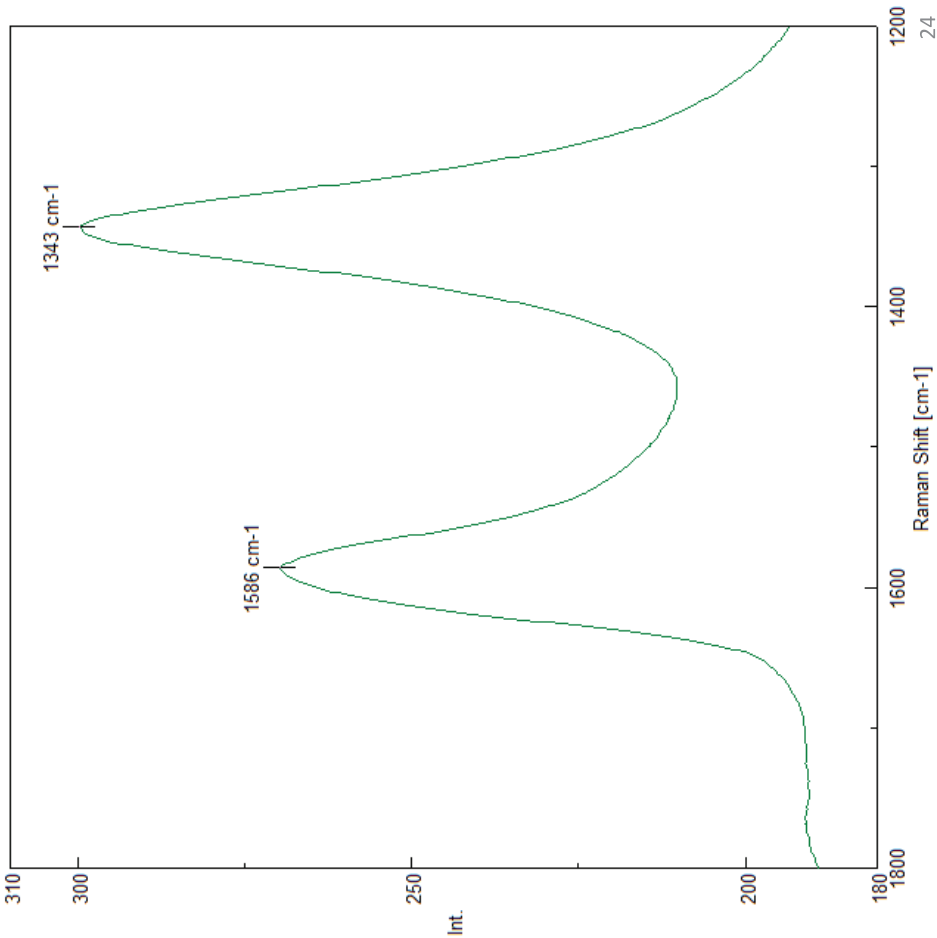
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8. MODERNA MOD grumo1

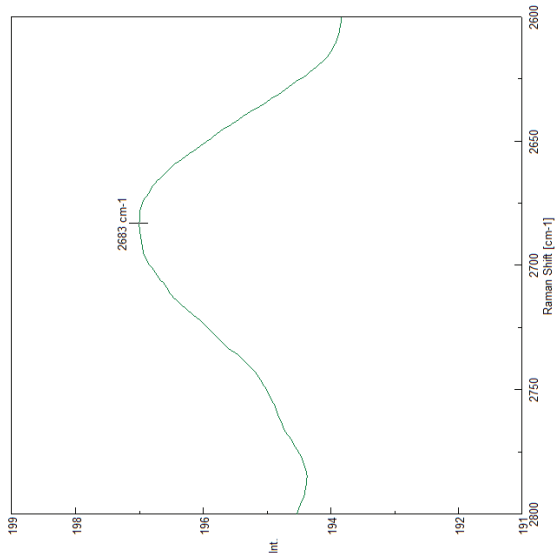


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8. MODERNA
MOD grumo1



$I_D/I_G = 1,11$

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2.2. GRUPO 2: OBJETOS CON SEÑALES COMPATIBLES CON ESTRUCTURAS DE GRAFITO, GRAFENO Y DERIVADOS

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PÁGINA

25/53



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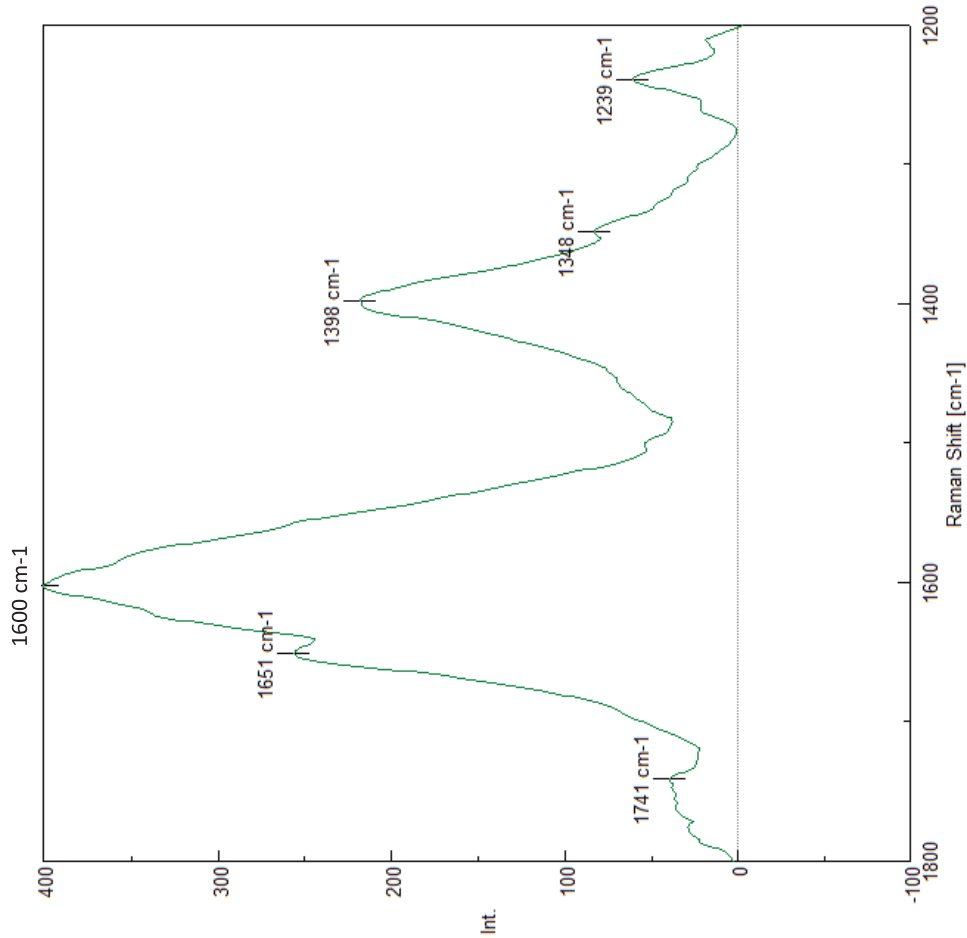
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OBJETOS ANALIZADOS

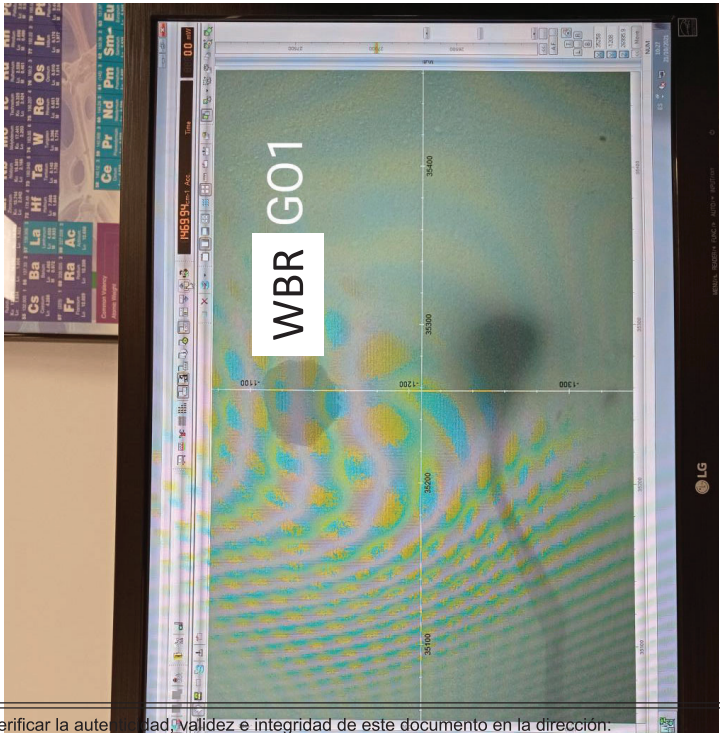
GRUPO 2

9	PFIZER 2 WBR GO1	
10	PFIZER 2 WBR GO6a	
11	PFIZER 2 WBR 2 GO7	
12	PFIZER 2 WBR UP GO1	
13	PFIZER 2 WBR UP GO3b	
14	PFIZER 2 WBR UP GO4	
15	PFIZER 2 WBR DOWN GO2	
16	PFIZER 2 WBR DOWN GO3	
17	PFIZER 2 WBR DOWN GO5	
18	PFIZER 3 ROS OBJ 1	
19	PFIZER 3 ROS 2 OBJ 1	
20	PFIZER 3 ROS 2 OBJ 2	
21		PFIZER 4 Pdown grumo1
22		PFIZER 4 Pdown grumo2
23		PFIZER 4 Pdown grumo3
24		ASTRAZENECA AZ MIT UP CARB5
25		ASTRAZENECA AZ MIT UP CARB6
26		JANSSEN JAN GO1
27		JANSSEN JAN GO3
28		JANSSEN JAN GO4

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9. PFIZER 2
WBR G01



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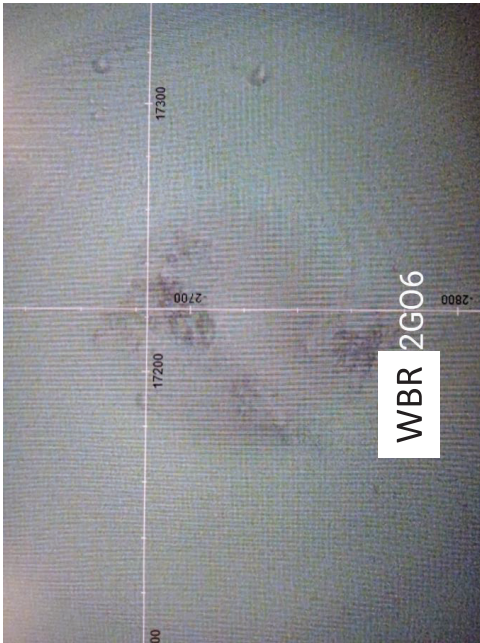
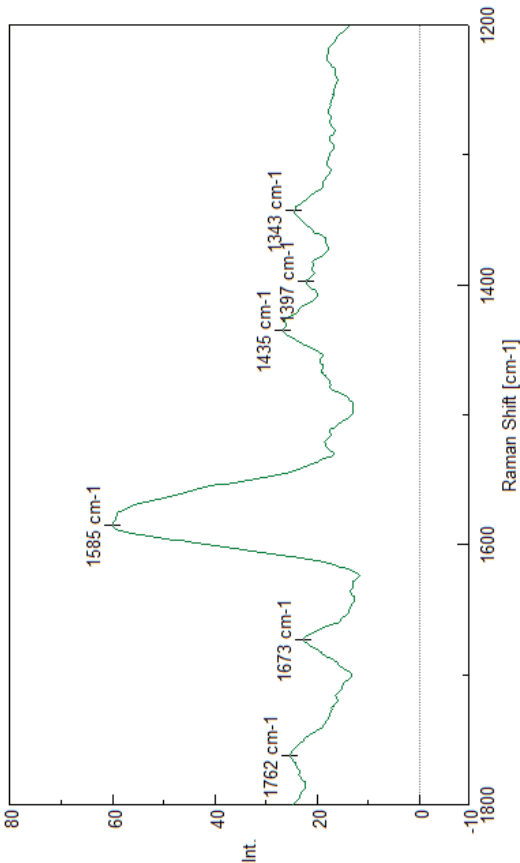
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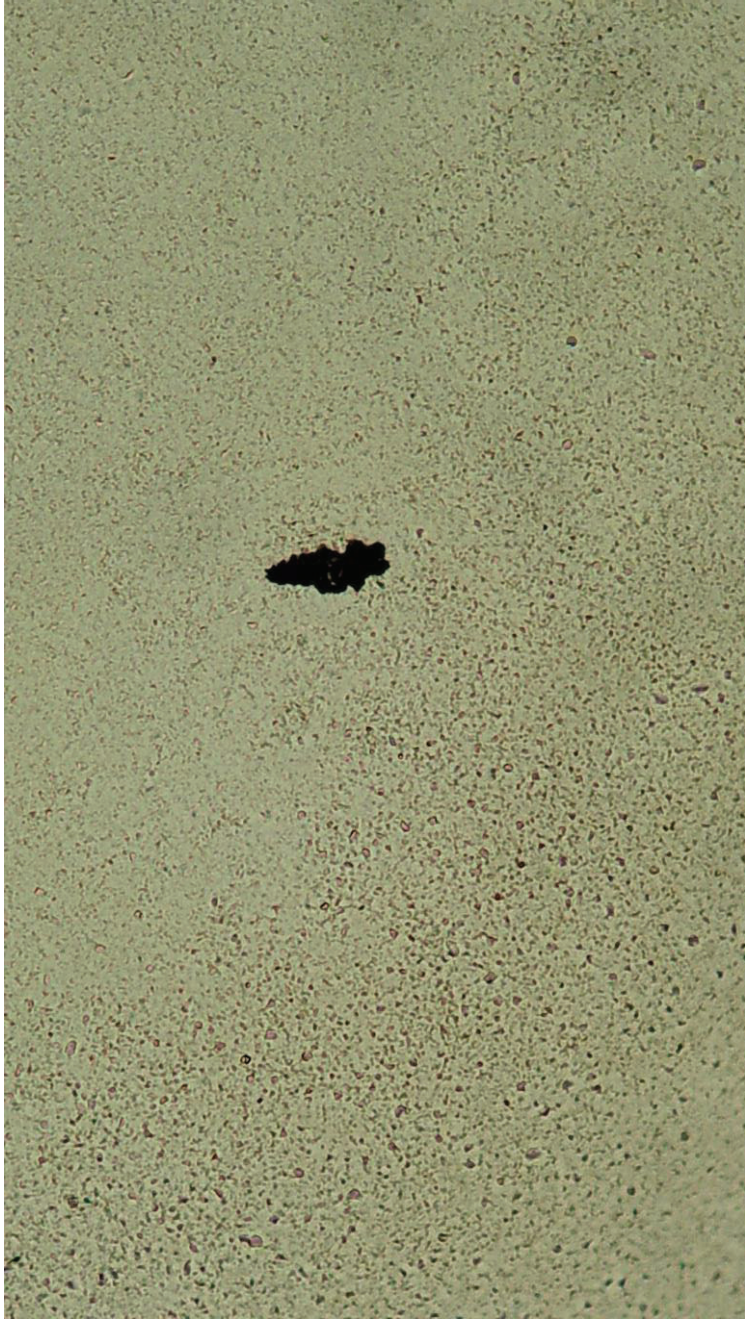
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10. PFIZER 2 WBR GO6a



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11. PFIZER 2
WBR2 GO7

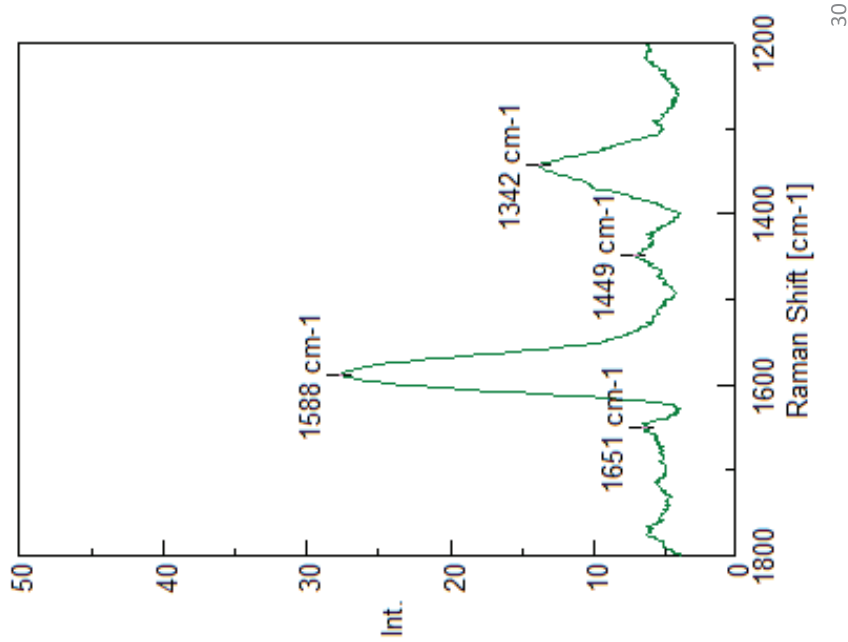


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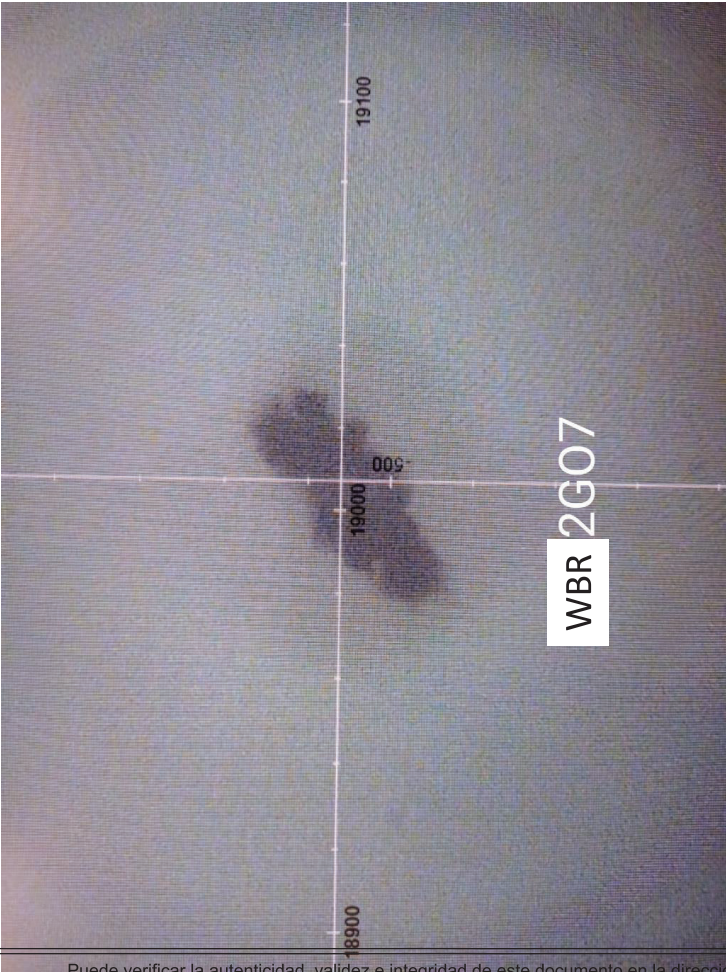
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11. PFIZER 2
WBR GO 7



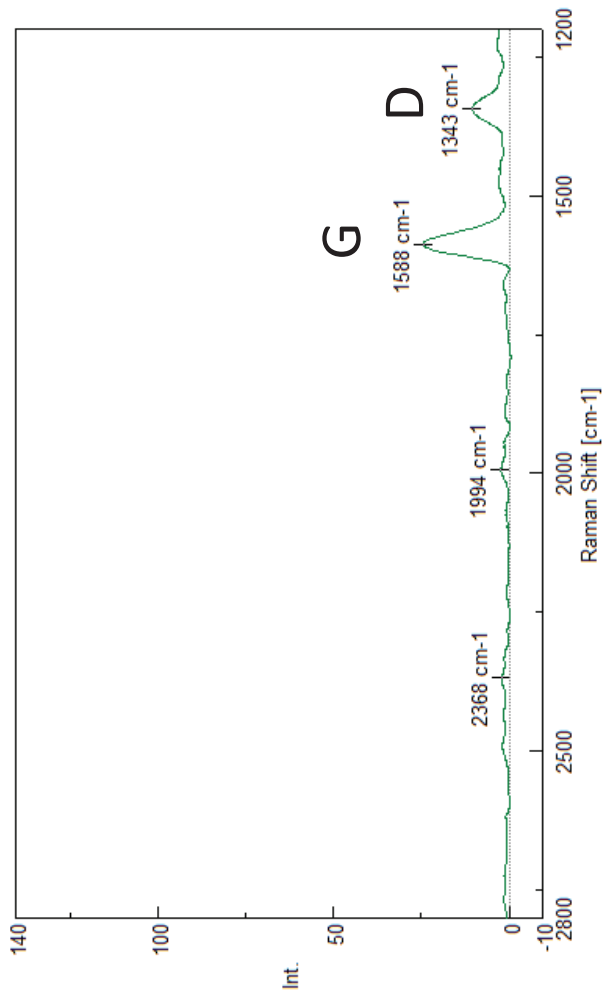
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$I_D/I_G = 0,48$

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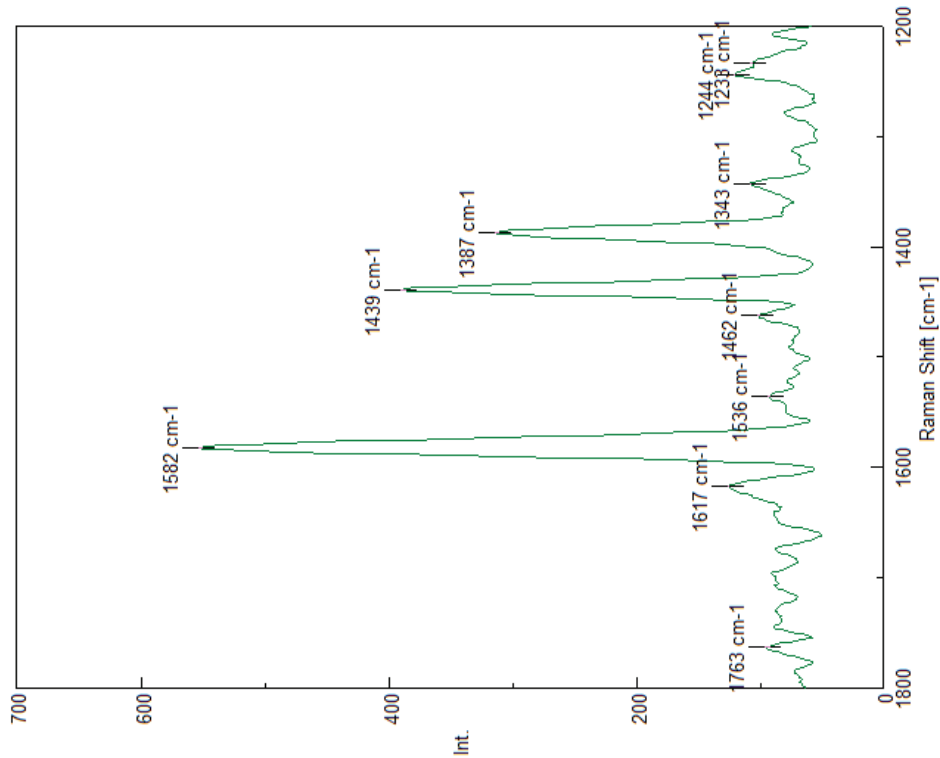
11. PFIZER 2
WBR GO7 (1200-2800 cm)



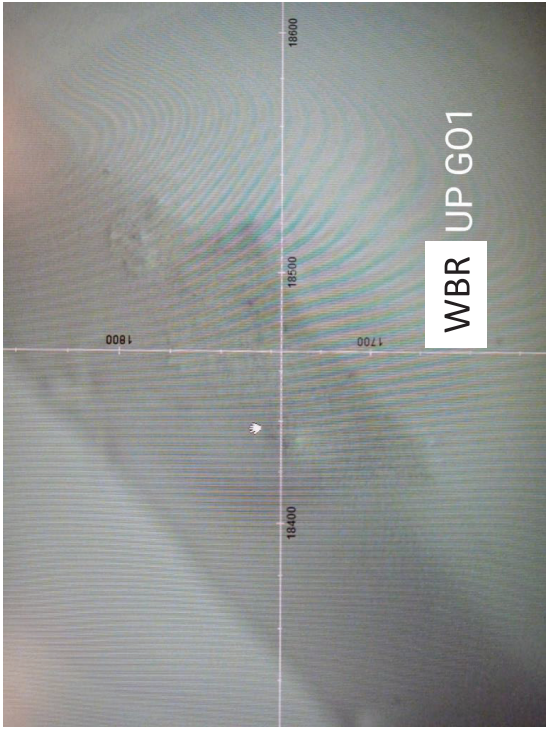
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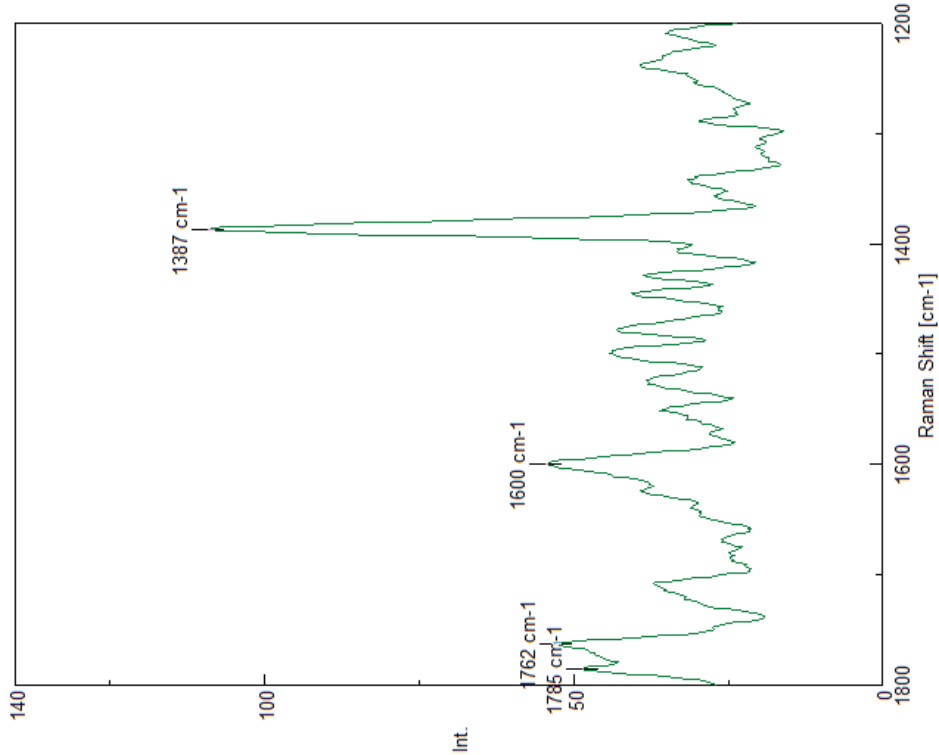


12. PFIZER 2
WBR UP GO1



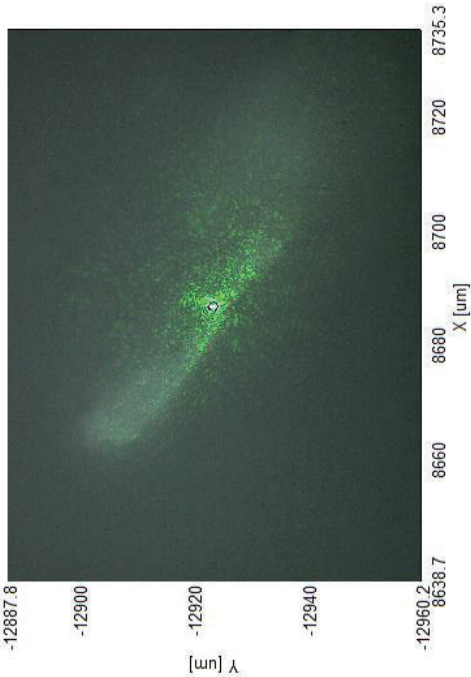
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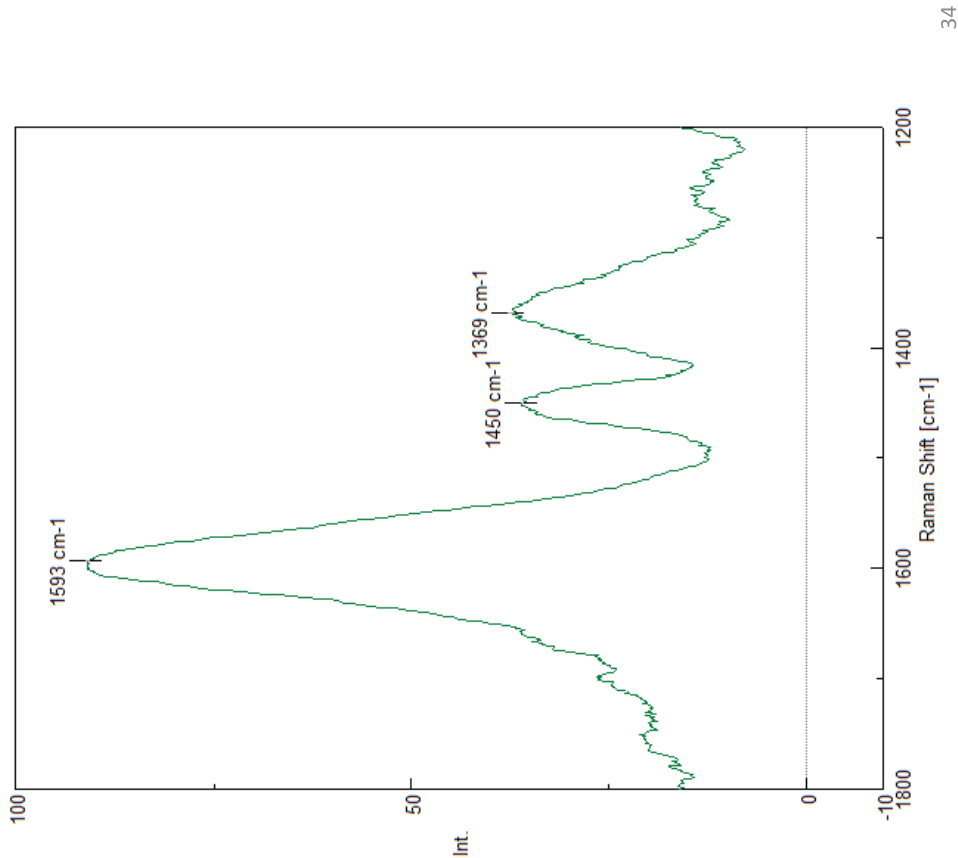
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13. PFIZER
WBR UP GO3b



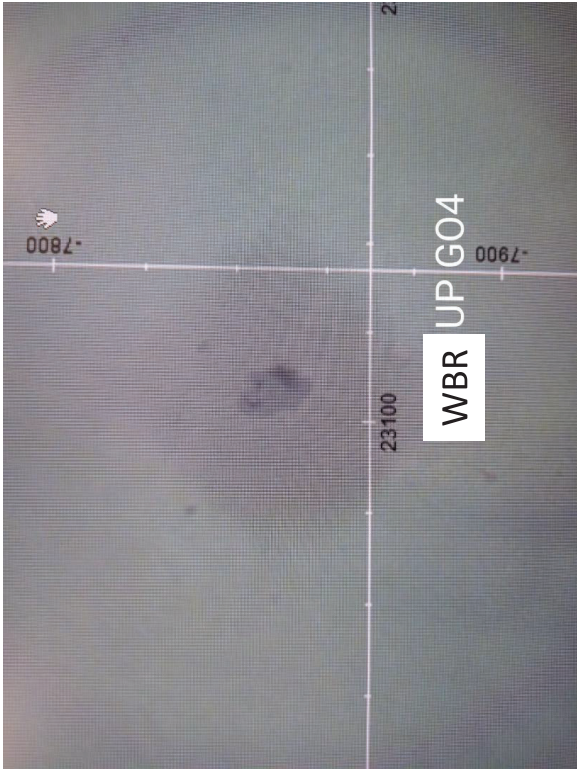
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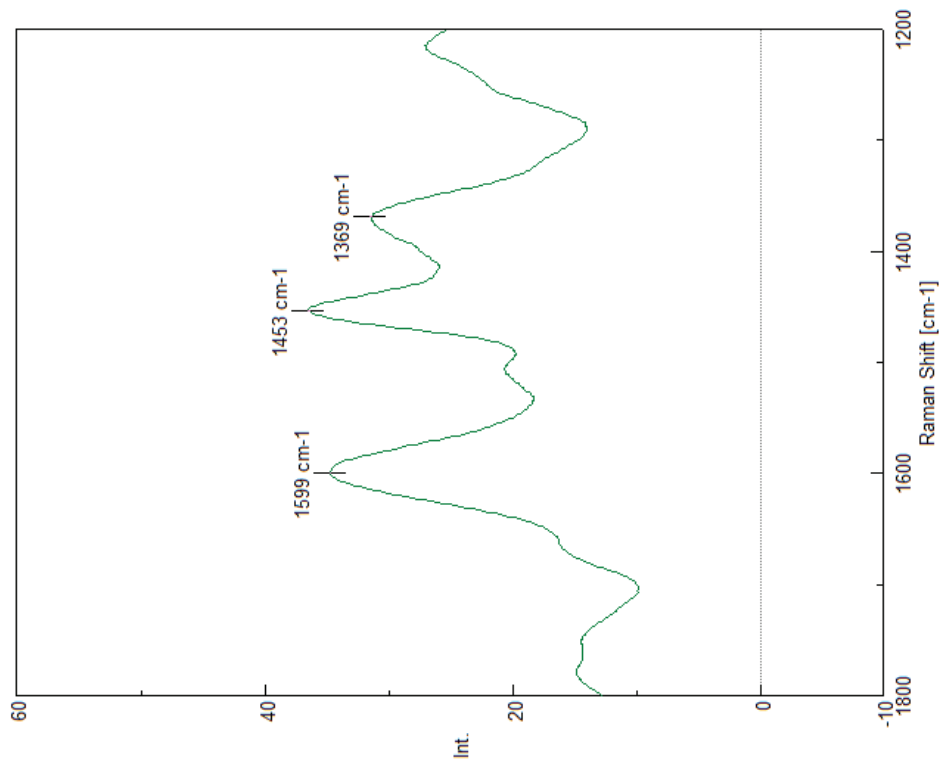
34

14. PFIZER 2
WBR UP GO4



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15. PFIZER 2
WBR DOWN GO2

Foto N/A

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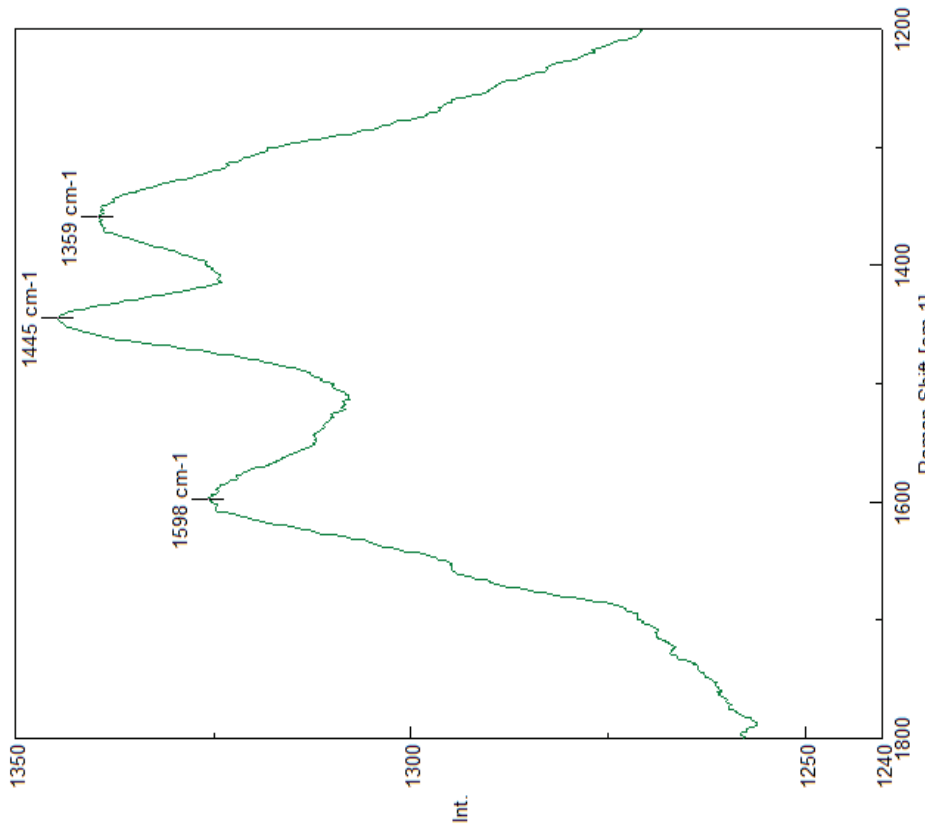
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35/53

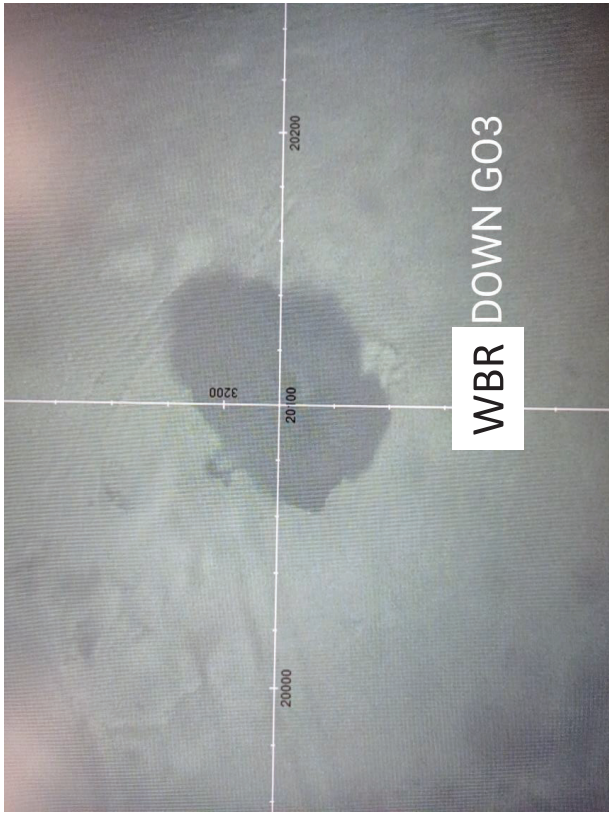


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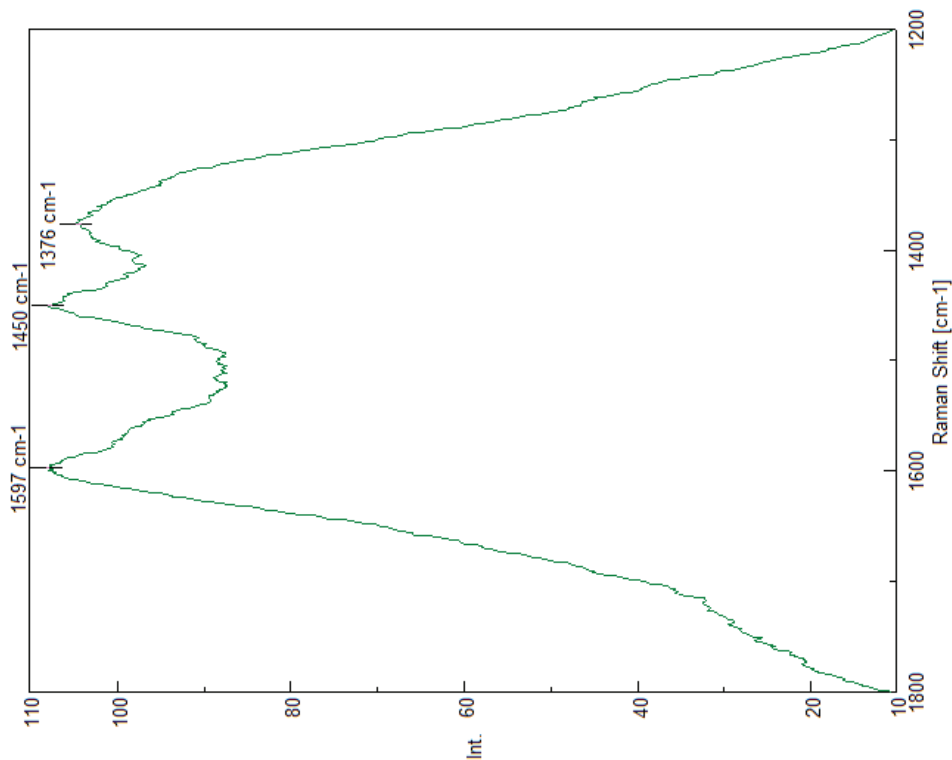
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16. PFIZER 2
WBR DOWN GO3



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17. PFIZER 2
WBR DOWN GO5

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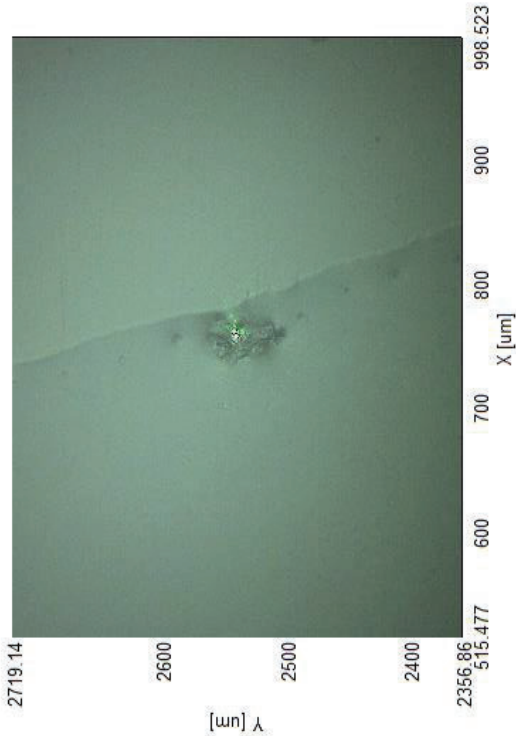
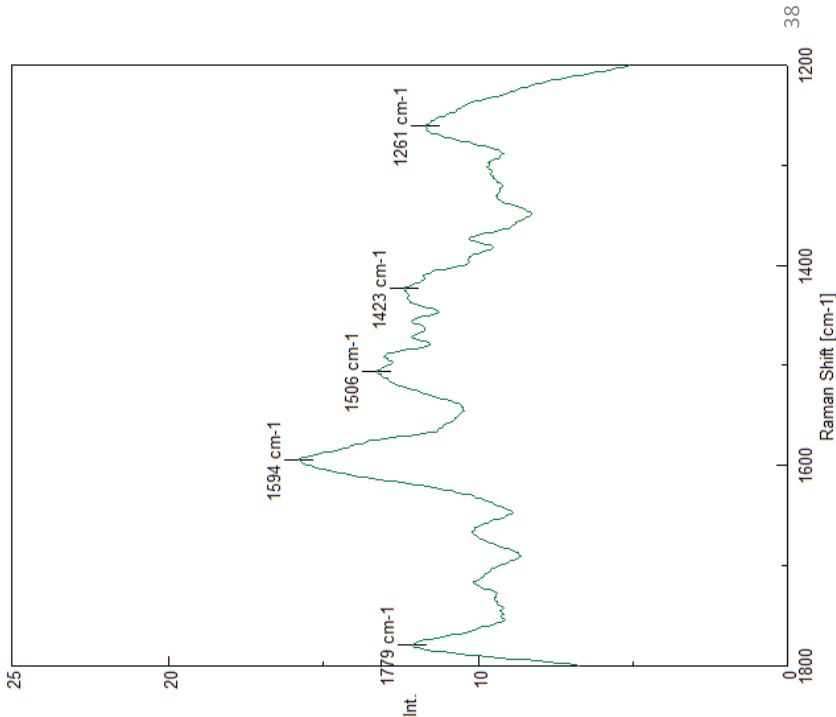
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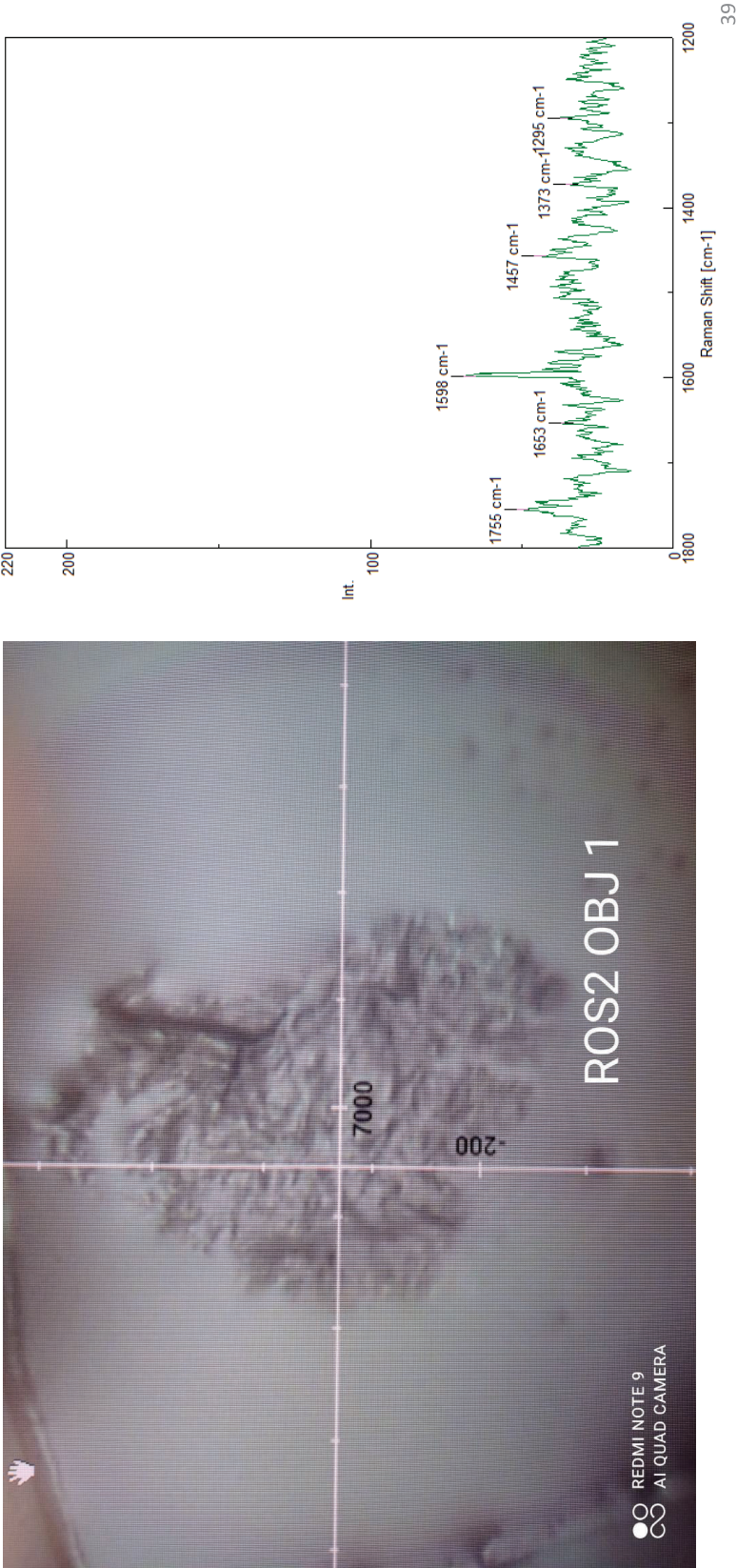
18. PFIZER 3
Ros OBJ 1



