



Certificate of Analysis

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
COMPOSITION AND STRENGTH		
Appearance (Visual) Appearance	Section (9)(2)(b)(ii)	Meets test
Appearance (Particles) Visible Particulates		Meets test
Subvisible Particulate Matter Subvisible particles		570 Particles/container 7 Particles/container
Potentiometry pH		7.3
Osmometry Osmolality		574 mOsmol/kg
Dynamic Light Scattering (DLS) LNP Size LNP Polydispersity		72 nm 0.2
Fluorescence assay RNA Encapsulation RNA Content		93 % 0.50 mg/mL
HPLC-CAD ALC-0315 Content ALC-0159 Content DSPC content Cholesterol content		7.03 mg/mL 0.87 mg/mL 1.53 mg/mL 3.04 mg/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

Pfizer Internal Use

Page 1/2

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		
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 IN-PROCESS 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:

Section (9)(2)(a)

Title: QP Product Specialist

Date: 10/02/2021

Title: QP Product Specialist

Date: 10/02/2021

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies. Distribution to third parties without prior permission is prohibited.

MSB

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

1



Subject CN MSB
Subject DN Section (9)(2)(a),CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email Section (9)(2)(a)
Serial # 103155442024134641897105422308128156249
Issuer DN CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
Signing Time 10 Feb 2021 14:40:045+0100

- The Certificate chain was successfully built to a Trusted Root Certificate.
- The Signer's identity is valid.
- The Document has not been modified since the signature was applied.

Released under the Official Information Act 1982

This page was added to the original document by the MSB Validation Service (SVS) as part of the process to convert active signature block content into inactive text. A full validation report of each signature is generated and cross-referenced using a numeric footnote annotation.

Audit Trail Report

Date	User	Document	Action	Details
10 Feb 2021 14:13:026+0100	Section (9)(2)(a)		Started	The custodian composed the ePak successfully. 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 : Section (9)(2)(a) User Email : Section (9)(2)(a)
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 (9)(2)(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	Document viewed by signer. 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: I approve this document 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 : Section (9)(2)(a) User Email : Section (9)(2)(a) Document UUID : fc5cac05-f4d9-4cd7-a4a5-3f674ba7c916
10 Feb 2021 14:40:045+0100			Completed	The ePak completed the workflow successfully custodian. User UUID : Section (9)(2)(a) User Email : Section (9)(2)(a)

Released under the Official Information Act 2000