

## Certificate of Analysis PFIZER MANUFACTURING BELGIUM NV

PFIZER MANUFACTURING BELGIUM NV RIJKSWEG 12 B-2870 PUURS (BELGIUM) Section (9)(2)(a)

Batch Number: EP9605 Date Generated: 10/02/2021

Product Name: COMIRNATY™ (COMIRNATY 195x0.45ml GVL PUU-F2-BNT EU)

Material Number: F000052227

Date of Manufacture: 13/01/2021

Expiration Date: 30/06/2021

Importing Country: All countries that accepted Marketing Authorisation Application

REGISTERED TESTS ACCEPTANCE CRITERIA RESULT				
REGISTERED TESTS	ACCEPTANCE CRITERIA	KESULI		
COMPOSITION AND STRENGTH	10			
Appearance (Visual)	Section (Q)(2)(h)(ii)	Meets test		
Appearance	Section (9)(2)(b)(ii)	Meets test		
Appearance (Particles) Visible Particulates		Meets test		
Subvisible Particulate Matter		570 Destinier/contriner		
Subvisible particles		570 Particles/container 7 Particles/container		
Potentiometry		7.3		
Osmometry Osmolality		574 mOsmol/kg		
Dynamic Light Scattering (DLS) LNP Size		72 nm		
LNP Polydispersity		0.2		
Fluorescence assay		00.04		
RNA Encapsulation		93 % 0.50 mg/mL		
RNA Content  HPLC-CAD	+	0.30 Hig/IIIL		
ALC-0315 Content		7.03 mg/mL		
ALC-0159 Content		0.87 mg/mL		
DSPC cortent		1.53 mg/mL		
Cholesterol content		3.04 ng/mL		
Container content		_		
Vial content (volume)		Not less than 0.406 mL		
IDENTITY				
HPLC-CAD				
Lipid identities		Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)		
RT-PCR				
Identity of encoded RNA sequence		Confirmed		

Pfizer Internal Use
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REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
POTENCY		
Cell-based Flow Cytometry In Vitro Expression	Section (9)(2)(b)(ii)	71 %
PURITY		
Capillary Gel Electrophoresis RNA Integrity		72 %
ADVENTITIOUS AGENTS		<b>N</b> 9
Endotoxin (LAL) Bacterial endotoxins		<5.00 EU/mL
Sterility Sterility		No growth detected

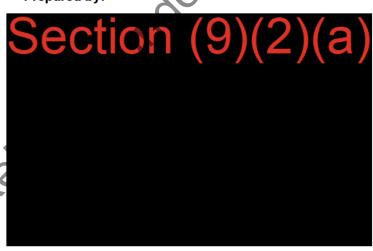
I HEREBY CERTIFY THAT THE ABOVE INFORMATION IS AUTHENTIC AND ACCURATE.

QUALITY ASSURANCE REVIEW: THE BATCH DOCUMENTATION FOR THE ABOVE LISTED LOT OF PRODUCT HAS BEEN REVIEWED AND ALL ASPECTS WERE FOUND ACCEPTABLE. ALL DEVIATIONS HAVE BEEN THOROUGHLY REVIEWED AND APPROVED. THE RESULTS OF ALL INPROCESS TESTING MEET THE REQUIREMENTS. THE BATCH HAS ALSO BEEN TESTED AND CONFORMS TO ALL MAA SPECIFICATIONS AND INTERNAL CONTROL TARGETS. ALL BATCH DOCUMENTATION IS RETAINED AT PFIZER MANUFACTURING BELGIUM NV AND AVAILABLE FOR REVIEW.

MANUFACTURING/PACKAGING REVIEW: THE BATCH DOCUMENTATION FOR THE ABOVE LISTED LOT OF PRODUCT HAS BEEN REVIEWED AND ALL ASPECTS OF THE MANUFACTURING AND PACKAGING WERE JUDGED ACCEPTABLE AND CONSISTENT WITH THE REQUIREMENTS OUTLINED IN THE MAA AND MASTER MANUFACTURING DOCUMENTS. ALL MANUFACTURING DEVIATIONS HAVE BEEN THOROUGHLY REVIEWED AND APPROVED.

ALL ACTIVITIES ARE PERFORMED BY QUALIFIED PEOPLE, UNDER THE SUPERVISION OF THE QUALIFIED PERSON.

Prepared by:



Title: QP Product Specialist

Date: 10/02/2021

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Date: 10/02/2021

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## **MSB**

## Validation Report as of: 10 Feb 2021 15:10:048+0100

Subject CN MSB

Subject DN ,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US

Email

Serial # 103155442024134641897105422308128156249

Issuer DN

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## **Audit Trail Report**

Date	User	Document	Action	Details
10 Feb 2021 14:13:026+0100	Section (9)(2)(a)	Dodnicit	Started	The custodian composed the ePak succesfully. User UUID: Section (9)(2)(a) User Email: Section (9)(2)(a)
10 Feb 2021 14:13:027+0100			RequestSent	Sign request sent to ePak recipient. User UUID : Section (9)(2)(a) User Email : Section (9)(2)(a)
10 Feb 2021 14:13:027+0100			RequestSent	Sign request sent to ePak recipient. User UUID : <mark>Section (9)(2)(a)</mark> User Email : <mark>Section (9)(2)(a)</mark>
10 Feb 2021 14:13:033+0100		20210210_1411_ANEV_DP_CO A_MAA_EP9605.pdf	DocumentViewed	Document viewed by signer.  User UUID : Section (9)(2)(a)  User Email: section (p)(a)  Document UUID : fc5cac05-f4d9-4cd7-a4a5-3f674ba7c916
10 Feb 2021 14:38:003+0100		20210210_1411_ANEV_DP_CO A_MAA_EP9605.pdf	DocumentViewed	User UUID : Section (9)(2)(a) User Email : Section (9)(2)(a) Document UUID : fc5cac05-f4d9-4cd7-a4a5-3f674ba7c916
10 Feb 2021 14:39:012+0100		20210210_1411_ANEV_DP_CO A_MAA_EP9605.pdf	Signed	The recipient signed the document with no comments.  Comments: None  Reason: Laprove, this docliment as author User UUID: Section (9)(2)(a)  User Email: Section (9)(2)(a)  Document UUID: fc5cac05-f4d9-4cd7-a4a5-3f674ba7c916
10 Feb 2021 14:40:045+0100		20210210_1411_ANEV_DP_CO A_MAA_EP9605.pdf	Signed	The recipient signed the document with no comments.  Comments: None  Reason: I approve this document.  User UUID: Back 19(2)  User Email Section 19(4)  Document UUID: 1656ac05-f4d9-4cd7-a4a5-3f674ba7c916
10 Feb 2021 14:40:045+0100			Completed	The ePak completed the workflow successfully custodian.
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