Certificate of Analysis

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

Batch Number: FN4207 **Date Generated:** 02-Dec-2021

Product Name: COMIRNATY™ (COMIRNATY 0.5mg/ml 195x0.45ml GVL PU PFE)

Material Number: F000054476

Date of Manufacture: 29-Oct-2021

Expiration Date: 30-Jun-2022

Importing Country: All countries that accepted Marketing Authorisation Application or WHO Emergency Use Listing

REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
COMPOSITION AND STRENGTH		
Appearance (Visual) Appearance	9(2)(b)(ii)	MEETS TEST
Appearance (Particles) Visible Particulates		MEETS TEST
Subvisible Particulate Matter Subvisible particles		310 Particles >= 10 µm per container 13 Particles >= 25 µm per container
Potentiometry pH		7.4
Osmometry Osmolality		574 mOsm/kg
Dynamic Light Scattering (DLS) LNP Size LNP Polydispersity		74 nm 0.1
Fluorescence assay RNA Encapsulation RNA Content		96 % 0.49 mg/mL
HPLC-CAD ALC-0315 Content ALC-0159 Content DSPC content Cholesterol content		6.07 mg/mL 0.83 mg/mL 1.43 mg/mL 2.94 mg/mL
Container content Vial content (volume)		>=0.406 mL
IDENTITY		
HPLC-CAD Lipid identities		MEETS TEST
RT-PCR Identity of encoded RNA sequence		Identity confirmed

REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
POTENCY		
Cell-based Flow Cytometry In Vitro Expression	9(2)(b)(ii)	72 %
PURITY		
Capillary Gel Electrophoresis RNA Integrity		65 %
ADVENTITIOUS AGENTS		
Endotoxin (LAL) Bacterial endotoxins		<5.00 EU/mL
Sterility Sterility		No growth observed

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:

9(2)(a)

Title: QP Delegate

Date: 02/12/2021

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