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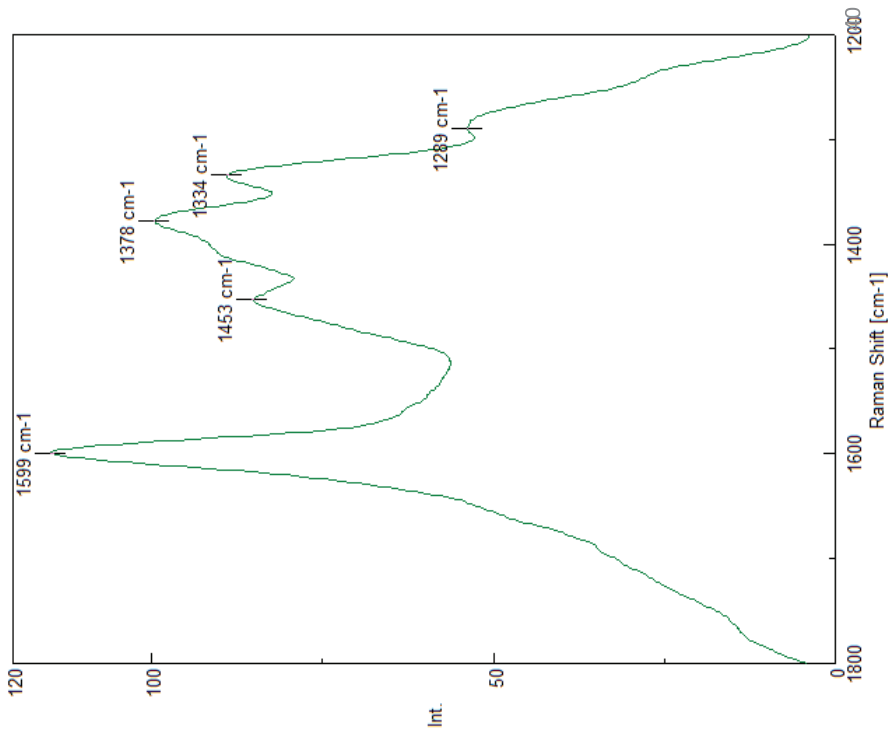
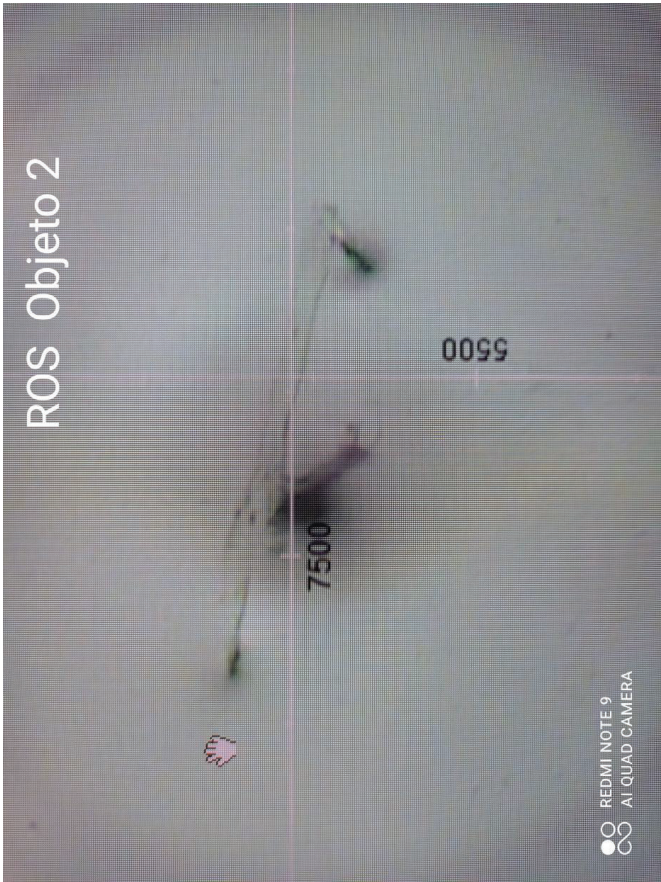
19. PFIZER 3
ROS 2 OBJ 1



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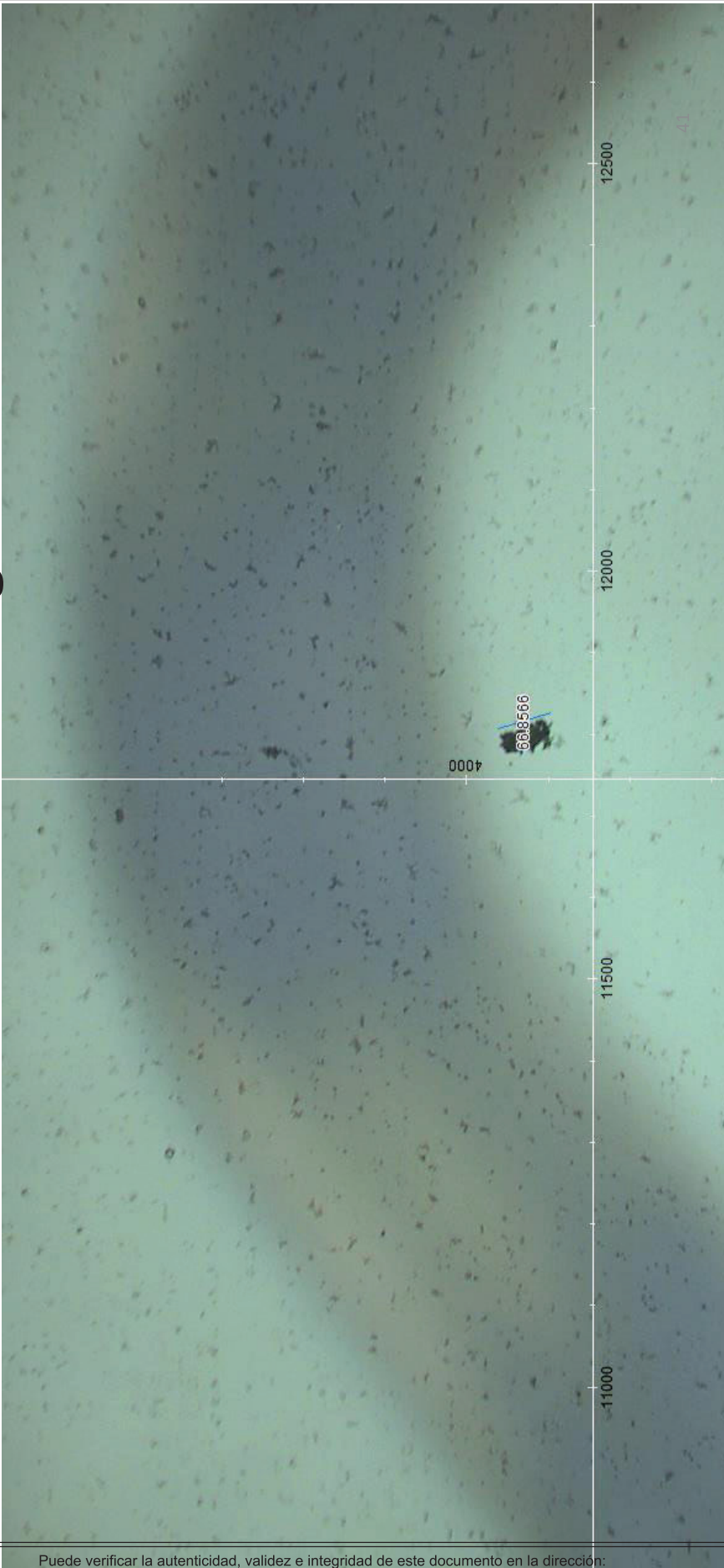
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20. PFIZER 3
ROS 2 OBJ2



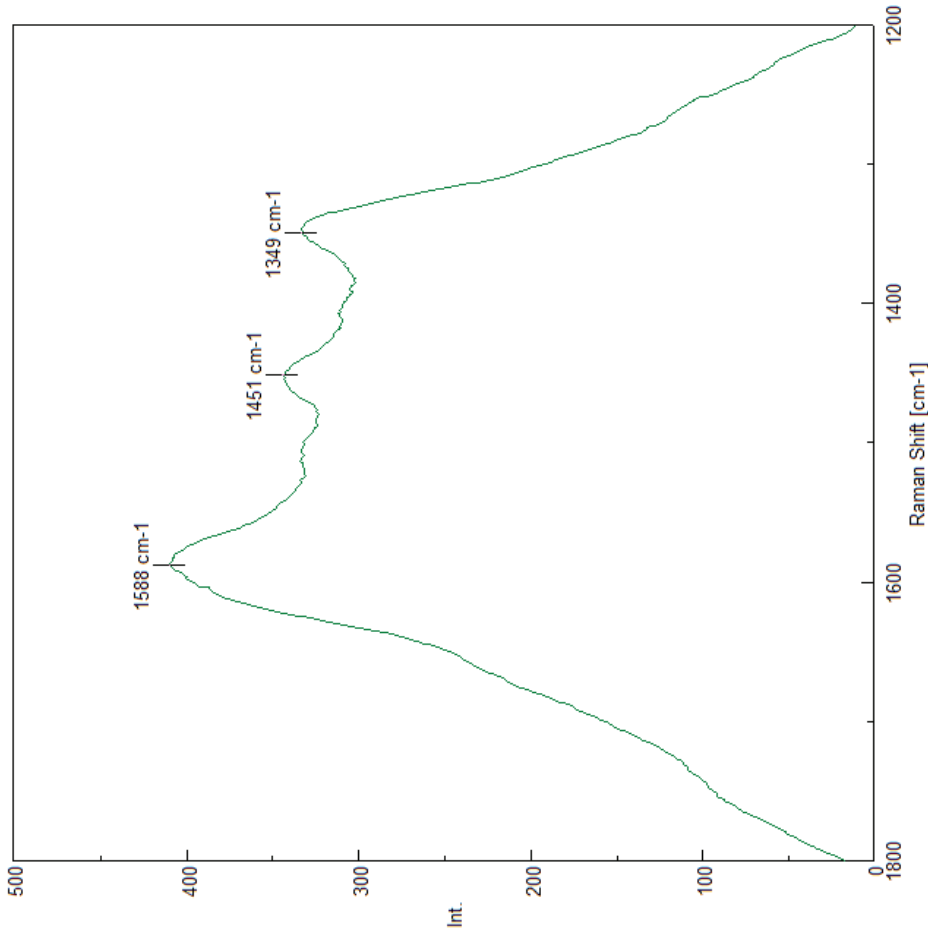
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21. PFIZER 4: Pdown grumo1



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21. PFIZER 4:
Pdown grumo1

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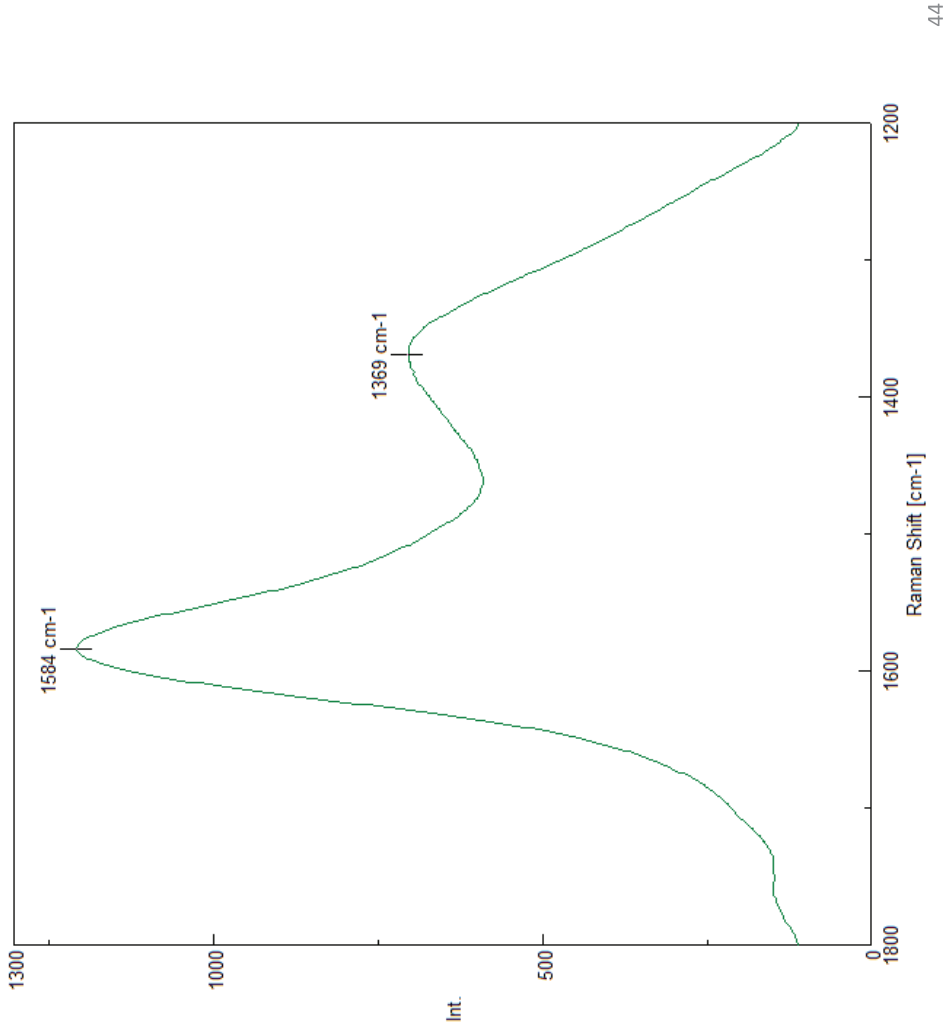
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22. PFIZER 4
Pdown grumo2



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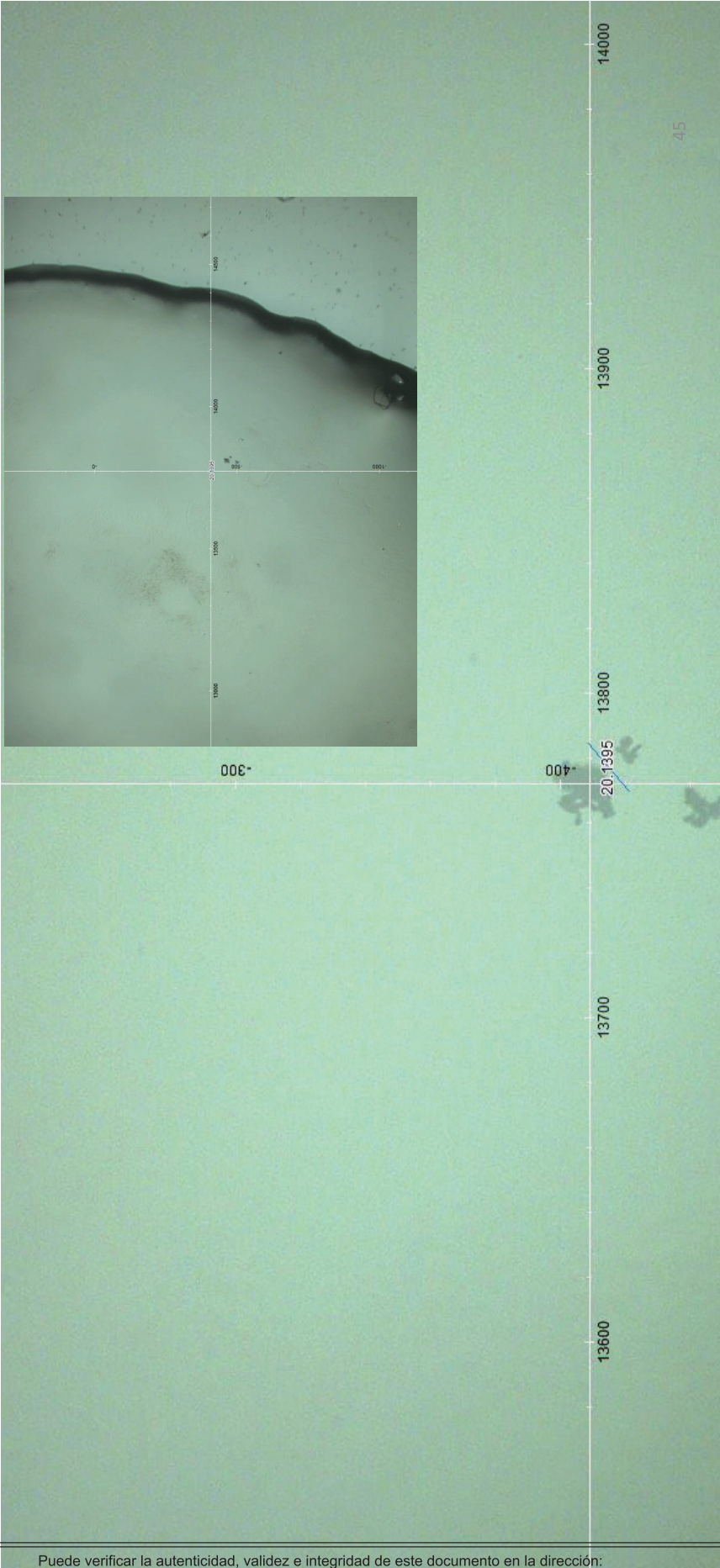
22. PFIZER 4
Pdown grumo2

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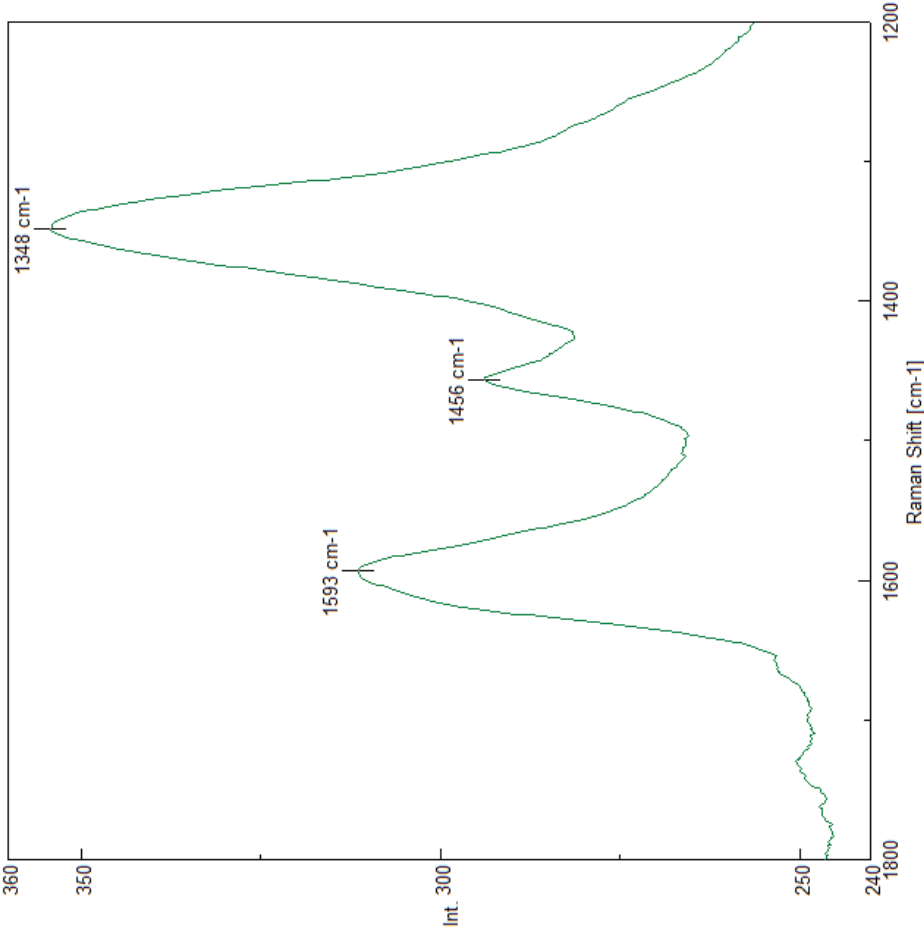
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23. PFIZER 4
Pdown grumo 3



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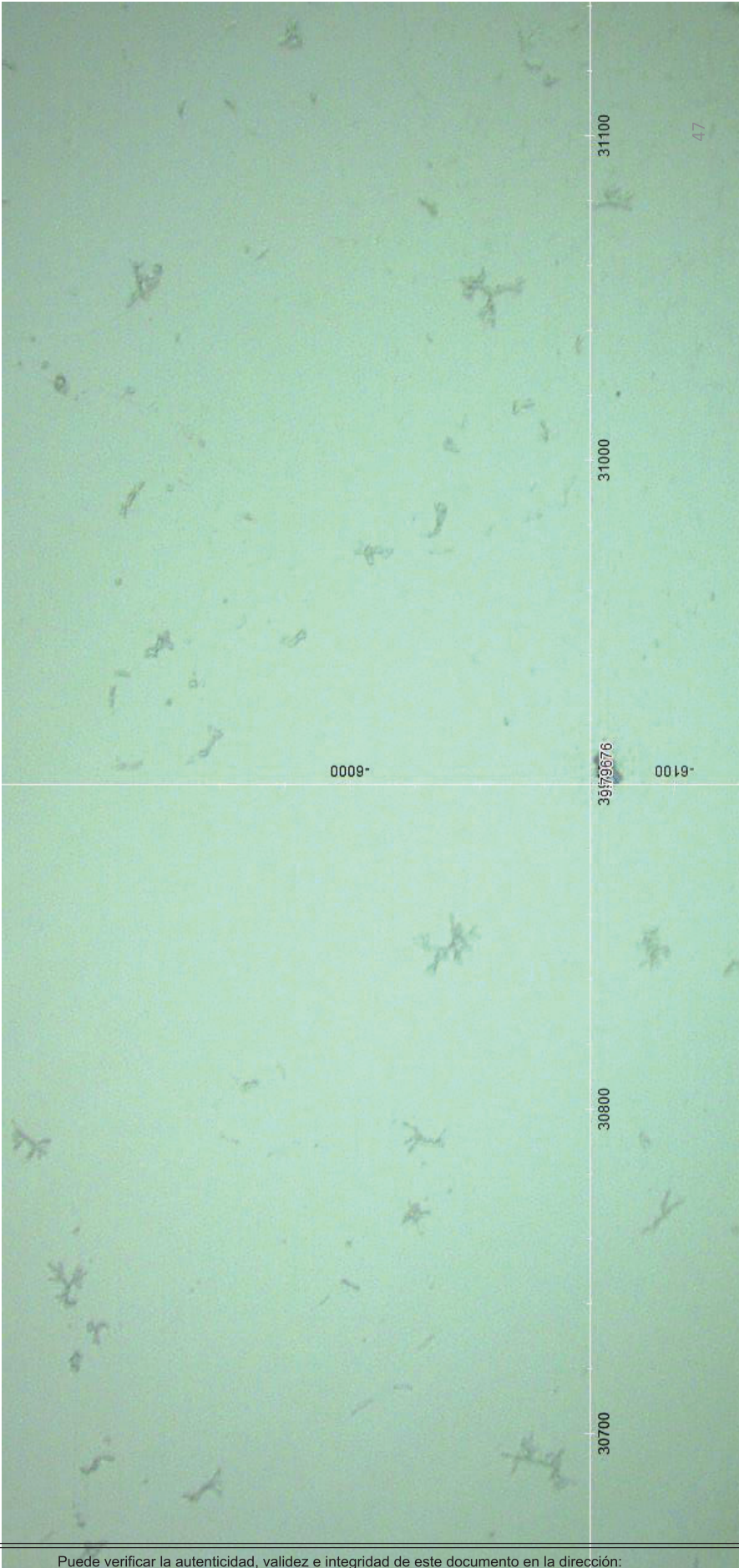
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23. PFIZER 4
Pdown grumo 3

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24. ASTRAZENECA
AZ MIT UP CARB5



