cc: STN 125742-0/2229/FC

Reason for Submission
■ For Release
☐ For Surveillance
☐ For Licensing Action*
STN: _____
☐ Corrected Protocol

Lot Number:
License Name of Product: [COVID-19 mRNA Vaccine (nucleoside modified)]

Manufacturer Name: Pharmacia & Upjohn Company LLC

Manufacturer Address: 7000 Portage Rd., Kalamazoo, MIC 49001 USA

Trade name: COMIRNATY

Date of Manufacturing: 00/00/0000 Expiration Date: 00/00/0000

Fill Information

Container Type:	Vial	**Volume per container:**	0.45mL
Approved Storage Period:	6 months	**Storage Temperature:**	-90°C to -60°C
Number of containers manufactured:		**Number of Doses per container:**	6
Number of containers for release:			
Volume of single human dose:	30 µg/Dose	**Start Date of period of Validity:**	Date of Manufacture

All tests conducted on this lot are reported and pass specifications as required.

Signature: _____ Date:_____
Title: Authorized Official
Electronic Protocol # - 202xxxxx.P0

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Lot Number:

License Name of Product: [COVID-19 mRNA Vaccine (nucleoside modified)]

Manufacturing Site: Pharmacia & Upjohn Company LLC, 7000 Portage Rd., Kalamazoo, MIC 49001 USA

Date of Manufacture: **Date of Expiry:**

Date of Fill:

Product Information:

COMPONENTS

Component Description	Batch Number	Date of Manuf.	Manufacture Site	Quantity	Target Concentration
BNT162b2 Drug Substance					(b) (4)
LNP Fabrication					N/A
Bulk Drug Product Formulation					N/A

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Table 1. Filled Vaccine Quality Control Tests

Test	Test Method	Specification	Date of Test	Result
Appearance	Appearance (Visual)	White to off-white suspension		
Appearance (Visible Particulates)	Appearance (Particles)	May contain white to off-white opaque amorphous particles		
Subvisible Particles	Subvisible Particulate Matter	(b) (4)		
pH	(b) (4)	6.9 - 7.9		
Osmolality	Osmometry	(b) (4)		
LNP Size	Dynamic Light Scattering (DLS)			
LNP Polydispersity	Dynamic Light Scattering (DLS)			
RNA Encapsulation	Fluorescence assay			
RNA content	Fluorescence assay			
ALC-0315 content	HPLC-CAD			
ALC-0159 content	HPLC-CAD			
DSPC content	HPLC-CAD			
Cholesterol content	HPLC-CAD			
Vial content	Container Content			
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)		

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Table 1 (Continued) Filled Vaccine Quality Control Tests

Test	Test Method	Specification	Date of Test	Result
Identity of encoded RNA sequence	RT-PCR	Identity confirmed		
In Vitro Expression	Cell-based Flow Cytometry	(b) (4)		
RNA Integrity	Capillary Gel Electrophoresis			
Bacterial Endotoxin	Endotoxin (LAL)			

Abbreviations: LNP = Lipid nanoparticles; CAD = charged aerosol detector; RT-PCR = reverse transcription polymerase chain reaction; LAL = Limulus amebocyte lysate; EU = endotoxin unit

Filled Vaccine Quality Control Tests (cont.)

Sterility

Method: (b) (4) **Type:** Final Container

Container: Sterility-(b) (4)

Date On Test	Medium/Temperature	Date Off Test	Specification	Test Result
	(b) (4)		No growth observed	
			No growth observed	

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Filled Vaccine Quality Control Tests (Continued)

Lipid Identity

Specification (b) (4) **Limit** **Result** _____

Lipid	**Standard Retention Times (RT)**	**Sample Retention Time**	(b) (4)
ALC-0315 content			
ALC-0159 content			
DSPC content			
Cholesterol content			

Lot Number:

License Name of Product: [COVID-19 mRNA Vaccine (nucleoside modified)]

Filled Vaccine Quality Control Tests (Continued)

RNA encapsulation and content test

Test date _____

Test method _____

Specification: RNA Encapsulation (b) (4) **Result** _____

Specification: Content RNA Content (b) (4) mg/mL Result _____

Sample/Control	Acceptance Criteria	Result
R^2 for Standard A	(b) (4)	
R^2 for Standard B		
Total RNA (mg/mL)		
Encapsulated RNA (mg/mL)		

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Filled Vaccine Quality Control Tests (Continued)

Identity of encoded RNA sequence test

Test method **RT-PCR**

Test date _____

Specification **Identity confirmed** **Result** _____

Sample/Control	Lot number	Replicate	Ct value	Acceptance criteria	Pass/Fail
DP Sample		1		(b) (4)	
		2			
		3			
Positive PCR Control		1			
		2			
		3			
Positive (b) (4) Control		1			
		2			
		3			
Negative PCR Control		1			
		2			
		3			
Negative (b) (4) Control		1			
		2			
		3			

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Filled Vaccine Quality Control Tests (Continued)

In Vitro Expression Assay

Test date _____

Test method _____

Specification (b) (4) **cells positive**

	Acceptance Criteria	Result
(b) (4) Lot number		
Positive Control lot number	(b) (4)	
% cell viability		
Average Number of Cells Counted for Sample		
Test Result (% positive cells)		

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Lot Number:

