CERTIFICATE OF ANALYSIS

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Generated Date: 06-2021

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

Item: F000051489

Title: PFE-BNT 0.5MG/ML COVIDVX 25X2ML GVL EUA

Expiration Date: 31-Oct-2021
Date Of Manufacture: 29-May-2021
Specification: US EUA LIMIT

LOT NUMBER: FC3181

ASSOCIATED LOT: FE3195, EY0567

TEST NAME	TEST METHOD	SPECIFICATION	<u>UNITS</u>	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) (4)	Subvisible Particulate Matter - USP <787> (b) (4)	(b) (4)	particles/container	(b) (4)
Subvisible Particles (b) (4)	Subvisible Particulate Matter - USP <787> (b) (4)		particles/container	
Subvisible Particles	Subvisible Particulate Matter - USP <787> (b) (4)		None	Meets Test
pН	(b) (4)	7.4 ± 0.5	None	(b) (4)
Osmolality	Osmometry – USP <785>	(b) (4)	mOsmol/kg	(5) (1)
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

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TEST NAME	TEST METHOD	SPECIFICATION	<u>UNITS</u>	RESULT
Vial Content (Volume) Identity of Encoded RNA	Container content RT-PCR	Not less than (b) (4) Identity confirmed	mL None	(b) (4) Positive
Sequence 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.

Laura A Mroczek

Laura A Mroczek 29 Jun 2021 21:11:042-0400

REASON: I approve this document.

eba2dd86-4ab8-4864-84be-d726a2e553af

(b) (6) (b) (6) 29 Jun 2021 22:34:058-0400

REASON: I approve this document.

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