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30800

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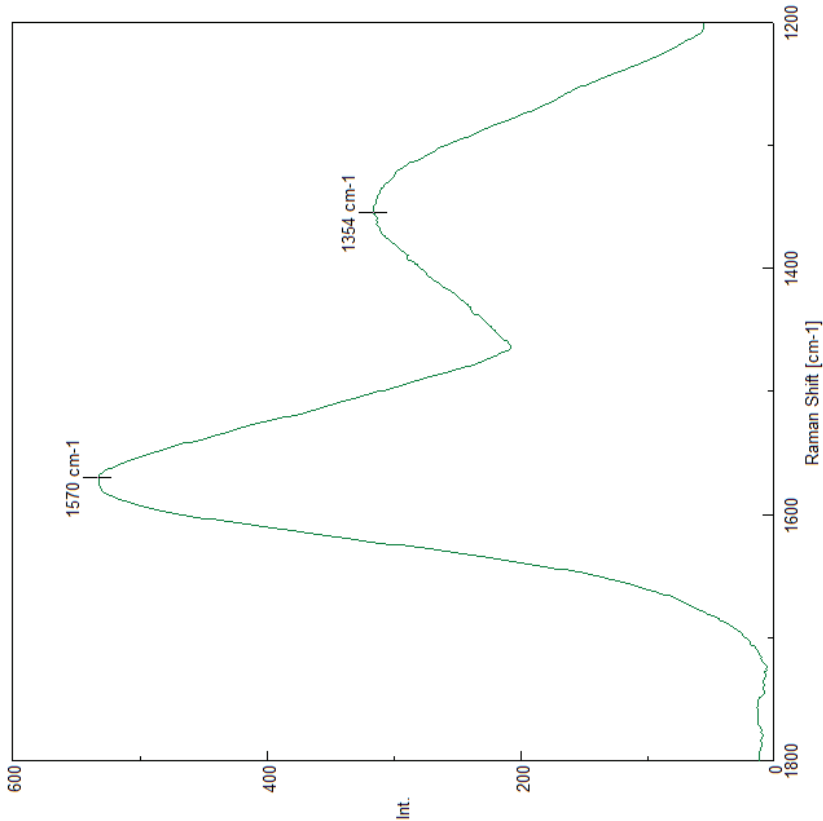
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48

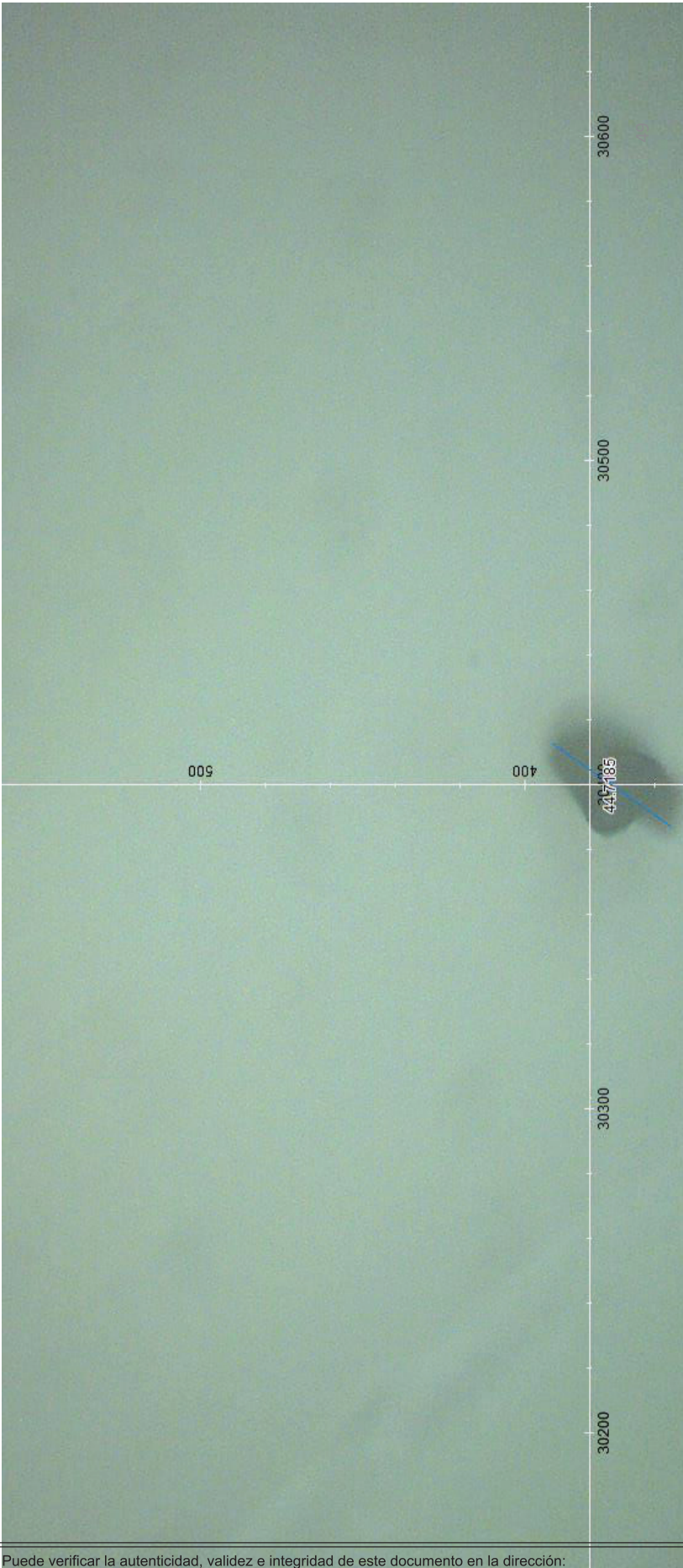
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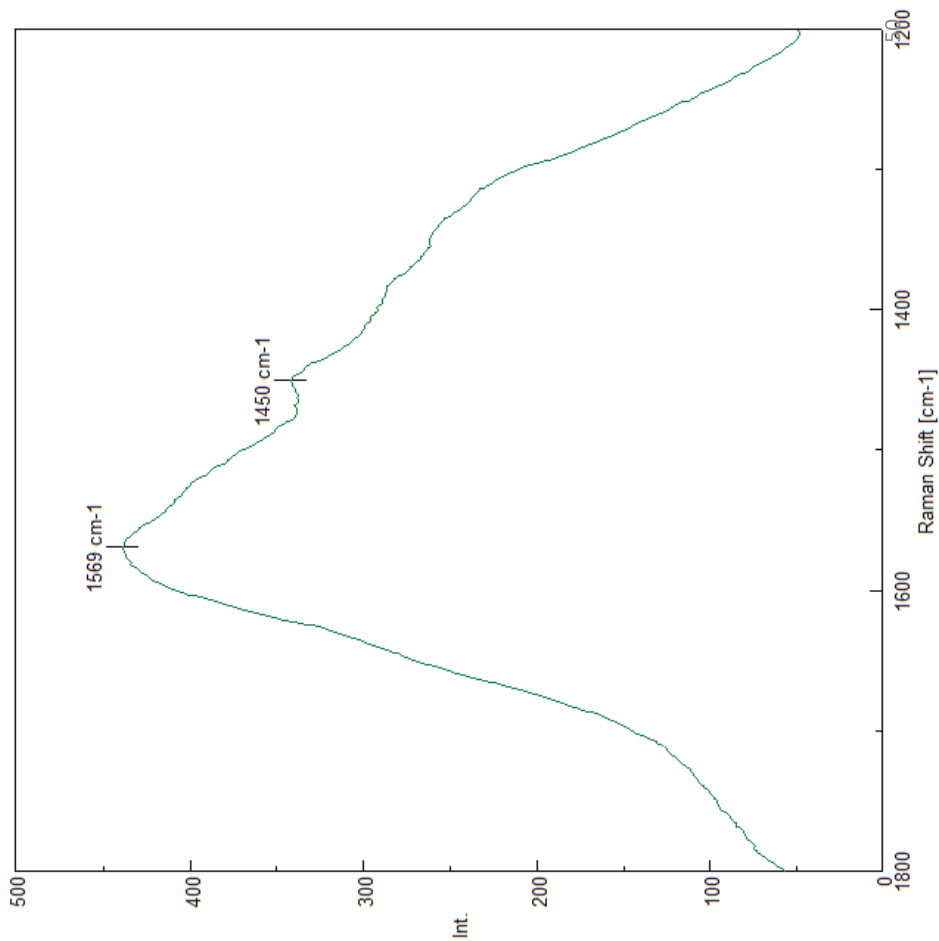
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25. ASTRAZENECA
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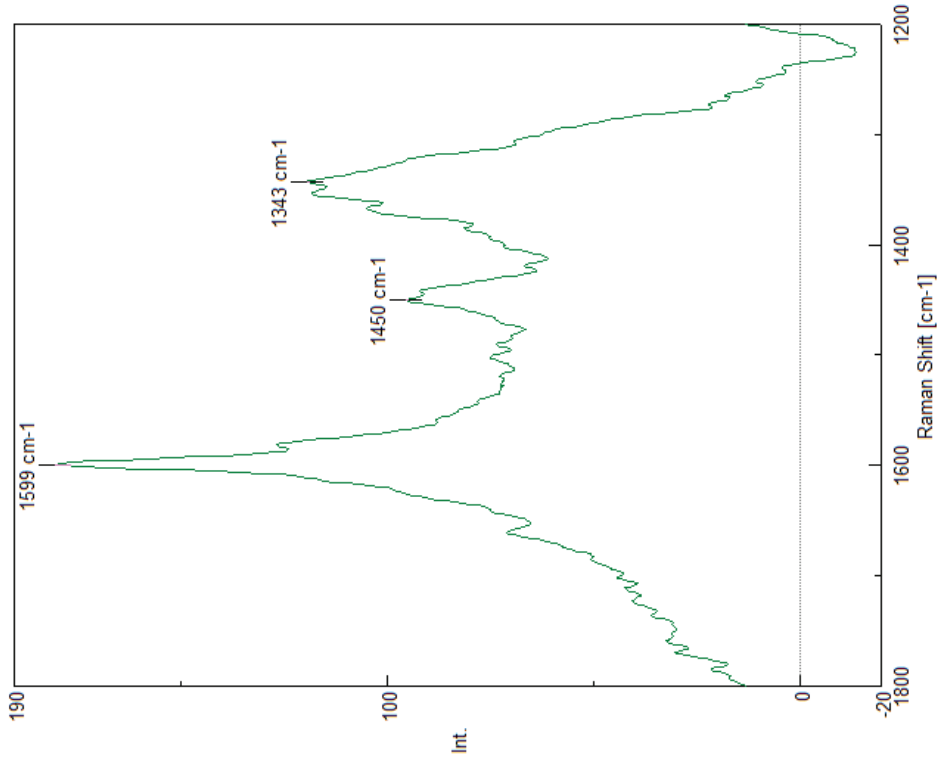
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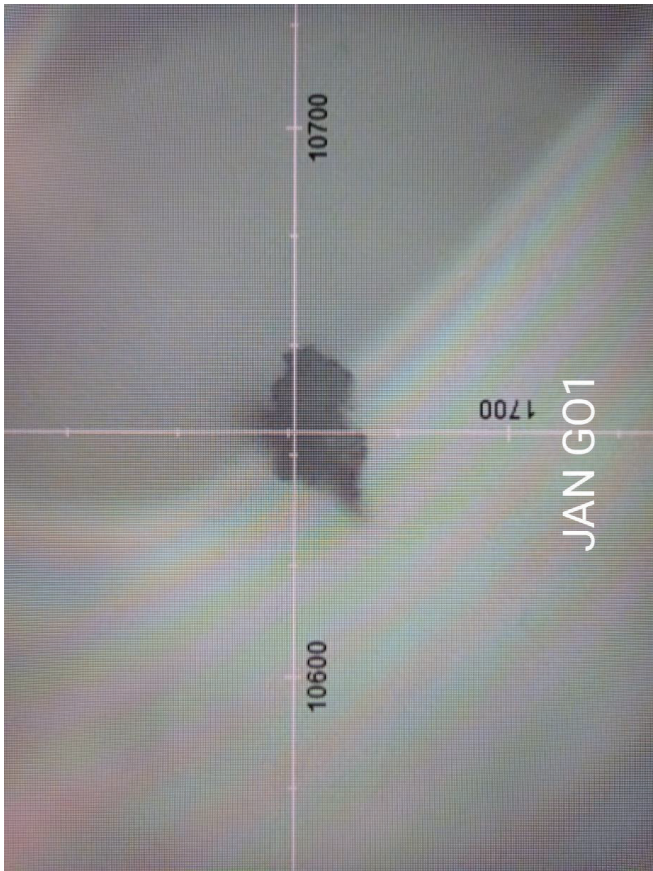
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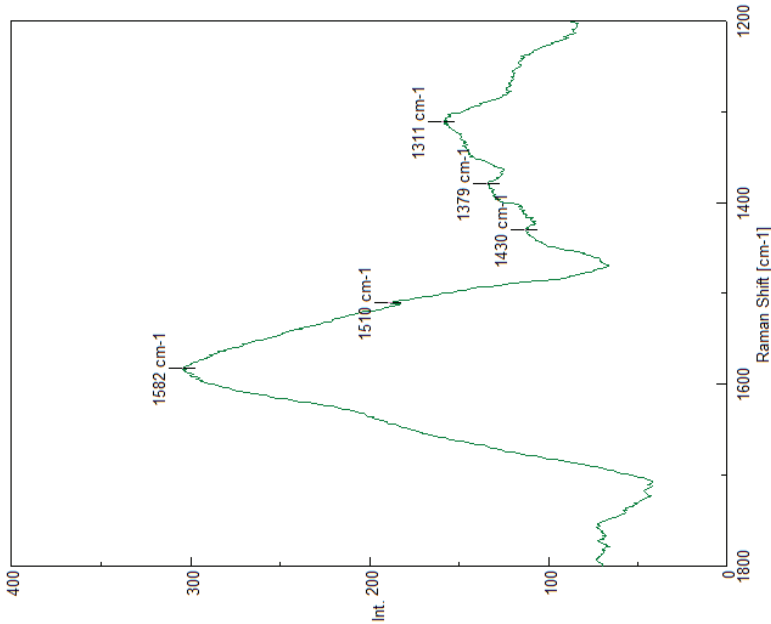
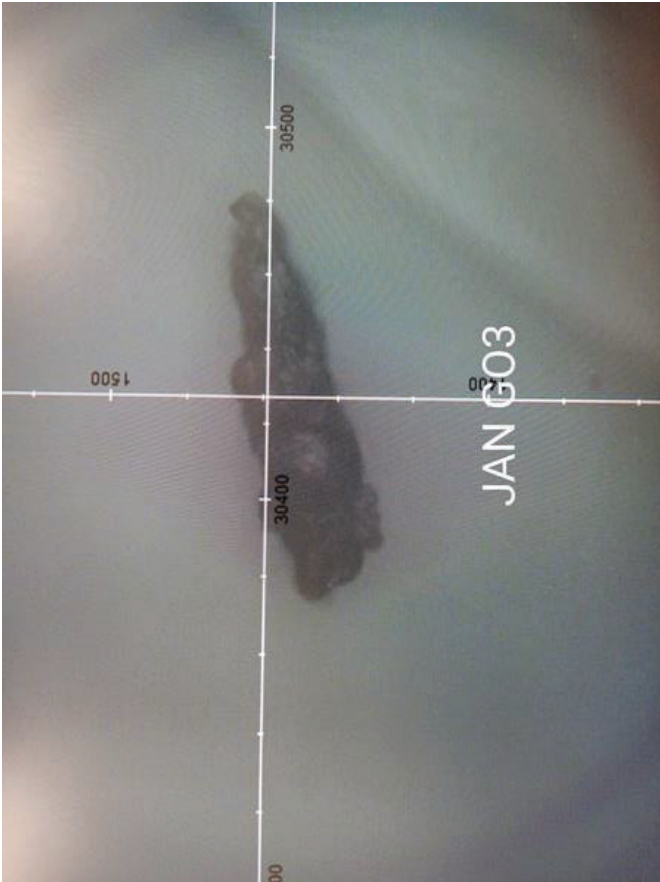
26. JANSSEN
JAN GO1



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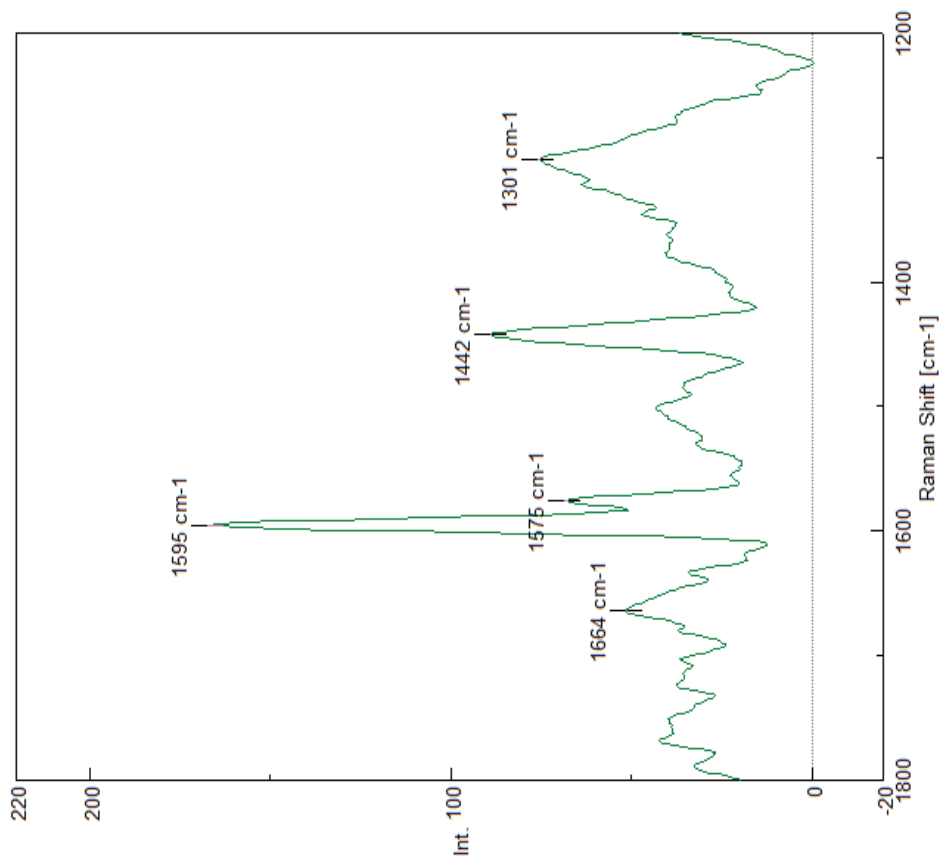
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27. JANSSEN
JAN GO3

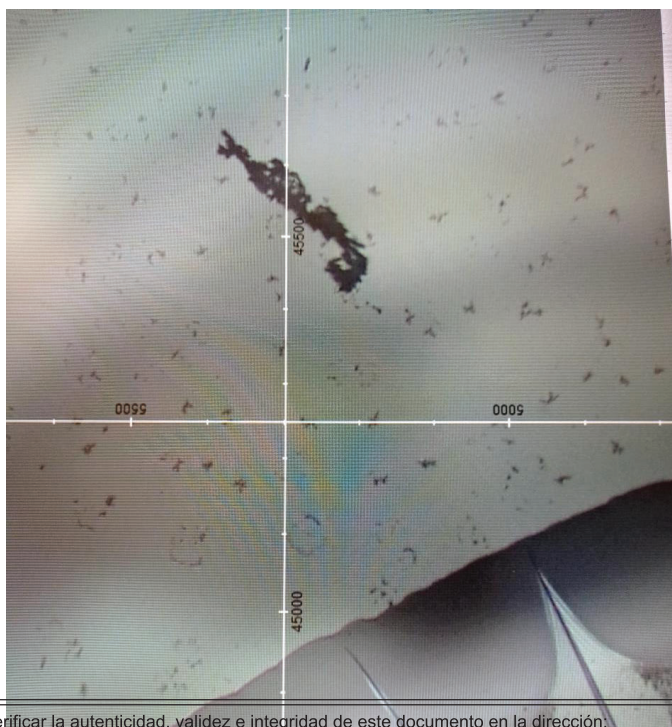


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28. JANSSEN
JAN GO4



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DETECCIÓN DE OXIDO DE GRAFENO
EN SUSPENSIÓN ACUOSA (COMIRNATY™ (RD1))

ESTUDIO OBSERVACIONAL EN MICROSCOPIA ÓPTICA Y ELECTRÓNICA

Informe provisional (I)
28 de Junio de 2021



Prof. Dr. Pablo Campra Madrid
Doctor en Ciencias Químicas y Licenciado en Ciencias Biológicas
ESCUELA SUPERIOR DE INGENIERIA
UNIVERSIDAD DE ALMERÍA, ESPAÑA

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AVISO IMPORTANTE

Seguidamente se presenta un estudio microscópico, observacional y meramente descriptivo de la muestra problema.

La identificación definitiva del material dominante en la muestra precisa de ulteriores fraccionamientos y análisis espectroscópicos específicos que permitan caracterizar la estructura del material.

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Antecedentes

- **D. Ricardo Delgado Martín** solicita PRESTACIÓN DE SERVICIOS de Investigación a la UAL denominada:

“DETECCIÓN DE GRAFENO EN MUESTRA DE SUSPENSIÓN ACUOSA”

- El 10/06/2021 se recibe por mensajería 1 vial, etiquetado con el texto siguiente:

- **“COMIRNATY™ .Sterile concentrate. COVID-19 mRNA. 6 doses after dilution. Discard date/time:PAA165994.LOT/EXP: EY3014 08/2021”**

- Procedencia y trazabilidad: se desconoce
- Estado de conservación: refrigerado
- Mantenimiento durante el estudio: refrigerado
- **Codificación de la muestra problema a analizar: RD1**

3

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Observaciones preliminares de la muestra problema RD1

Descripción:

- Vial sellado, con goma y tapa de aluminio intactas, de 2ml de capacidad, conteniendo una suspensión acuosa turbia de 0,45 ml.
- Se realiza extracción y cuantificación de RNA
- Se observa presencia de microbiología nanométrica no caracterizada, visible a 600X en microscopio óptico

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Procesamiento de la muestra

1. Dilución en suero fisiológico estéril al 0,9% (0,45 ml + 1,2 ml)
2. Fraccionamiento por polaridad: 1,2 ml hexano+120 ul de muestra RD1
3. Extracción de fase hidrofílica
4. Extracción y cuantificación de RNA en la muestra
5. Microscopía electrónica y ópticas de fase acuosa

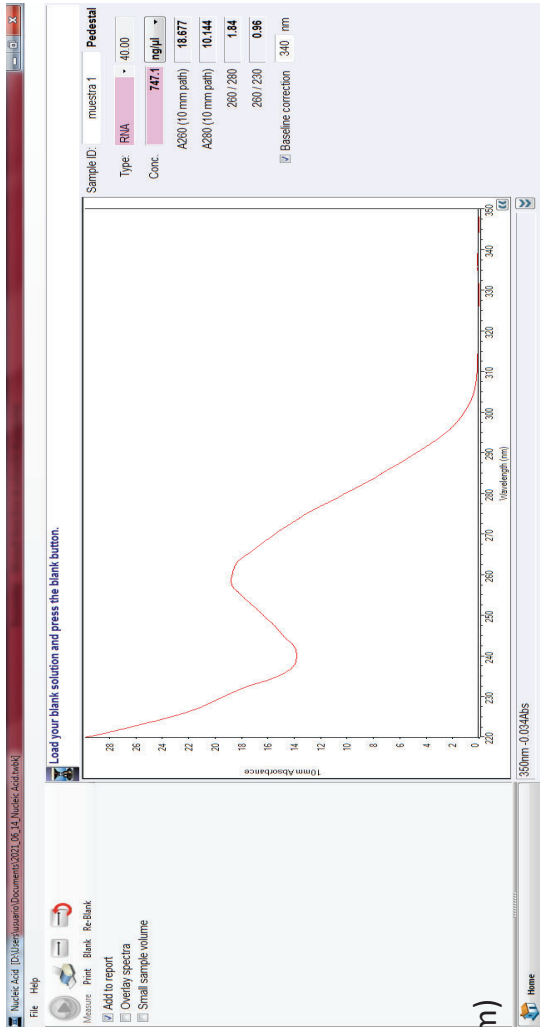
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Análisis preliminar: extracción y cuantificación de Rna en la muestra

- Extracción RNA: Kit <https://www.fishersci.es/shop/products/ambion-purelink-rna-mini-kit-7/10307963>
- Cuantificación de absorbancia UV total en espectrofotómetro NanoDrop™ <https://www.thermofisher.com/order/catalog/product/ND-2000#/ND-2000>
- Cuantificación específica de Rna por fluorescencia QUBIT2.0: <https://www.thermofisher.com/es/es/home/references/newsletters-and-journals/bioprobex-journal-of-cell-biology-applications/bioprobex-issues-2011/bioprobex-64-april-2011/the-qubit-2-0-fluorometer-april-2011.html>

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Espectro de absorción UV de la muestra RD1 (Equipo Nano-drop)



Máximo de absorción de la MUESTRA RD1 (260-270 nm)

RNA. Presenta máximos habituales a 260 nm. Concentración total estimada por fluorometría QUBIT2.0 : **6 ng/ul**
El espectro revela presencia de elevada cantidad de sustancias o sustancia diferentes al Rna con máximo de absorción en la misma región, con un total estimado en **747 ng/ul** (estimación no calibrada)
El óxido de grafeno reducido (RGO) presenta máximos de absorción a 270 nm, **compatibles** con el espectro obtenido (*Thema et al, 2013. Journal of Chemistry ID 150536*)
El **máximo de absorción obtenido NO PERMITE DESCARTAR la presencia de grafeno en la muestra. La cantidad mínima de RNA detectado por QUBIT2.0 sólo explica un porcentaje residual de la absorción total UV de la muestra.**

OBJETIVO: Identificación microscópica de derivados de grafeno

METODOLOGIA:

- 1. Toma de imágenes en microscopia óptica y electrónica
- 2. Comparativa con imágenes de literatura y patrón de óxido de grafeno reducido

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MICROSCOPIA ELECTRONICA DE TRANSMISIÓN
(TEM)

Microscopio electrónico JEM-2100Plus

Tensión: 200 kV

Resolución 0,14 nm
Aumento hasta x1.200.000

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MICROSCOPIA ELECTRONICA DE TRANSMISIÓN (TEM)

La microscopía electrónica (TEM) se utiliza habitualmente para obtener imágenes de nanomateriales de grafeno. Se ha convertido en un instrumento bastante estándar y fácil de usar que es capaz de obtener imágenes de láminas de grafeno en capas individuales.