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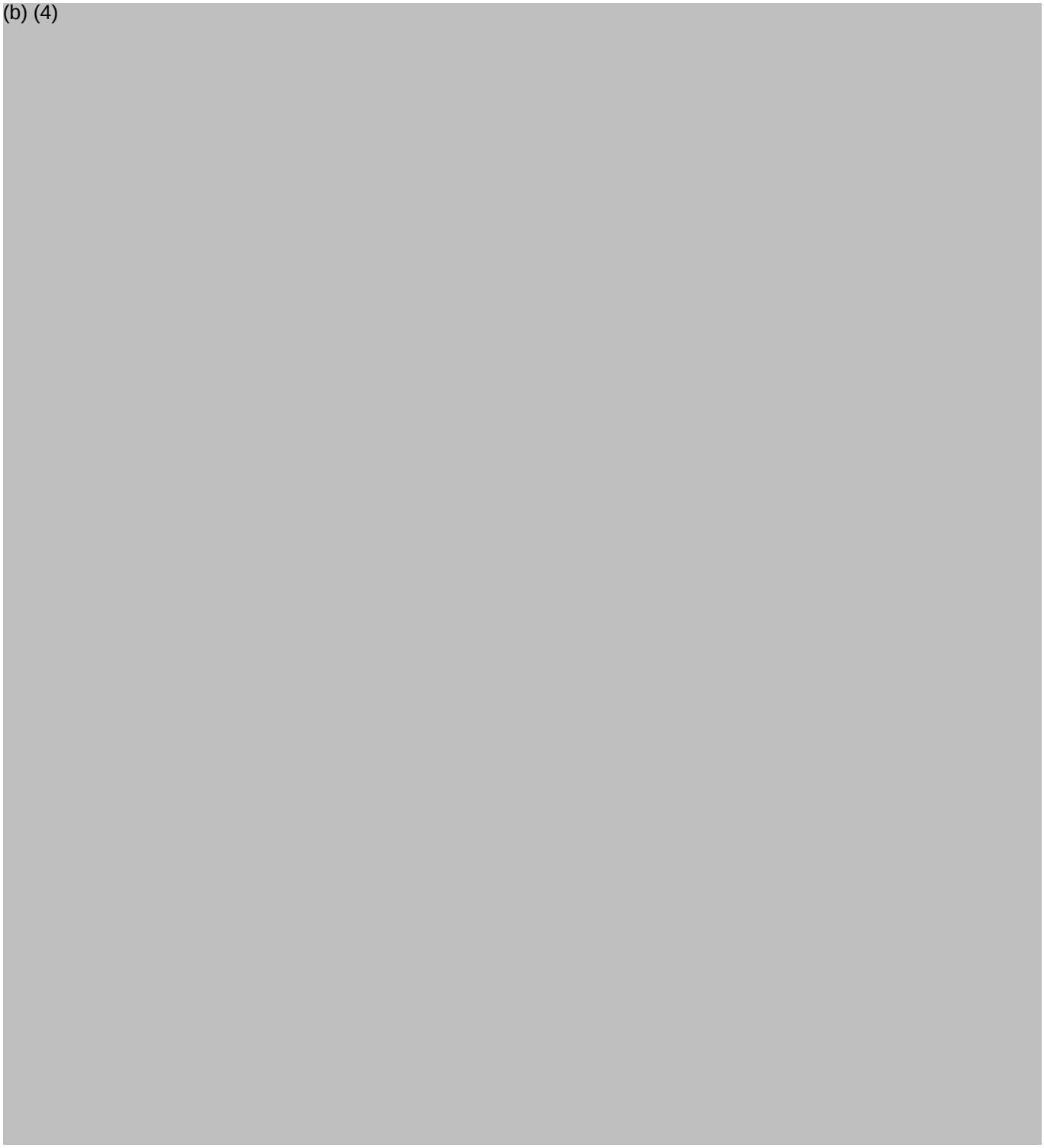
Filled Vaccine Quality Control Tests (Continued)

Limulus Amebocyte Lysate Test

(b) (4)



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Limulus Amebocyte Lysate (LAL) Test

(b) (4)

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Lot Number:

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BNT162b2 Drug Substance

Lot Number: **Manufacturing Site:**

Date of Manufacture: **Date of Expiry:**

Storage Temperature: - 25˚C to - 15˚C **Approved Storage Period:** (months

Consumed Quantity:

Table 1. Drug Substance Quality Control Tests

Test	Test Method	Specification	Date of Test	Result
Clarity	Appearance (Clarity)	(b) (4)		
Coloration	Appearance (Coloration)			
pH	(b) (4)			
Content (RNA Concentration)	UV Spectroscopy			
Identity of Encoded RNA Sequence	RT-PCR			
RNA Integrity	Capillary Gel Electrophoresis			
5'- Cap	RP-HPLC			
Poly(A) Tail	ddPCR			
Residual DNA Template	qPCR			
Residual dsRNA	Immunoblot			
Bacterial Endotoxin	Endotoxin (LAL)			
Bioburden	Bioburden			

Abbreviations: NTU = Nephelometric Turbidity Units; B = brown; RT-PCR = reverse transcription polymerase chain reaction; ddPCR = droplet digital PCR; qPCR = quantitative PCR; dsRNA = double stranded RNA; LAL = Limulus amebocyte lysate; EU = endotoxin unit; CFU = colony forming unit

Prepared By:

Approved By: