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Pfizer Global Supply,
7000 Portage Rd.
Kalamazoo,
MIC 49001 USA

Date:

Food and Drug Administration
Center for Biologics Evaluation and Research
Sample Custodian
10903 New Hampshire Avenue
W075-G707
Silver Spring, MD 20993-0002

Please consider this as an official request for batch release for the following product:

Trade Name:	COMIRNATY
Type of Container:	Vial
Storage Conditions:	-80˚C to -60˚C
Marketing Authorisation Holder:	
Batch Number:	ER8735
Date of Filling:	
Expiry Date:	31-Jul-2021
Total Quantity:	(b) (4)
Site of Manufacture:	PGS Kalamazoo, 7000 Portage Rd., Kalamazoo, MIC 49001 USA
Electronic Protocol Filename:	

Please find enclosed the Certificate of Analysis for the Drug Substance and Drug Product lots for this batch. Pfizer hereby submits the following lot as an electronic submission by Electronic Submissions Gateway (ESG). All tests conducted on this lot are reported and pass specifications as required.

Sample Status

- ☐ Sample Not Required due to COVID-19 Pandemic
- ☐ Sample Submitted with Protocol
- ☐ Sample Previously Submitted (include date) _____

Prepared By: Approved By:

Prepared By:

Approved By:

CERTIFICATE OF ANALYSIS

Generated Date: 03-2021

PHARMACIA & UPJOHN COMPANY LLC
(A SUBSIDIARY OF PFIZER INC)
7000 PORTAGE RD
KALAMAZOO, MI 49001-0199 USA

Item:	F000052022
Title:	PFE-BNT 0.5MG/ML COVIDVX 195X2ML GVL EUA
Expiration Date:	31-Jul-2021
Date Of Manufacture:	17-Feb-2021
Specification:	US EUA LIMIT
LOT NUMBER:	ER8735
ASSOCIATED LOT:	EP8574, EP8687

TEST NAME	TEST METHOD	SPECIFICATION	UNITS	RESULT
Appearance	Appearance (Visual)	White to off-white suspension	None	Meets Test
Appearance (Visible Particulates)	Appearance (Particles)	May contain white to off-white opaque, amorphous particles	None	Meets Test
Subvisible Particles (b)	Subvisible Particulate Matter - USP <787> (b) (4)	(b) (4)	particles/container	(b) (4)
Subvisible Particles (b)	Subvisible Particulate Matter - USP <787> (b) (4)		particles/container	
Subvisible Particles	Subvisible Particulate Matter - USP <787> (b) (4)		None	Meets Test
pH	(b) (4)	7.4 ± 0.5	None	(b) (4)
Osmolality	Osmometry – USP <785>	(b) (4)	mOsmol/kg	
LNP Size	Dynamic Light Scattering (DLS)		nm	
LNP Polydispersity	Dynamic Light Scattering (DLS)		None	
RNA Content	Fluorescence assay		mg/mL	
RNA Encapsulation	Fluorescence assay		%	
ALC-0315 Content	HPLC-CAD		mg/mL	
ALC-0159 Content	HPLC-CAD		mg/mL	
DSPC Content	HPLC-CAD		mg/mL	
Cholesterol Content	HPLC-CAD		mg/mL	
Lipid Identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	None	Positive

CERTIFICATE OF ANALYSIS

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TEST NAME	TEST METHOD	SPECIFICATION	UNITS	RESULT
Container Content for Injections	Volume of injections in containers	Not less than the sum of the nominal values of (b) (4)	None	Meets Test
Vial Content (Volume)	Container content	Not less than (b)	mL	(b) (4)
Identity of Encoded RNA Sequence	RT-PCR	Identity confirmed	None	Positive
In Vitro Expression	Cell-based Flow Cytometry	(b) (4)	% cells positive	(b) (4)
RNA Integrity	Capillary Gel Electrophoresis		% intact RNA	
Bacterial Endotoxins	Endotoxin (LAL)		EU/mL	
Sterility	Sterility	No growth detected	None	Meets Test

All documentation has been reviewed and found to be in compliance with the Master Production Documents and applicable Quality Agreements. The product meets specifications and was manufactured, packaged and tested under GMP conditions according to current approved control procedures.

Full Name: (b) (6)
Signature:
Date: 19-Mar-2021

Full Name: (b) (6)
Signature:
Date: 19-Mar-2021

Pharmaceutical Sciences

Worldwide Research & Development

Certificate of Analysis

Material Type:	Active Pharmaceutical Ingredient		
Material Description or Name:	PF-07305885 Drug Substance		
Material ID:	DS-001477	**Pfizer Lot Number:**	(b) (4)

Authorized By	
(b) (6)	(b) (4)

REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
Appearance (Clarity) Clarity	(b) (4)	
Appearance (Coloration) Coloration		
(b) (4) pH		
UV Spectroscopy Content (RNA Concentration)		
RT PCR Identity of Encoded RNA Sequence		
Capillary Gel Electrophoresis RNA Integrity		
RP HPLC 5-Cap		
ddPCR Poly (A) Tail		
qPCR Residual DNA Template		
Immunoblot dsRNA		
Endotoxin (LAL) Bacterial Endotoxins		
Bioburden Bioburden		