10

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DESCRIPCIÓN DE LA IMAGEN anterior

(de: Choucair et al, 2009. Gram-scale production of graphene based on solvothermal synthesis and sonication. Nature Nanotechnology 4(1):30-3

- Figura 2: “Imágenes TEM de las **láminas de grafeno aglomeradas**. La misma región de muestra se ve con diferentes aumentos y muestra claramente el grado de formación de la lámina y **la tendencia de las láminas a fusionarse en regiones superpuestas**. Es evidente una estructura inherente en forma de lámina que muestra **una intrincada matriz de pliegues de largo alcance**. Como las imágenes se toman en modo de transmisión, la opacidad relativa de las láminas individuales es el resultado de regiones interfaciales con superposición entre láminas individuales. Las láminas se extienden en dimensiones laterales sobre escalas de longitud micrométrica, que van desde 100 nm hasta más de 1.000 nm.”

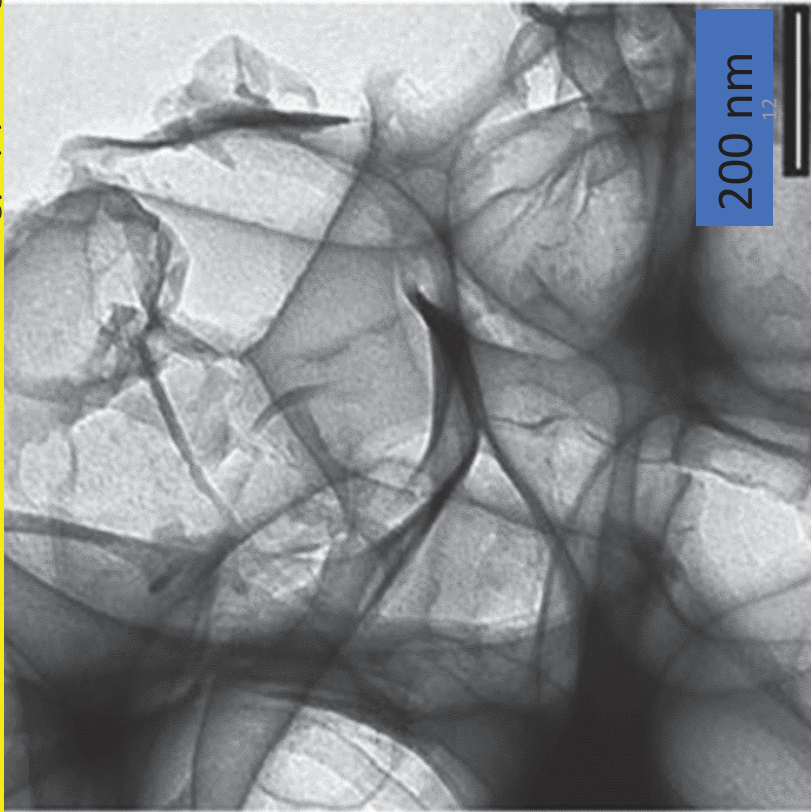
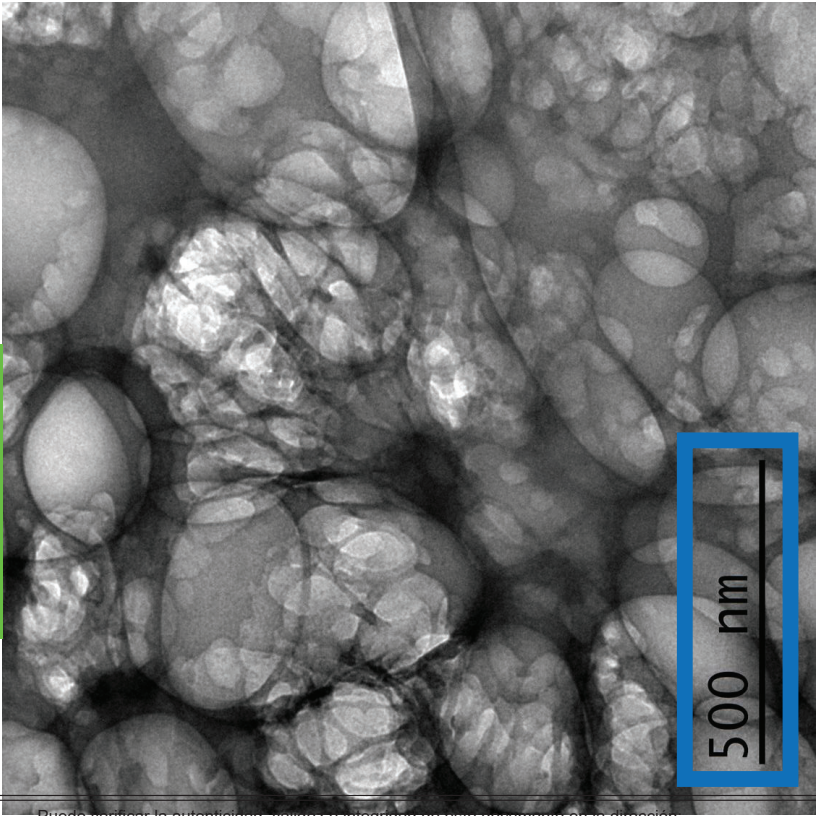
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RESULTADOS: Comparativa de muestra problema (RD1) con una imagen TEM de literatura

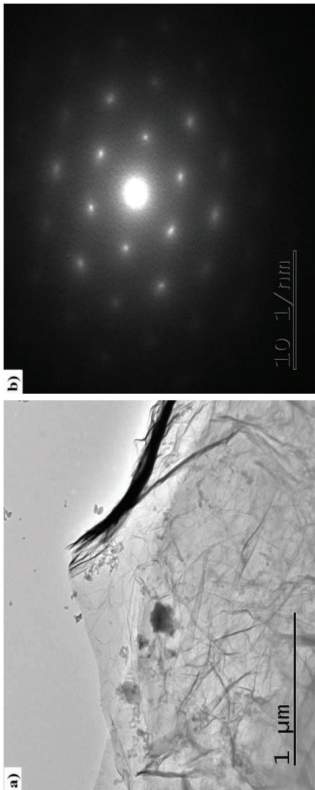
MUESTRA RD1

Choucair et al 2009. Nature Nanotechnology 4(1):30-3 Fig 2



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• **NOTA importante:** Para una IDENTIFICACIÓN definitiva del GRAFENO por TEM, es necesario complementar la observación con la caracterización estructural mediante obtención por EDS de un PATRÓN DE DIFRACCIÓN DE ELECTRONES característico (como la figura b mostrada abajo). El patrón correspondiente al grafito o el grafeno presenta una simetría hexagonal, y generalmente cuenta con varios hexágonos concéntricos. **No ha sido posible por el momento obtener este patrón por la escasez de muestra disponible para su procesamiento, y la disposición caótica y la densidad de los pliegues.**



Matéria (Rio J.) 23 (1) • 2018 • Characterization of graphene nanosheets obtained by a modified Hummer's method. Renata Hack et al.

14

Microscopio Óptico

Microscopio Biológico

CX43

Objetivos PLAN Fluor de 10x, 20x (DIC) y 40x (DIC)
Ocular: 10x

- Condensador ajustado en posición intermedia con efecto 3D (entre campo Claro (BF) y campo oscuro (DF))

15

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PATRON DE OXIDO DE GRAFENO REDUCIDO

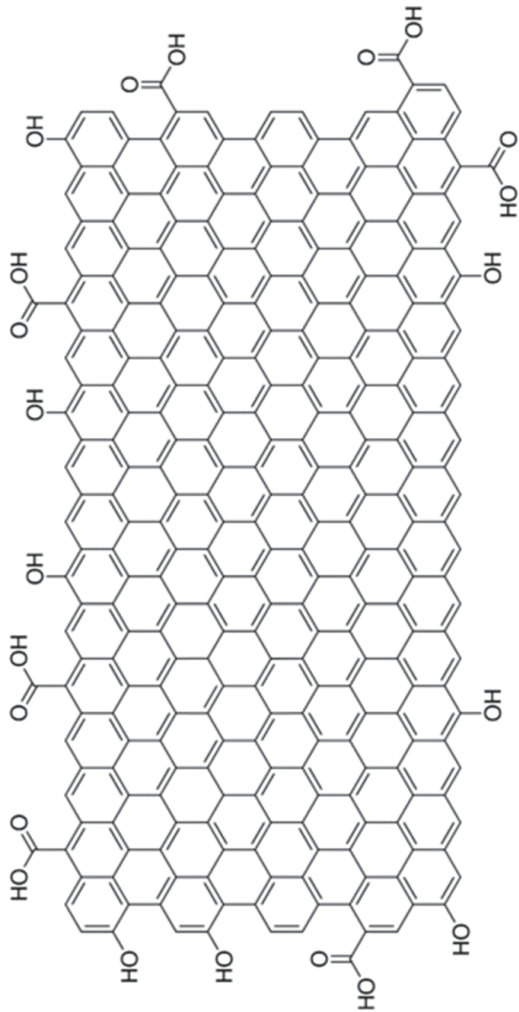


Imagen de literatura TEM de bajo aumento

“La figura muestra una imagen TEM de grafeno bicapa con bordes que tienden a enrollarse y doblarse ligeramente”

Qian, W., Hao, R., Hou, Y. et al. Solvothermal-assisted exfoliation process to produce graphene with high yield and high quality. Nano Res. 2, 706–712 (2009).

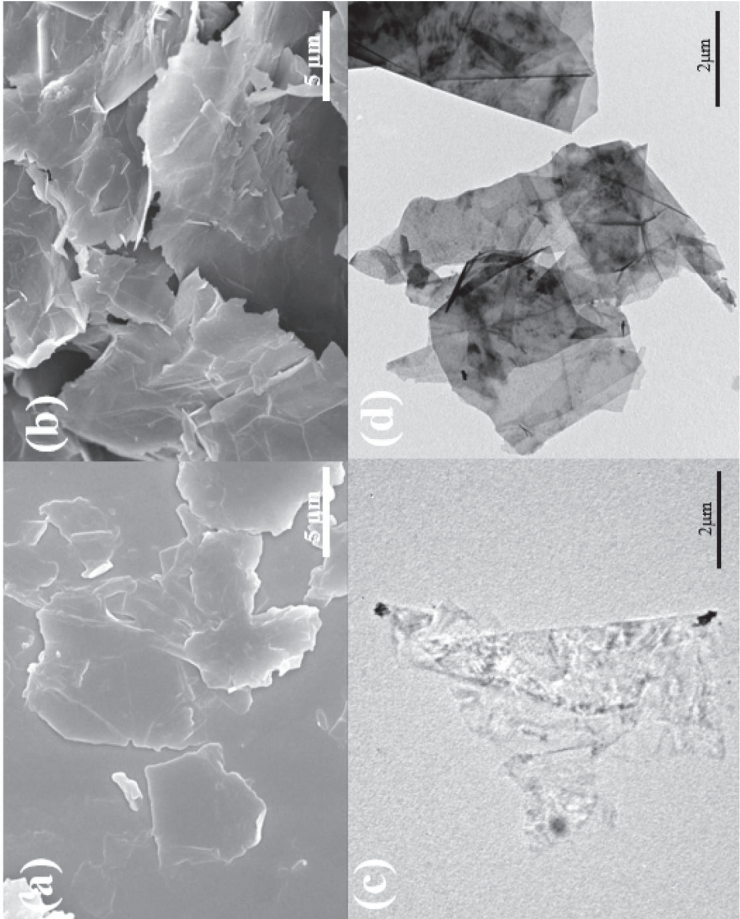


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IMAGENES DE LITERATURA. MICROSCOPIA ELECTRONICA A BAJO AUMENTO
MICROSCOPIA ELECTRONICA DE BARRIDO (SEM) (a) y (b) y TRANSMISION (TEM) (c) y (d)

Effects of Graphene Nanosheets with Different Lateral Sizes as Conductive Additives on the Electrochemical Performance of LiNi0.5Co0.2Mn0.3O2 Cathode Materials for Li Ion Batteries. Figure 2. SEM images of different graphene sheet sizes: (a) GN-13 and (b) GN-28, and transmission electron microscopy (TEM) images of different graphene sheet sizes: (c) GN-13 and (d) GN-28.

Husu et al. Polymers 2020, 12(5), 1162



Robust Magnetized Graphene Oxide Platform for In Situ Peptide Synthesis and FRET-Based Protease Detection

Kim et al, *Sensors* 2020, 20(18), 5275

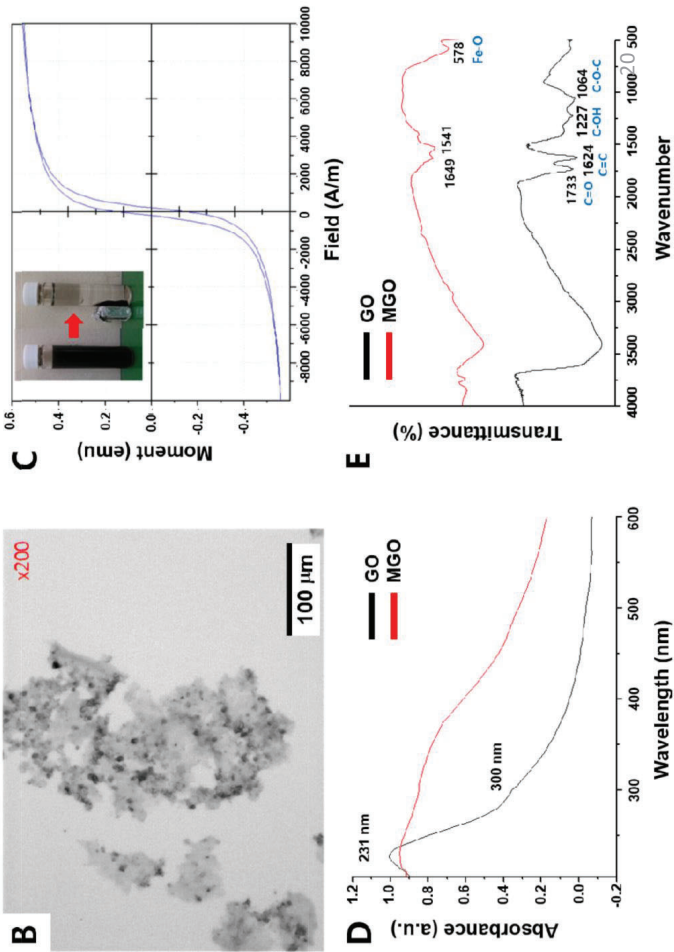


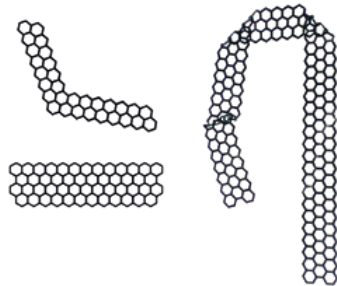
Figure 1. Preparation and characterization of graphene oxide (GO) and magnetic graphene oxide (MGO). (A) Schematic of MGO synthesis procedure. (B) Optical microscopy image of MGO. (C) Magnetic hysteresis loop of MGO. (D) UV/Vis absorption spectra of GO and MGO. (E) FT-IR spectra of GO and MGO.

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Comparativa de muestra RD1 al microscopio óptico con imágenes del patrón de OXIDO DE GRAFENO REDUCIDO (rGO)

Las imágenes ópticas de las láminas presentes en la muestra RD1 revelan gran similitud con las láminas exfoliadas a partir de sonicación del patrón rGO. Ambas muestras presentan láminas translúcidas interiormente rugosas, con perfiles irregulares, plegadas sobre sí mismas y con tendencia a enrollarse en los bordes. Las formas y dimensiones de las láminas son muy variables, presentando en ambas muestras láminas en cintas o bandas plegadas sobre sí mismas (*ribbons*).

En el ANEXO adjunto se muestran imágenes alternas de MUESTRA PATRON DE rGO y MUESTRA PROBLEMA RD1



<https://cen.acs.org/articles/86/i4/Graphene-Ribbons.html>

CONCLUSIONES Y RECOMENDACIONES

1. El estudio microscópico de la muestra aporta **sólidas evidencias de presencia probable de derivados de grafeno, si bien la microscopía no proporciona una prueba concluyente.** La identificación definitiva de grafeno, grafeno oxidado (GO) o grafeno, oxidado reducido (rGO) en la muestra RD1 precisa de la **CARACTERIZACIÓN ESTRUCTURAL** mediante el análisis de patrones espectrales específicos comparables a los publicados en literatura y a los obtenidos a partir de muestra patrón, obtenidos con técnicas espectroscópicas como XPS, EDS, RMN, FTIR o Raman, entre otras.
2. Los análisis de este informe corresponden a **UNA SOLA MUESTRA, limitada en volumen total disponible para procesar.** Es por tanto necesario realizar un muestreo significativo de viales similares para extraer conclusiones generalizables a muestras comparables, registrando origen, trazabilidad y control de calidad durante la conservación y transporte previas a los análisis.

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Exención de responsabilidad



Los resultados y conclusiones de este informe no implican posición institucional alguna de la Universidad de Almería

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VER ANEXO FOTOGRAFIAS DE LA MUESTRA

24

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DETECCIÓN DE OXIDO DE GRAFENO
EN SUSPENSIÓN ACUOSA (COMIRNATY™ (RD1))

ESTUDIO OBSERVACIONAL EN MICROSCOPIA ÓPTICA Y ELECTRÓNICA

Informe provisional (I)

ANEXO FOTOGRAFIAS

28 de Junio de 2021



Prof. Dr. Pablo Campra Madrid

Doctor en Ciencias Químicas y Licenciado en Ciencias Biológicas

ESCUELA SUPERIOR DE INGENIERIA

UNIVERSIDAD DE ALMERÍA, ESPAÑA

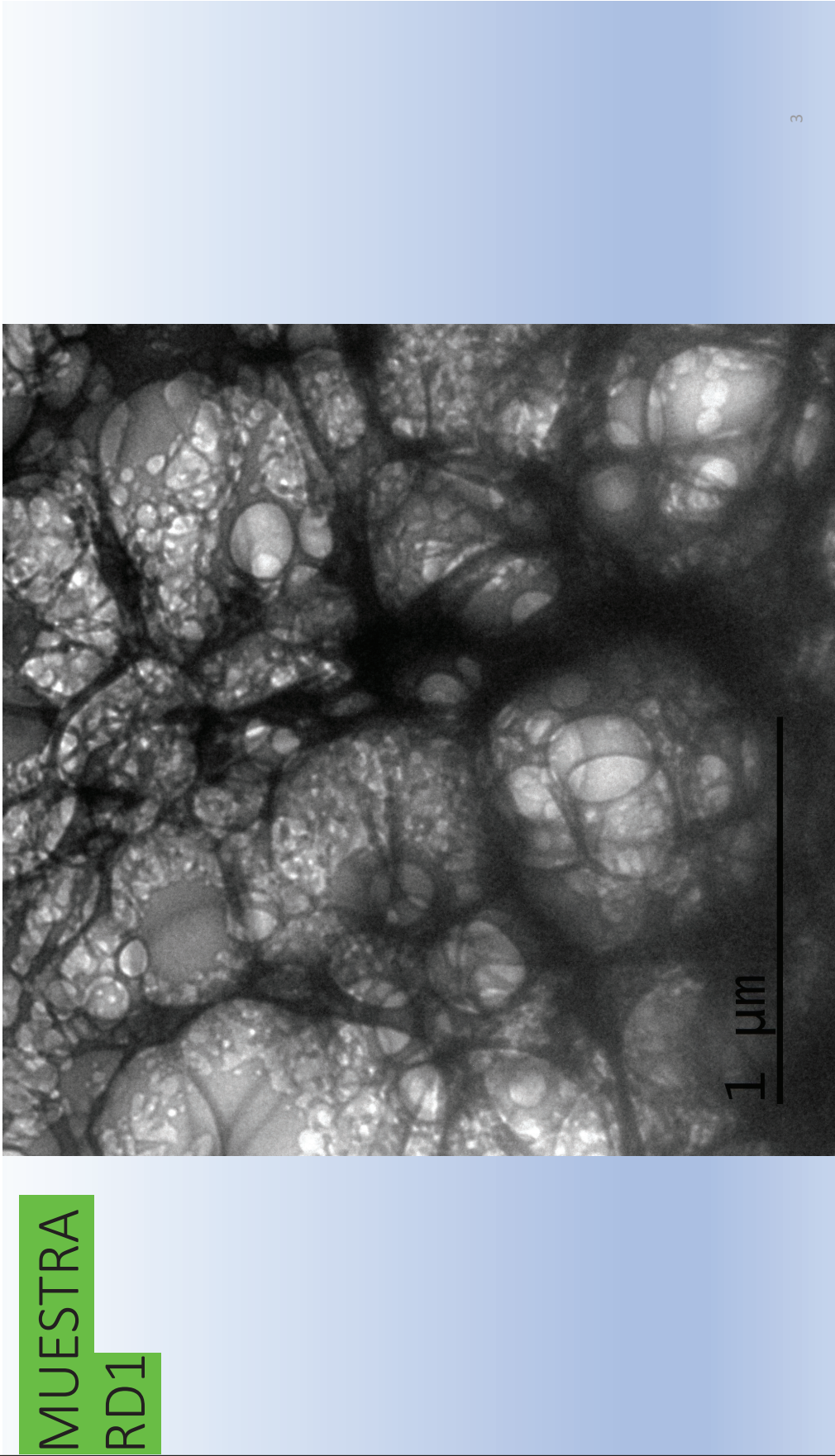
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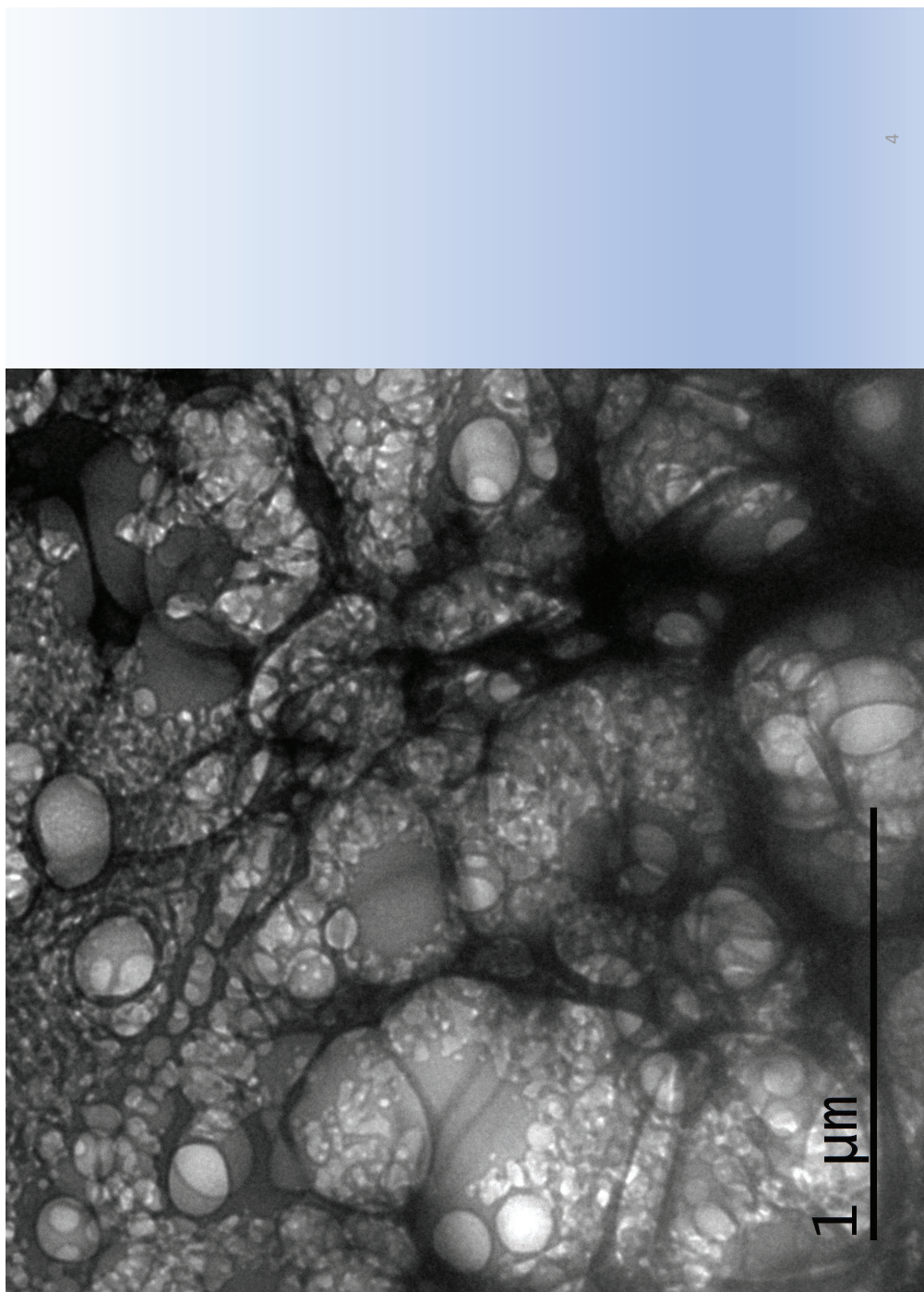
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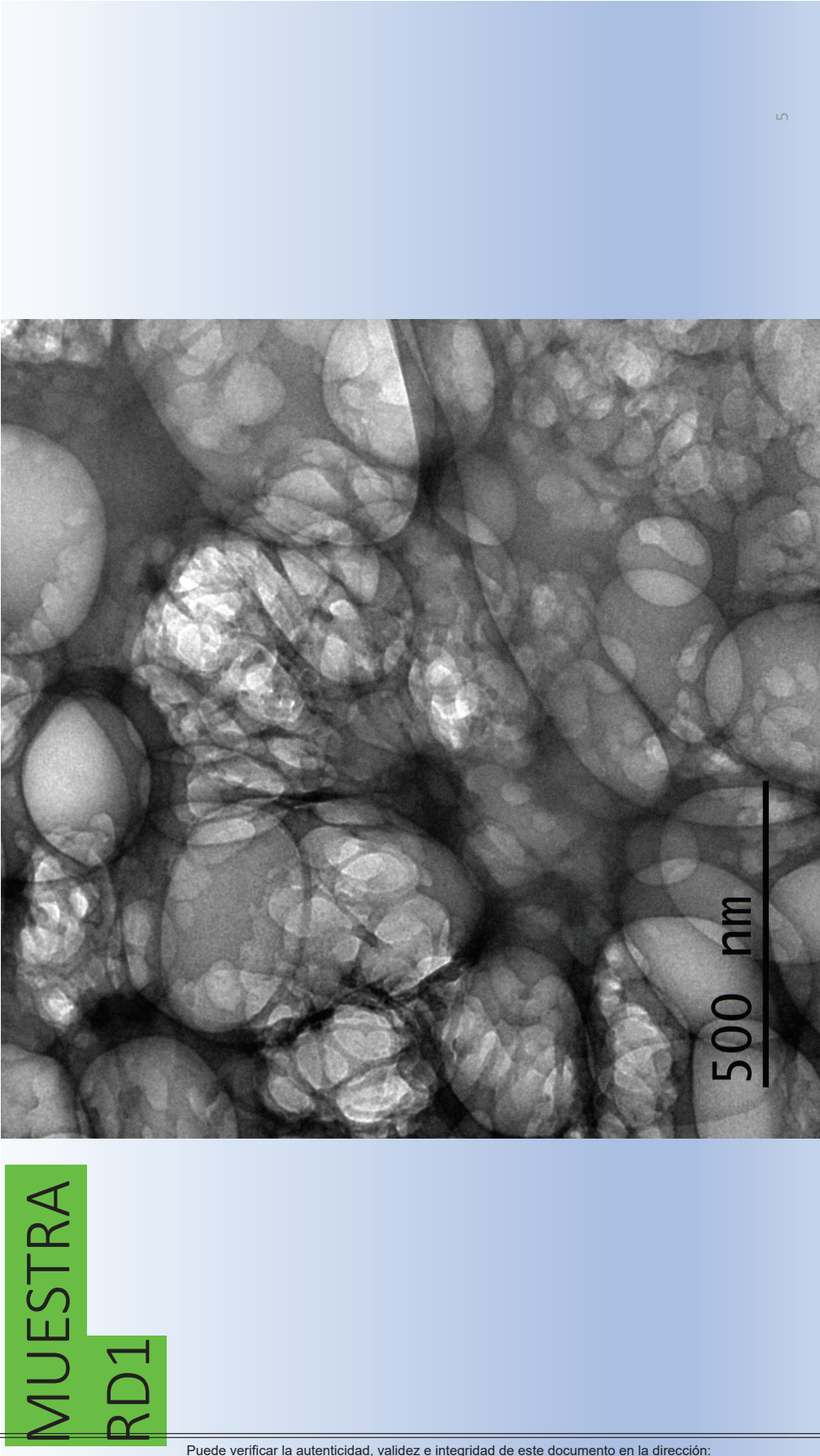
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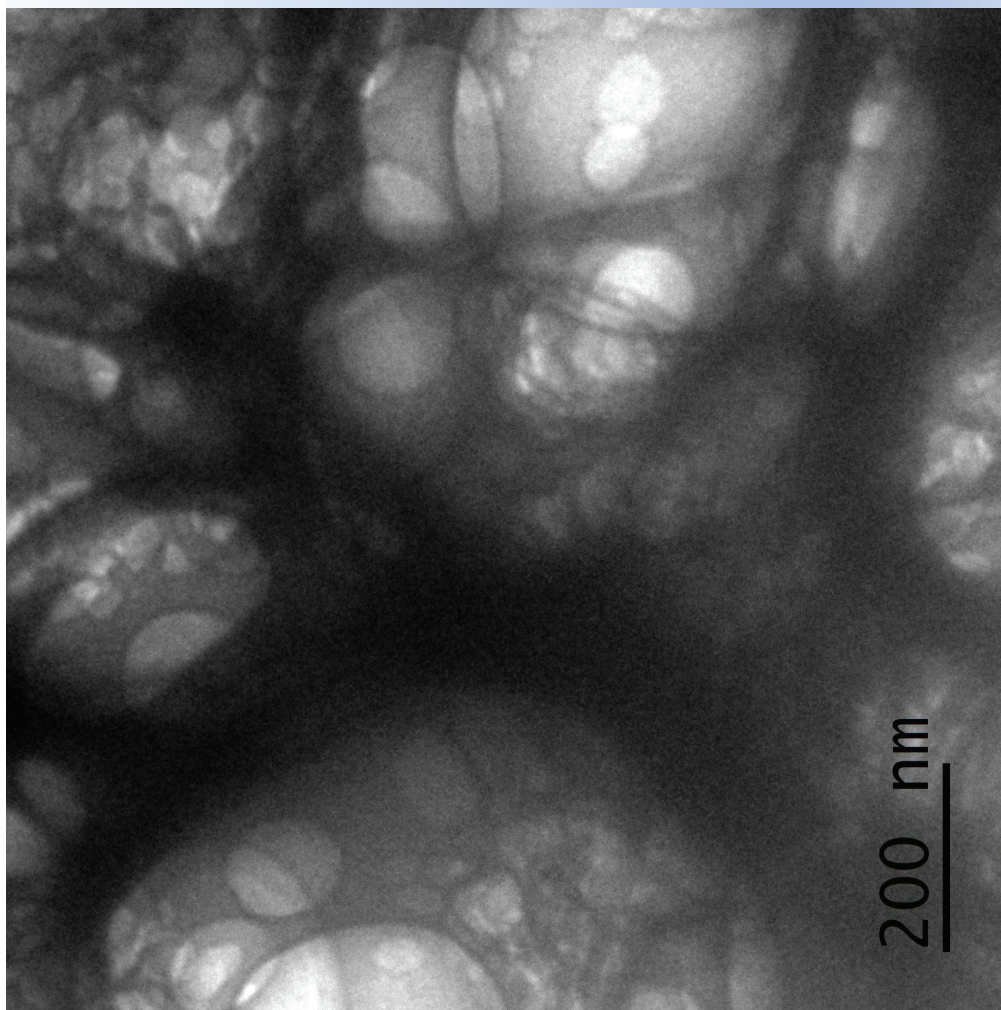
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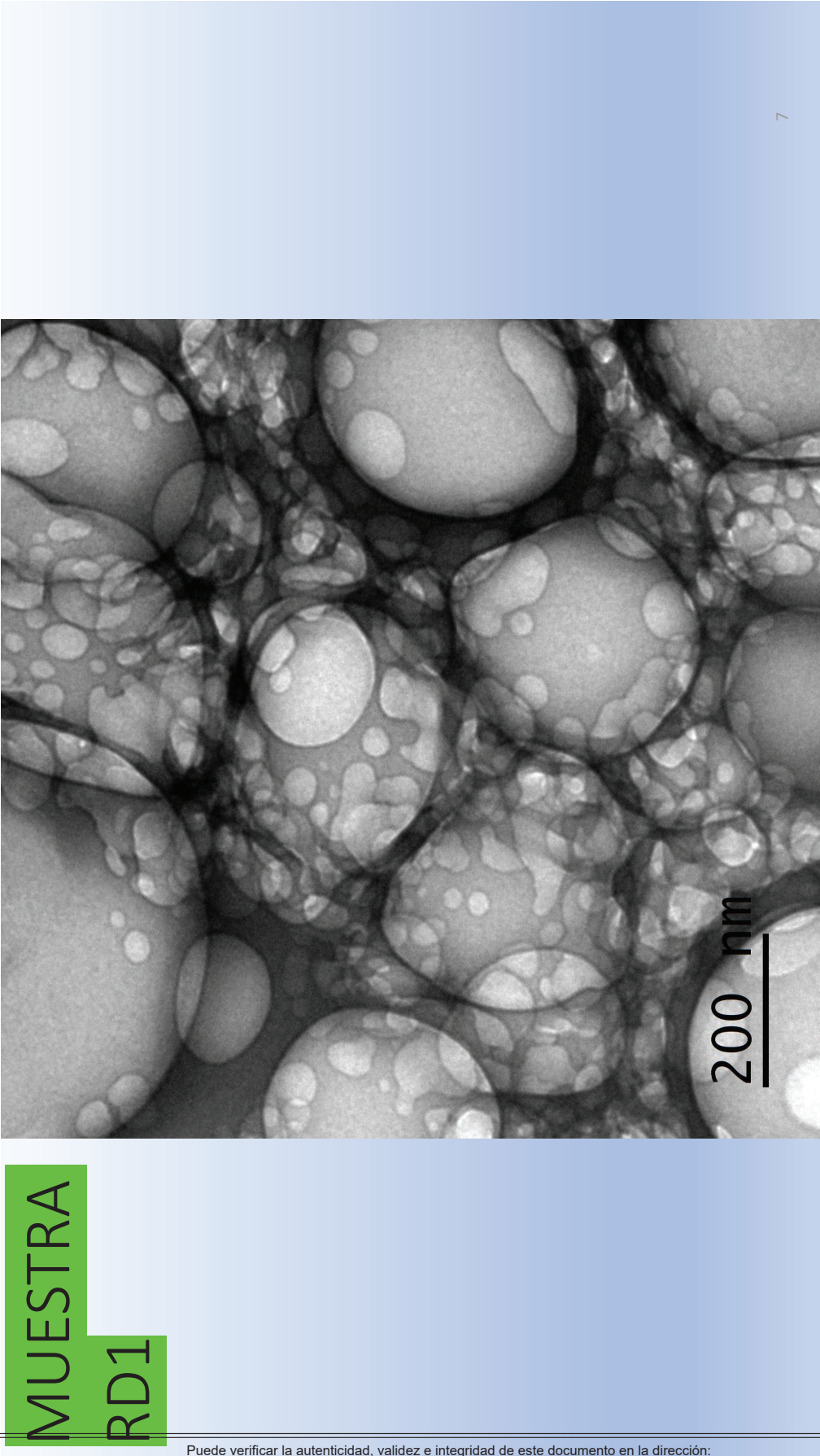
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MICROSCOPIA OPTICA

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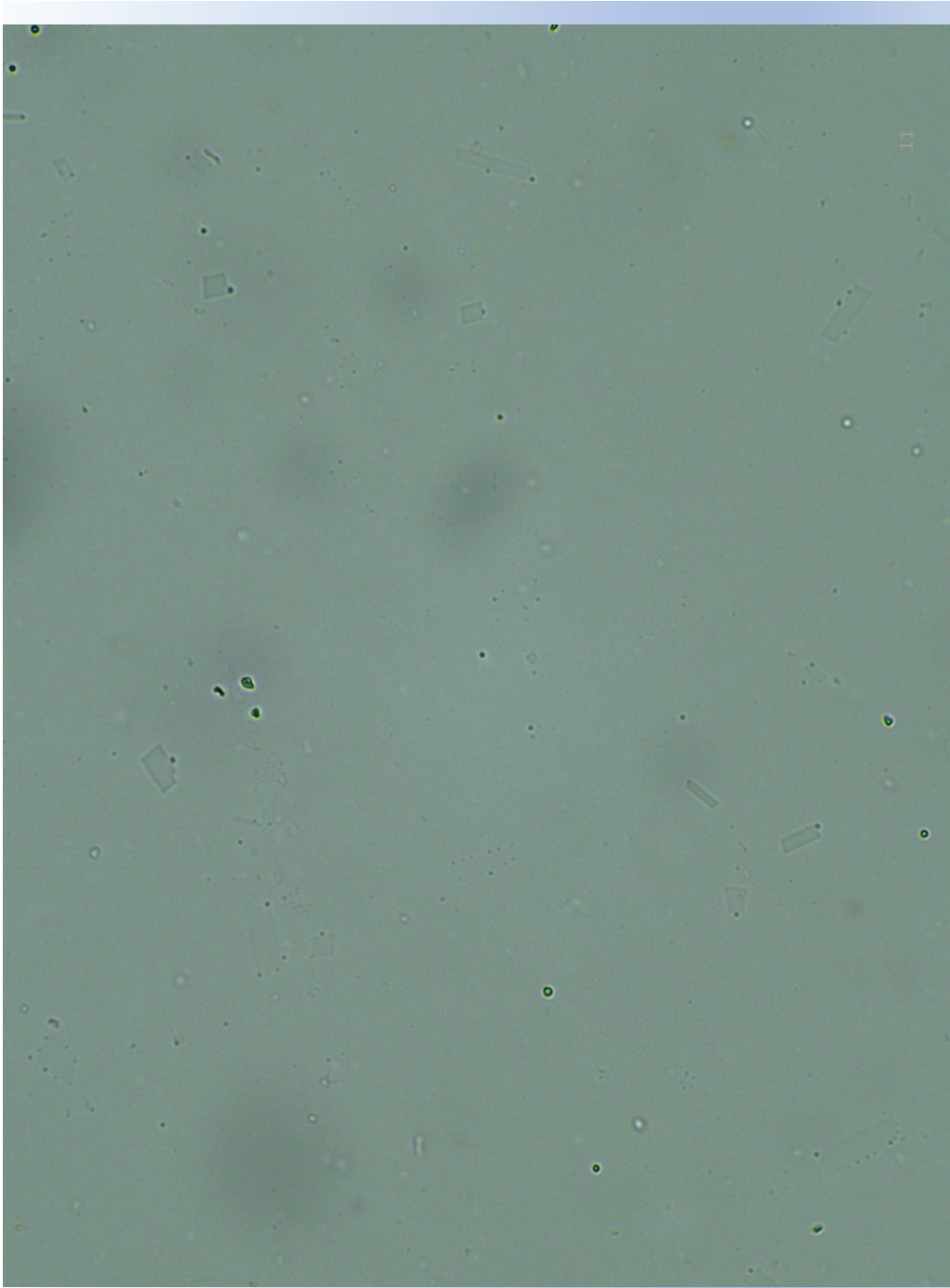
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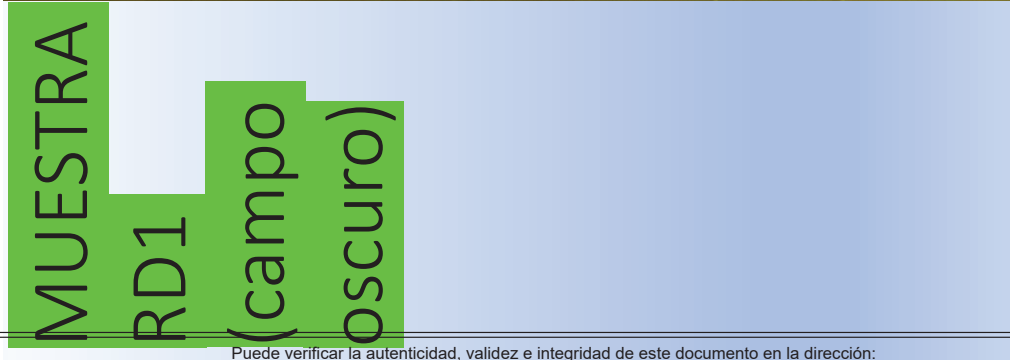
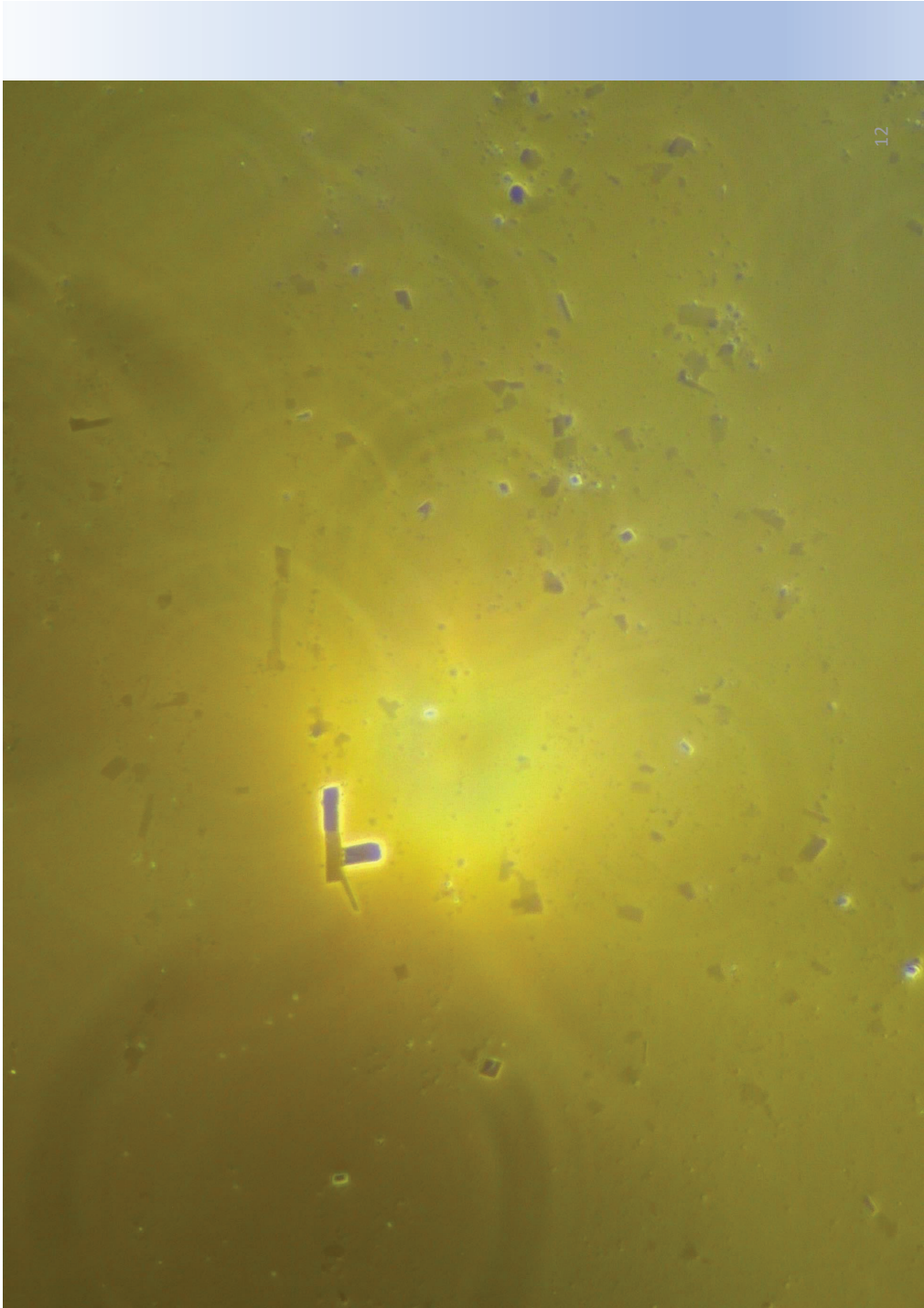


