



Date:

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

cc: 125742 _0/0003/FC

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

License Name of Product:	
Type of Container:	
Storage Conditions:	
Marketing Authorisation Holder:	
Batch Number:	
Date of Filling:	
Expiry Date:	
Total Quantity:	
Site of Manufacture:	
Electronic Protocol Filename:	

Please find enclosed the lot release protocol and genealogy diagram 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:

090177e19799c049\Approved\Approved On: 20-Jul-2021 14:44 (GMT)

REASON FOR SUBMISSION:
For Release

cc: 125742_0/0003/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 (b) (4)
BNT162b2 Drug Substance					
Formulated Bulk Batch					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.

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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)		

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; (b) (4)

LAL = Limulus ameocyte 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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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 amoebocyte lysate; EU = endotoxin unit; CFU = colony forming unit

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Genealogy Flowchart

(b) (4)



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