Certificate of Analysis

[redacted]

Batch Number: [redacted] **Date Generated:** 19-Jan-2022

Product Name: COMIRNATY™ Tris/Sucrose, 30 mcg/0.3 mL Dispersion for Injection (COMIRNATY 0.1mg/ml 10x2.25ml GVL EU)

Material Number: [redacted]

Date of Manufacture: 03.12.2021

Expiration Date: 31.05.2022

Importing Country: All countries that accepted Marketing Authorisation Application

REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
COMPOSITION AND STRENGTH		
Appearance (Visual) Appearance	White to off-white suspension	Meets test
Appearance (Particles) Visible Particulates	May contain white to off-white opaque, amorphous particles	Meets test
Subvisible Particulate Matter Subvisible particles	[redacted] CCI	
Potentiometry pH		
Osmometry Osmolality		
Dynamic Light Scattering (DLS) LNP Size LNP Polydispersity		
Fluorescence assay RNA Encapsulation RNA Content		
HPLC-CAD ALC-0315 Content ALC-0159 Content DSPC content Cholesterol content		
Container content Vial content (volume)		
IDENTITY		
HPLC-CAD Lipid identities	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Meets test
RT-PCR Identity of encoded RNA sequence	Identity confirmed	Identity confirmed

REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
POTENCY		
Cell-based Flow Cytometry In Vitro Expression	[redacted]	
PURITY		
Capillary Gel Electrophoresis RNA Integrity		
ADVENTITIOUS AGENTS		
Endotoxin (LAL) Bacterial endotoxin		
Sterility Sterility	No growth detected	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:

Name: [redacted] Title: QP delegate

Signatur[redacted] Date: 19/01/2022

Approved by:

Name: [redacted] Title: QP delegate

Signatu[redacted] Date: 19/01/2022