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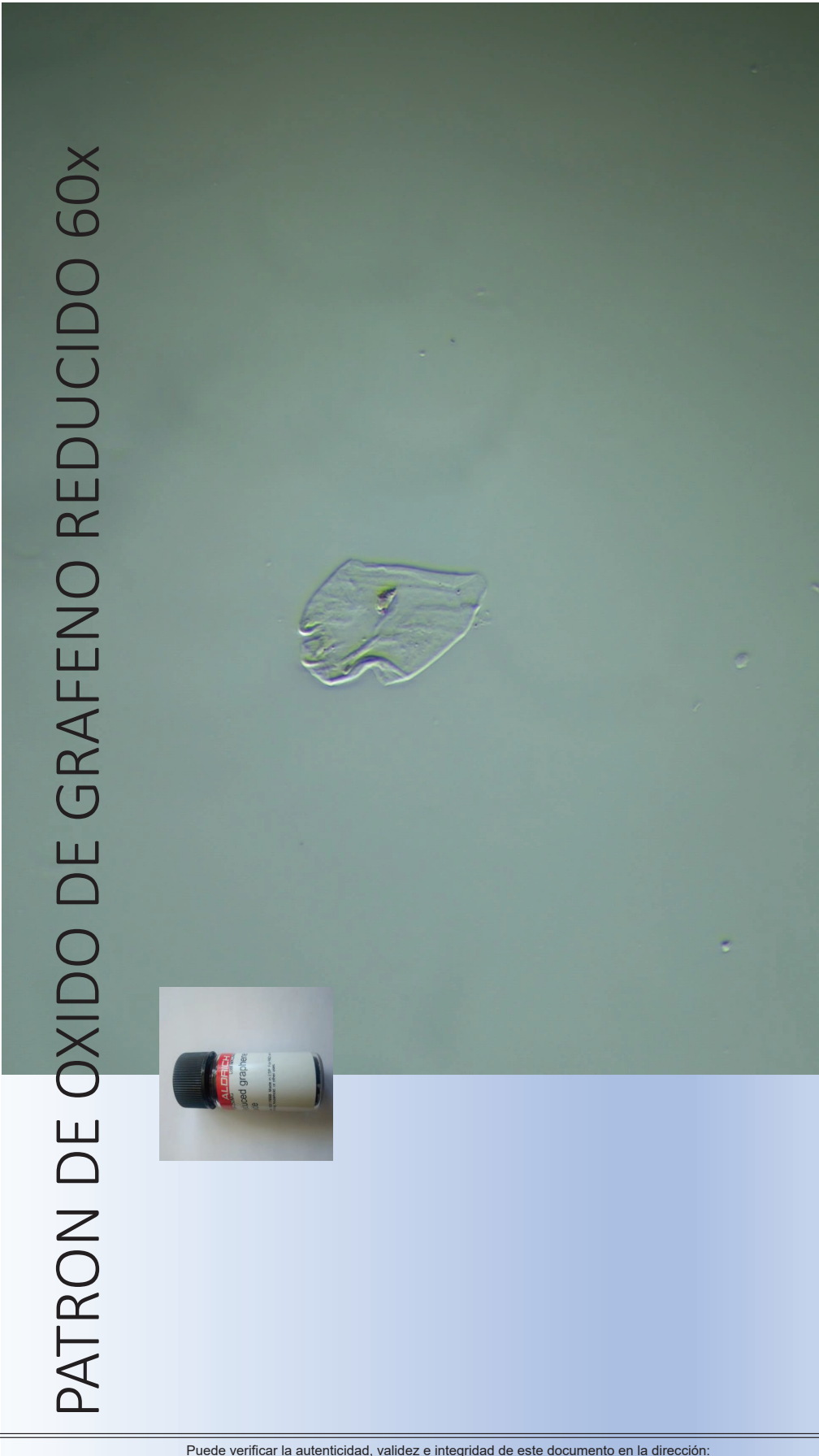


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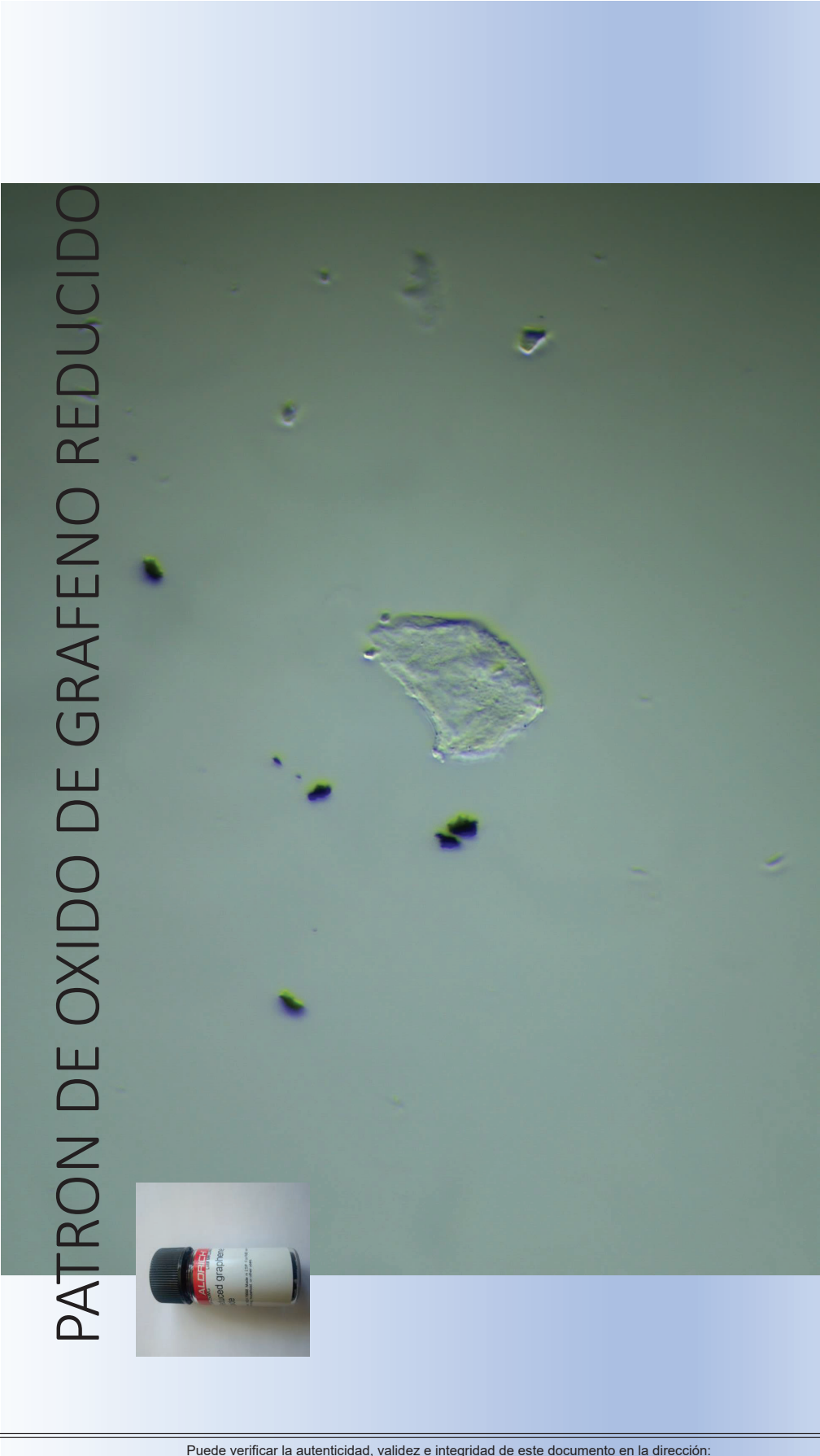


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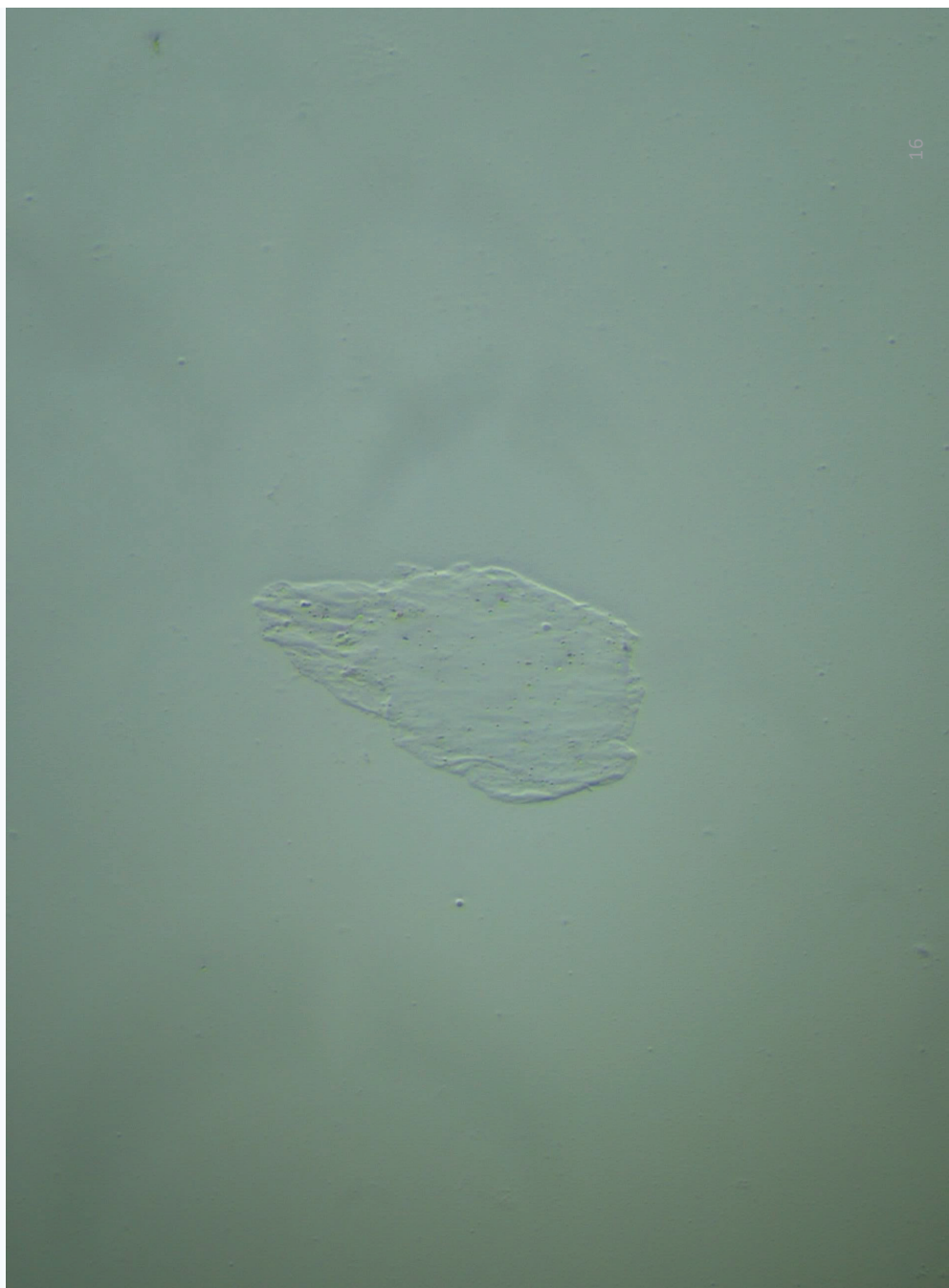
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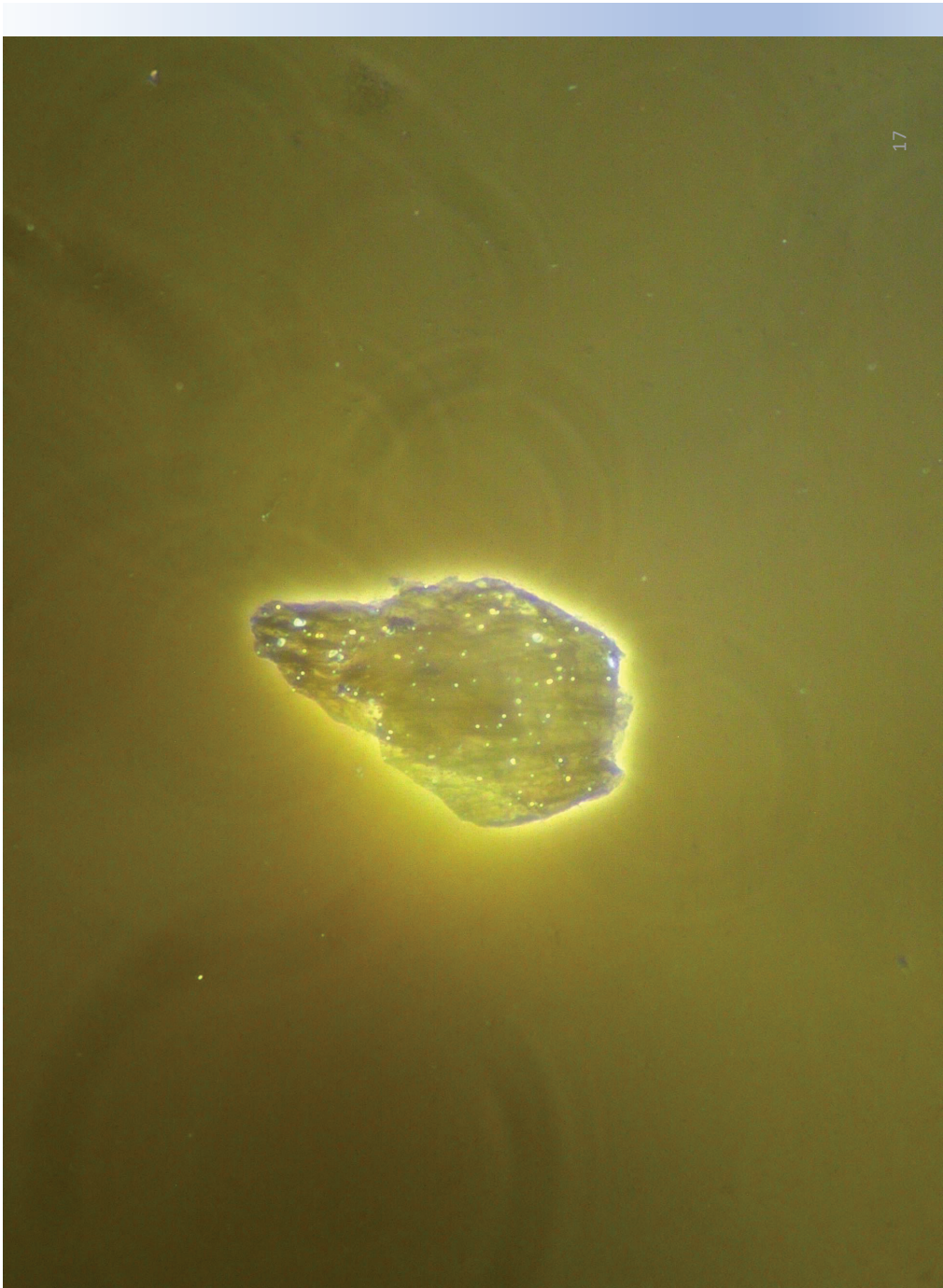
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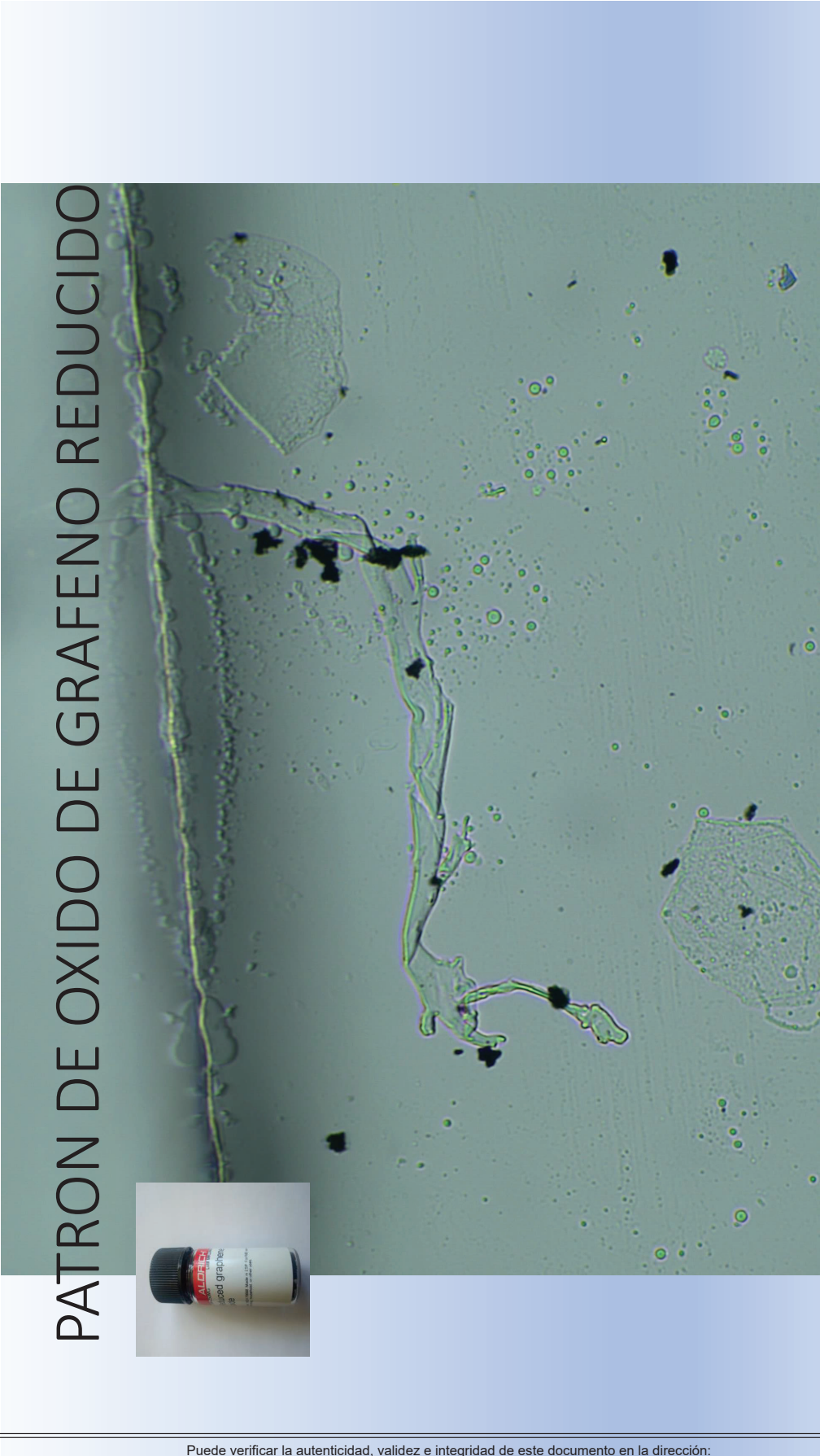
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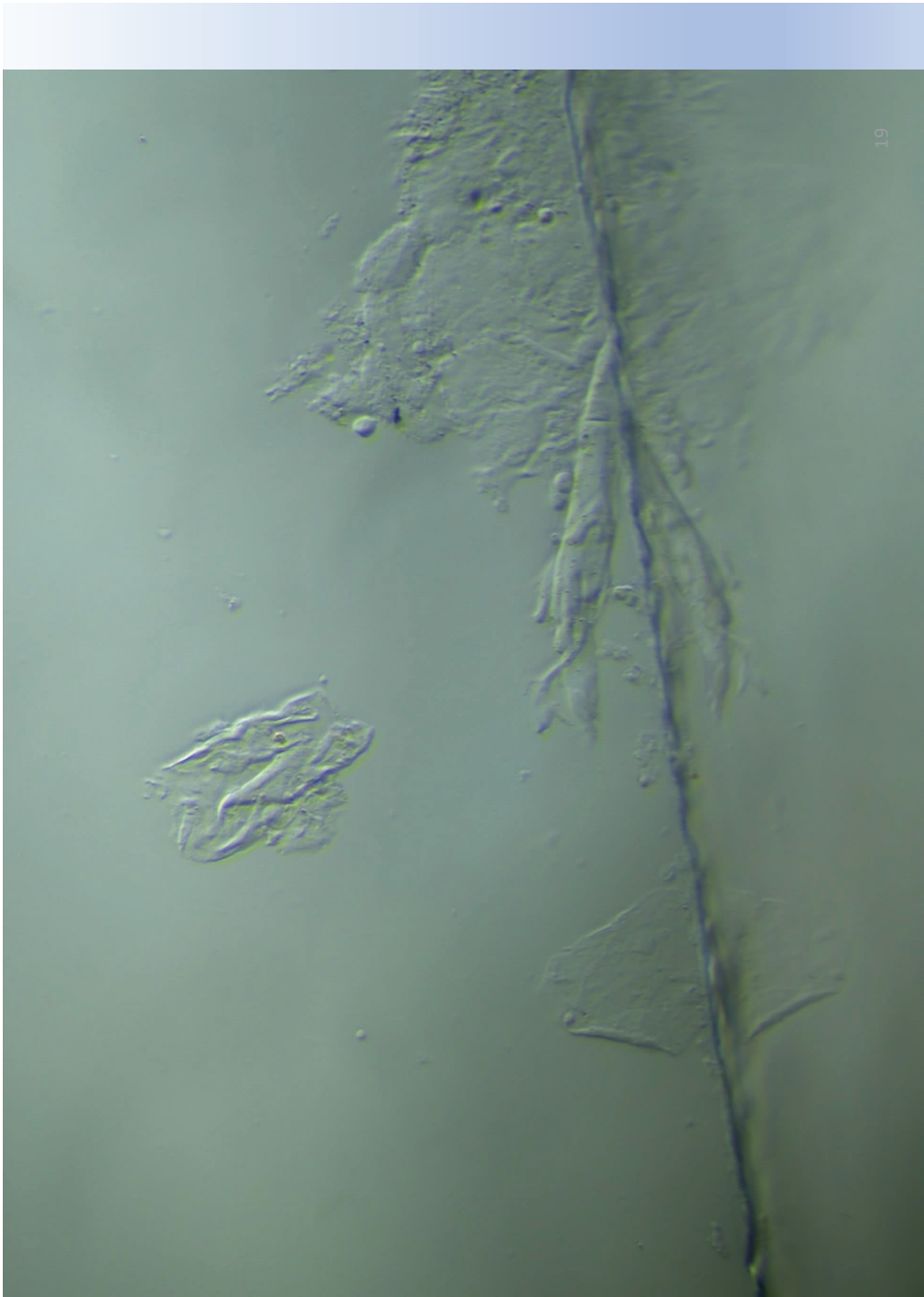


