Food and Drug Administration
Center for Biologics Evaluation and Research
Sample Custodian
10903 New Hampshire Avenue
WO75-G707
Silver Spring, MD 20993-0002

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

Date :

Subject: Electronic Protocol Signature Page

License No.: 0000 Company Name:_____

[COMPANY NAME] hereby submits the following lot as an electronic submission by Electronic Submissions Gateway (ESG). All test conducted on this lot are reported and pass specifications as required.

Proper name of product

STN	Lot Number	Lot Type	Electronic Protocol Filename
125742_0	000000000	FC	20100001.P0

Sample Status
☐ Sample Not Required
☐ Sample Submitted with Protocol
☐ Sample Previous Submitted: ___[DATE]___

Virus Verification

Software Name:	
Company Name:	Version:
Date of Definitions: DD/MM/YYYY	Date of Scan: DD/MM/YYYY

I certify that the submission is virus-free.
The approximate file size of this submission is ___ KB/MB.

Comments:

Signature of Authorized Official
Printed Name and Title of Signatory Title

cc: STN 125742-0/2229/FC

Lot Number:
License Name of Product:

Reason For Submission

__ For Release
__ For Surveillance
__ For Licensing Action
STN:

__ Corrected Protocol

Manufacturer Name:

Manufacturer Address:

Trade name:

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

Fill Information

Filling Date: 00/00/0000

Location:

Total Volume: 000 mL

Volume per Vial: 000 mL

Number of Vials filled: 0000

Storage Temperature:

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

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

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

cc: STN 125742-0/2229/FC

Lot Number:

License Name of Product:

Marketing Authorisation Holder Name and Address:

Manufacturing Site:

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

FILL INFORMATION

Container Type:		**Volume per container:**	
Approved Storage Period:		**Storage Temperature:**	
Number of containers manufactured:		**Number of Doses per container:**	
Number of containers for release:			
Volume of single human dose:		**Start Date of period of Validity:**	

All lot release tests conducted on this lot, as per the product license are reported and pass specifications as required.

Prepared By: **Approved By:**

Electronic Protocol # - 202xxxxx.P0

cc: STN 125742-0/2229/FC

Lot Number:

License Name of Product:

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)		

cc: STN 125742-0/2229/FC

Lot Number:

License Name of Product:

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	

cc: STN 125742-0/2229/FC

Lot Number:

License Name of Product:

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) Result _____

Sample/Control	Acceptance Criteria	Result
R^2 for Standard A	(b) (4)	
R^2 for Standard B		

cc: STN 125742-0/2229/FC

Lot Number:

License Name of Product:

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			

cc: STN 125742-0/2229/FC

Lot Number:

License Name of Product:

Filled Vaccine Quality Control Tests (Continued)

In Vitro Expression Assay

Test date _____

Test method _____

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

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

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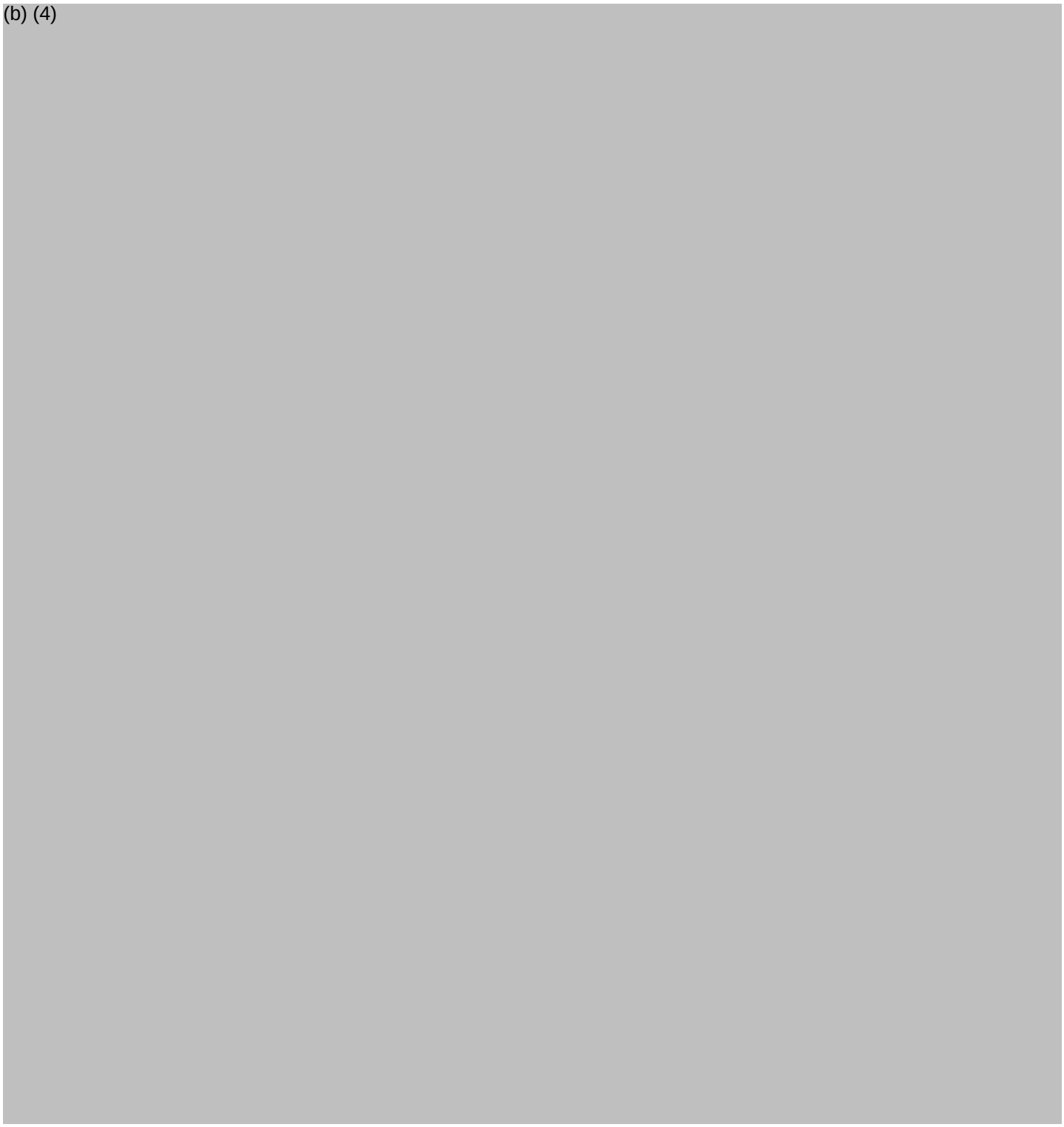
Lot Number:

License Name of Product:

Filled Vaccine Quality Control Tests (Continued)

Limulus Amebocyte Lysate Test

(b) (4)



cc: STN 125742-0/2229/FC

Lot Number:

License Name of Product:

Filled Vaccine Quality Control Tests (Continued)

Limulus Amebocyte Lysate Test

(b) (4)

cc: STN 125742-0/2229/FC

Lot Number:

License Name of Product:

BNT162b2 Drug Substance

Lot Number: **Manufacturing Site:**

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

Storage Temperature: **Approved Storage Period:**

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: