Certificate of Analysis

PFIZER MANUFACTURING BELGIUM NV
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Batch Number: EJ6796 **Date Generated:** 21/12/2020

Product Name: COMIRNATY™ (PF07302048 VAC 195x0.45ml GVL FC2-A UNIV)

Material Number: F000051208

Date of Manufacture: 13/11/2020

Expiration Date: 30/04/2021

Importing Country: All countries that accepted Marketing Authorisation Application

REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
COMPOSITION AND STRENGTH		
Appearance (Visual)[a] Appearance		
Appearance (Particles)[a] Visible Particulates		
Subvisible Particulate Matter[a] Subvisible particles		
Potentiometry[a] pH		
Osmometry[a] Osmolality		
Dynamic Light Scattering (DLS)[a] LNP Size LNP Polydispersity		
Fluorescence assay[a] RNA Encapsulation RNA Content	5.1.1c	
HPLC-CAD[a] ALC-0315 Content ALC-0159 Content DSPC content Cholesterol content		
Volume of injections in containers[a] Container content for injections		
IDENTITY		
HPLC-CAD[a] Lipid identities		
RT-PCR[a] Identity of encoded RNA sequence		
POTENCY		

Cell-based Flow Cytometry[a] In Vitro Expression	5.1.1c
PURITY	
Capillary Gel Electrophoresis[a] RNA Integrity	
ADVENTITIOUS AGENTS	
Endotoxin (LAL) Bacterial endotoxins	
Sterility Sterility	

a. 5.1.1c

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: 5.1.2e Title: QP Trainee

Signature: 5.1.2e Date: 21/12/2020

Approved by:

Name: 5.1.2e Title: QP Product Specialist

Signature: 5.1.2e Date: 21/12/2020

5.1.2e