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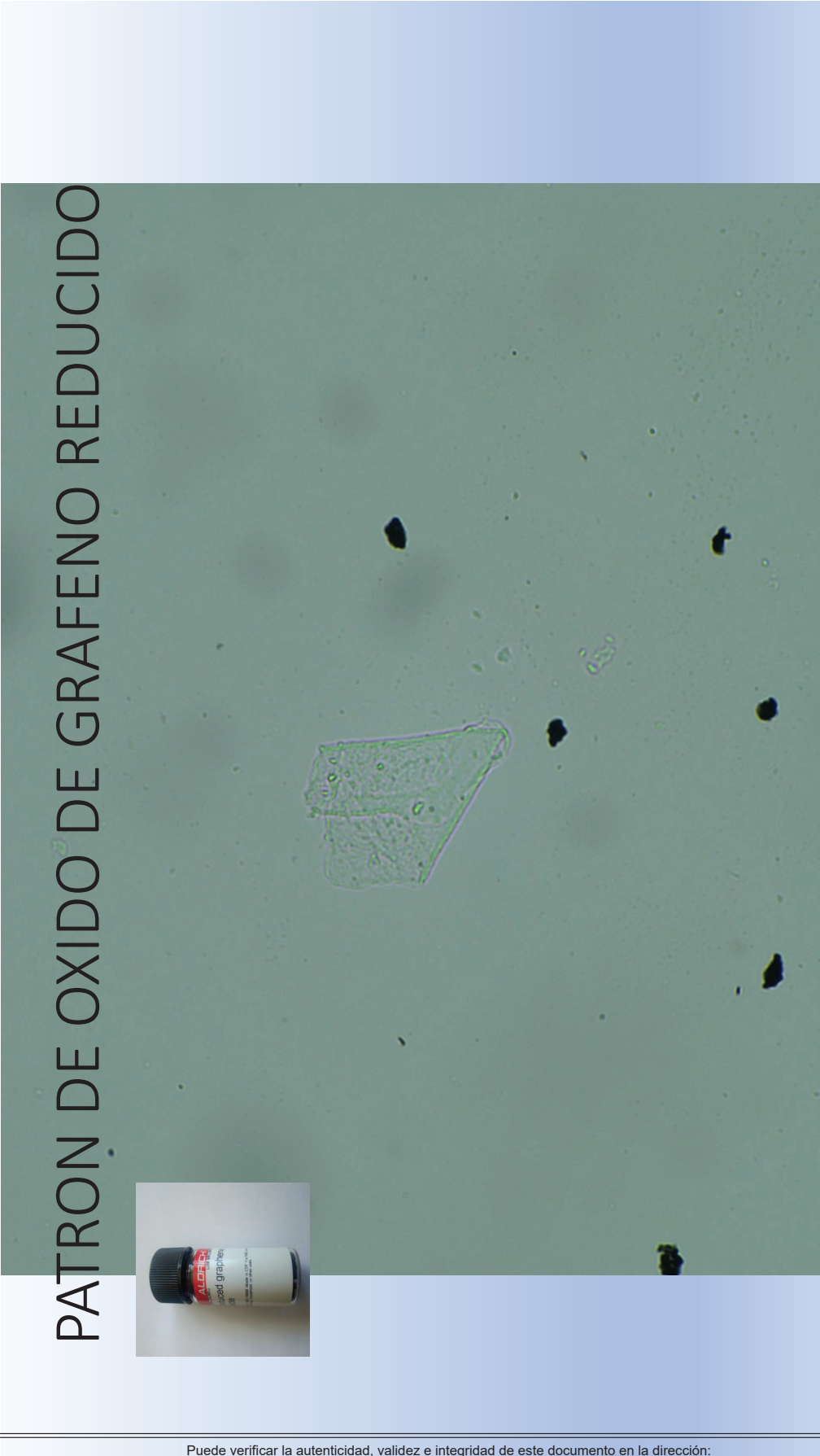
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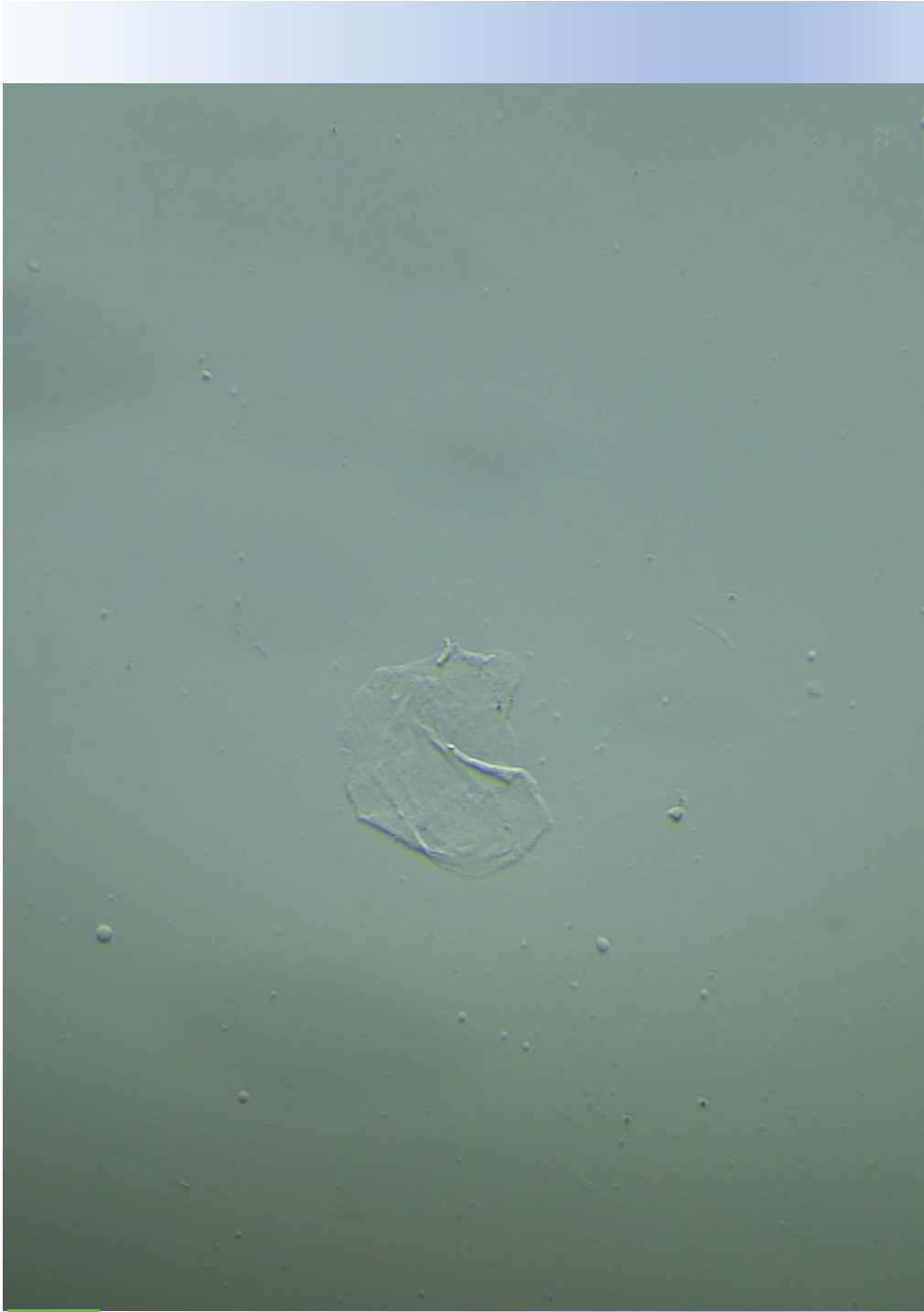


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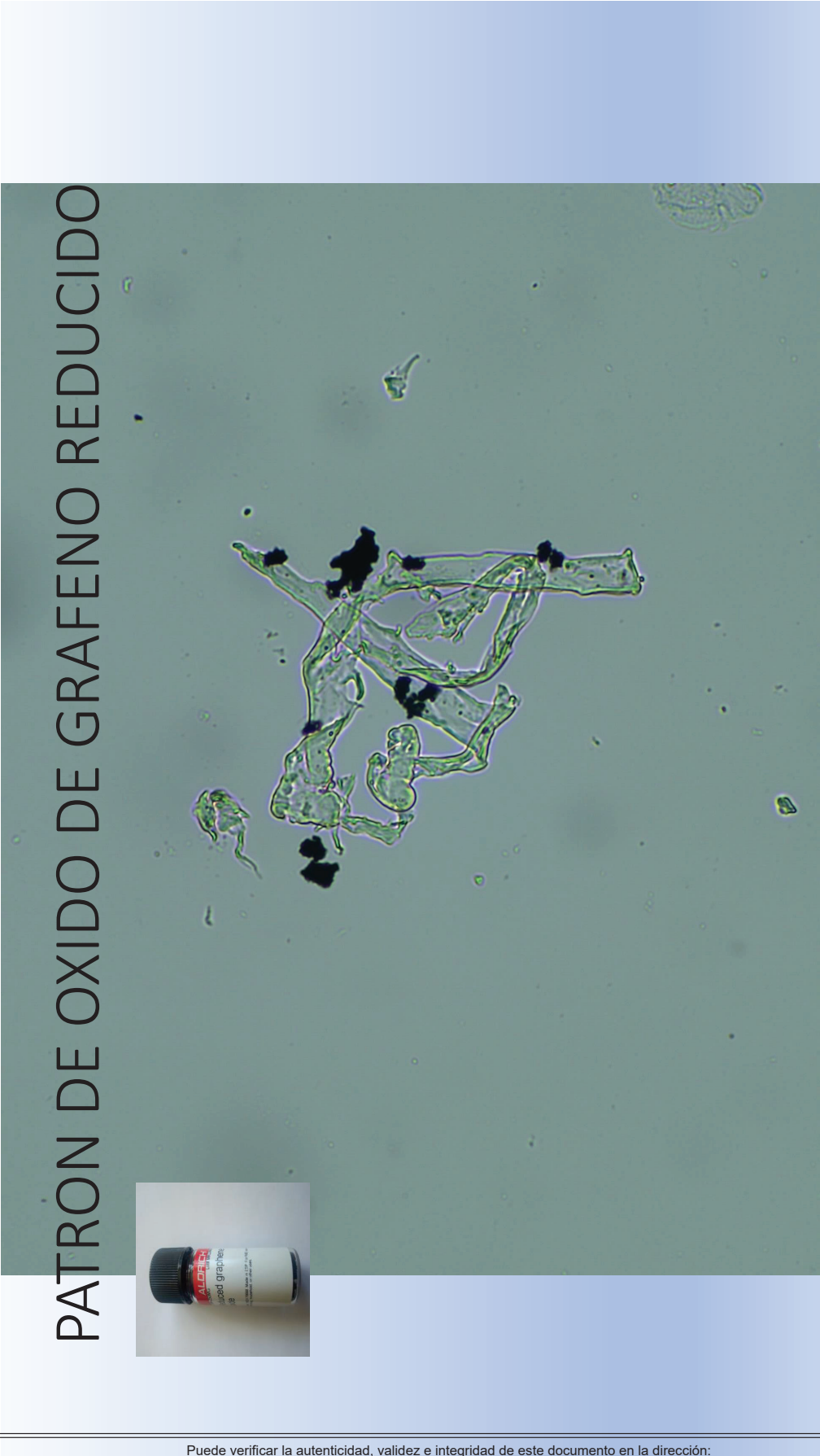


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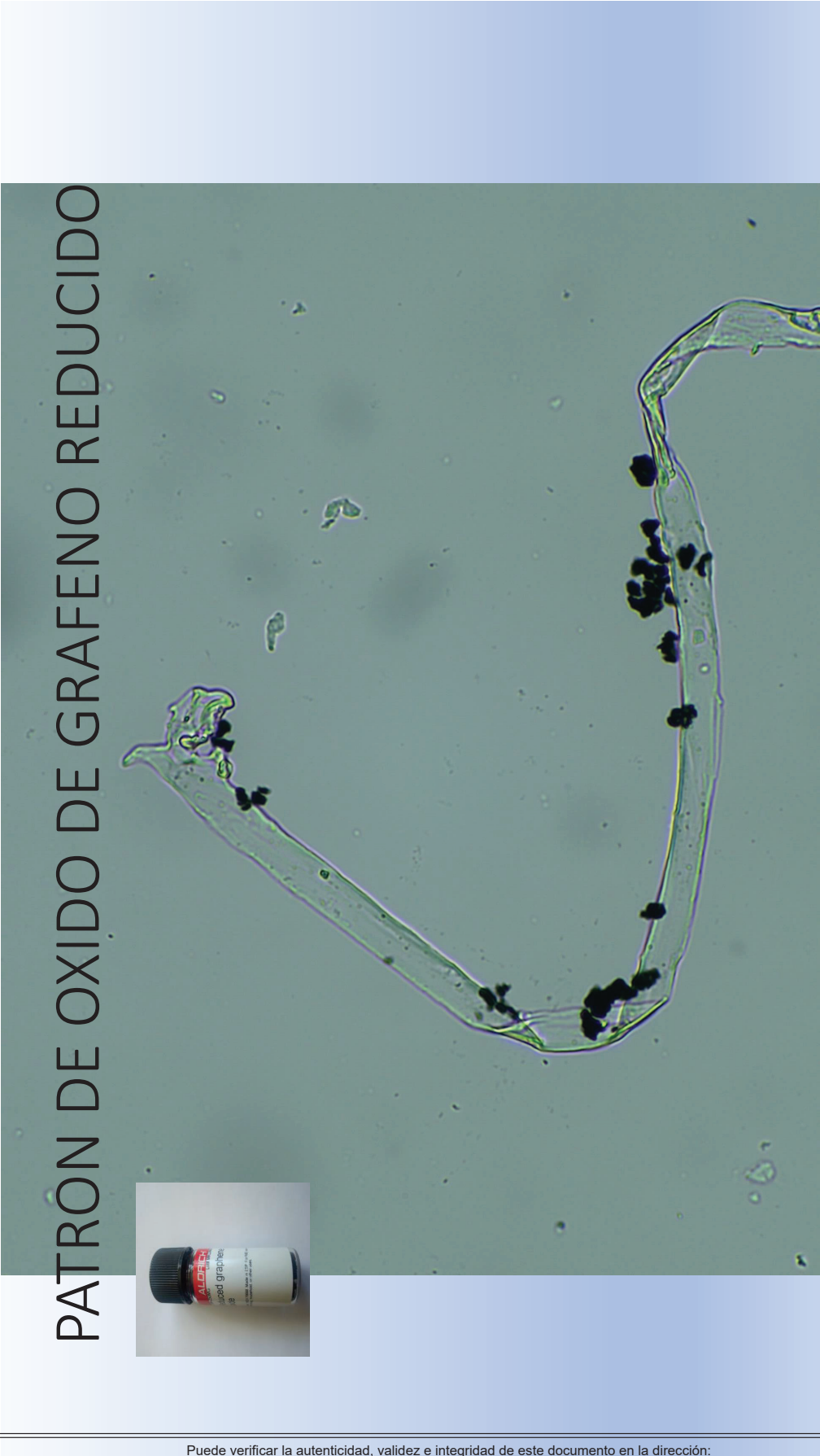


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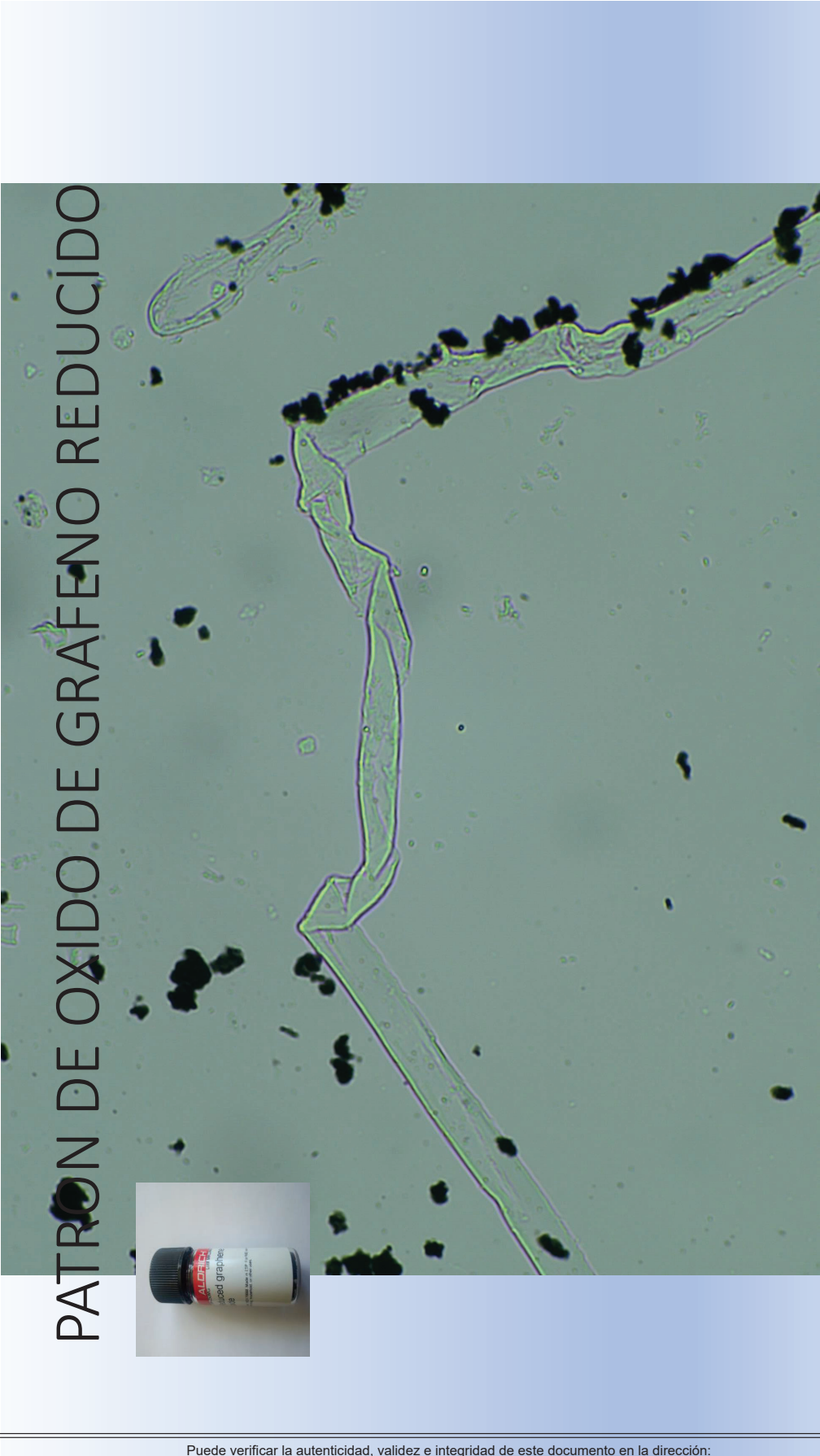
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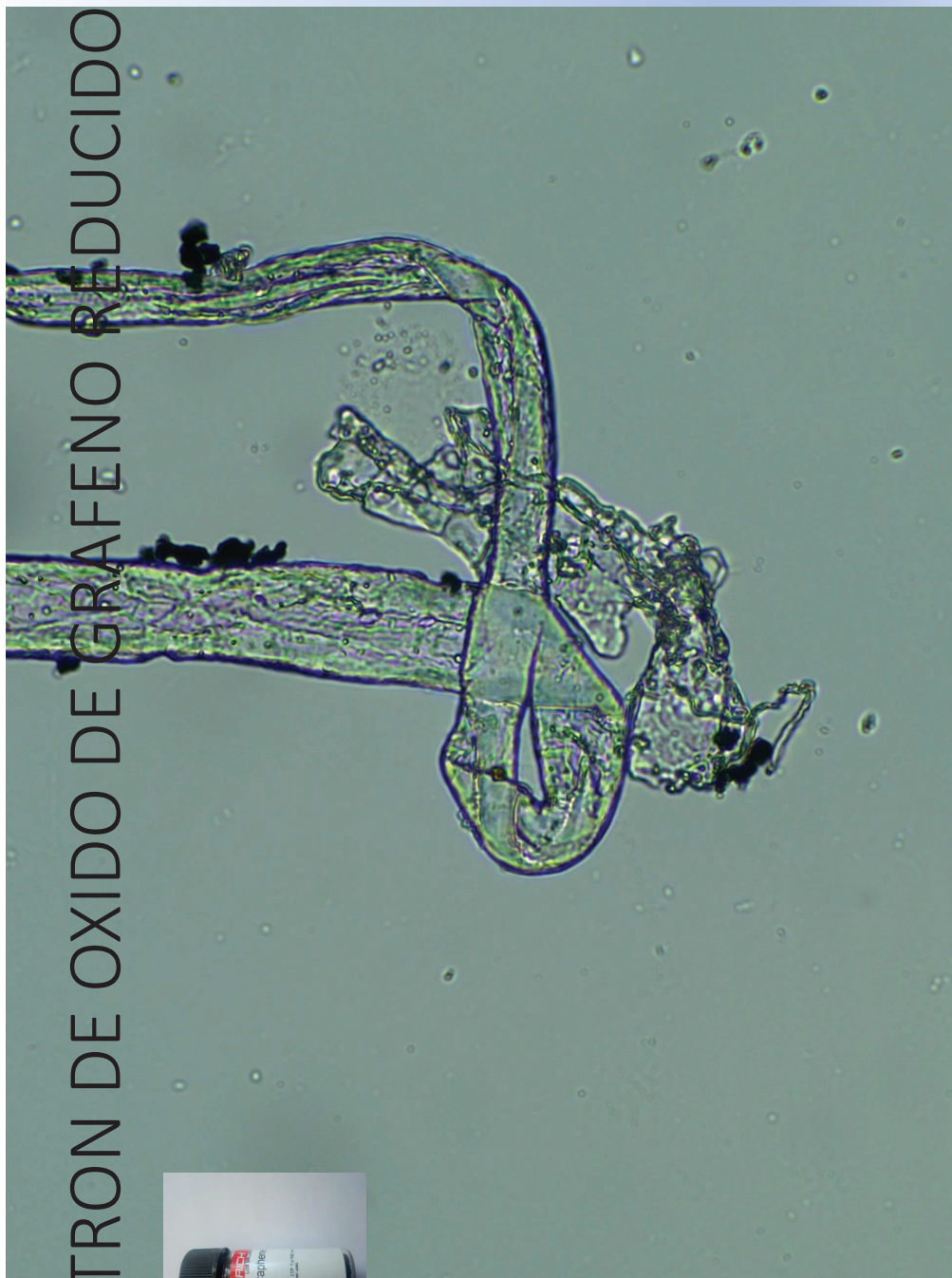
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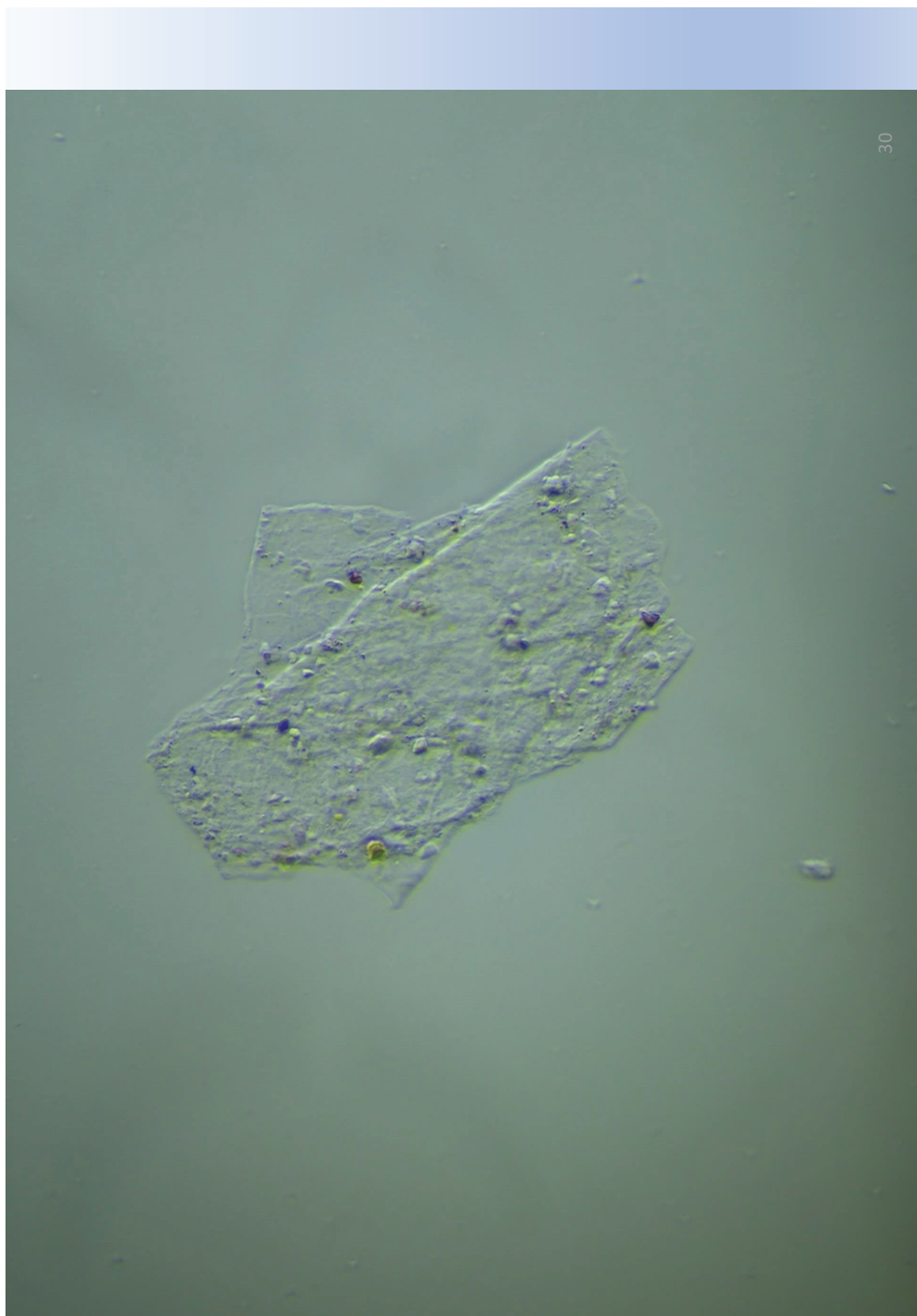
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