



Pfizer Global Supply
Rijksweg 12,
2870 Puurs,
Belgium

Date: 01 Dec 20

The National Institute for Biological Standards and Control
The Medicines and Healthcare products Regulatory Agency
Blanche Lane, South Mimms, Potters Bar
HERTS EN6 3QG
U.K.

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

Trade Name:	COVID-19 mRNA Vaccine BNT162b2
Type of Container:	Vial
Storage Conditions:	-80°C to -60°C
Marketing Authorisation Holder:	BioNTech Manufacturing GmbH, An der Goldgrube 12, 55131 Mainz, Germany
Batch Number:	EJ0553
Date of Filling:	01 Oct 20
Expiry Date:	28 Feb 21
Total Quantity:	
Site of Manufacture:	PGS Puurs, Rijksweg 12, 2870 Puurs, Belgium

Please find enclosed the lot release protocol and genealogy diagram for this batch. The lot release protocol has been reviewed by a Qualified Person and found to be satisfactory.

I herewith certify that COVID-19 mRNA Vaccine BNT162b2 batch N° EJ0553 was manufactured and tested according to procedures and complies with the quality requirements. This includes that, for any materials derived from ruminants (bovine, ovine, caprine) used in the manufacture and/or formulation of the batch of product specified above, all measures have been taken to demonstrate compliance with Directive 2001/83/EC and amending Directives 2003/63/EC and 2004/27/EC.

Prepared By: [REDACTED]

01 Dec 2020
16:08:033-0500
Date: [REDACTED]

Approved By: aef620e9-a359-4114-9f96-1981bf4d6cd5 [REDACTED]

01 Dec 2020
16:09:020-0500
Date: [REDACTED]

REASON FOR SUBMISSION

☒	FOR RELEASE
☐	FOR SURVEILLANCE
☐	FOR LICENSING ACTION, STN#
☐	CORRECTED PROTOCOL

Lot Number: EJ0553

Trade Name of Product: COVID-19 mRNA Vaccine BNT162b2

Future Marketing Authorization Holder Name and Address: BioNTech Manufacturing GmbH, An der Goldgrube 12, 55131 Mainz, Germany

Manufacturing Site: PGS Puurs, Rijksweg 12, 2870 Puurs, Belgium

Date of Manufacture: 25 Sep 20

Date of Expiry: 28 Feb 21

Date of Fill: 01 Oct 20

Product Information:

COMPONENTS

Component Description	Batch Number	Date of Manufacture	Manufacture Site	Quantity	Target Concentration
BNT162b2 Drug Substance	20Y513C510	10 Sep 20	Pfizer Andover		
Formulated Bulk Batch	BCV4/07	30 Sep 20	Polymun Scientific GmbH		N/A
Formulated Bulk Batch	EJ0070	25 Sep 20	Pfizer Puurs		N/A

FILL INFORMATION

Container Type:	Vial	Volume per container:	0.45mL
Approved Storage Period:	6 months	Storage Temperature:	-80°C to -60°C
Number of containers manufactured		Number of Doses per container:	5
Number of containers for release:			
Volume of single human dose:	30 µg/Dose	Start Date of period of Validity:	Date of Manufacture

Certification by qualified person taking the overall responsibility for production and control of the product was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirements. This includes that, for any materials derived from ruminants (bovine, ovine, caprine) used in the manufacture and/or formulation of the batch of product specified above all measures have been taken to demonstrate compliance with Directive 2001/83/EC and amending Directives 2003/63/EC and 2004/27/EC.

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Lot Number: EJ0553

Name of Product: COVID-19 mRNA Vaccine BNT162b2

Table 1. Filled Vaccine Quality Control Test

Test	Test Method	Specification	Date of Test	Result
Appearance	Appearance (Visual)	White to off-white suspension	21 Oct 20	White to off-white suspension
Appearance (Visible Particulates)	Appearance (Particles)	May contain white to off-white opaque amorphous particles	21 Oct 20	Essentially free from visible particulates
Subvisible Particles	Subvisible Particulate Matter	Particles $\geq 10\mu\text{m}$: ≤ 6000 per container	15 Oct 20	
		Particles $\geq 25\mu\text{m}$: ≤ 600 per container	15 Oct 20	
pH	Potentiometry	6.9-7.9	21 Oct 20	
Osmolality	Osmometry		22 Oct 20	
LNP Size	Dynamic Light Scattering (DLS)		20 Oct 20	
LNP Polydispersity	Dynamic Light Scattering (DLS)		20 Oct 20	
RNA Encapsulation	Fluorescence assay		08 Oct 20	
RNA content	Fluorescence assay		08 Oct 20	
ALC-0315 content	HPLC-CAD		09 Oct 20	
ALC-0159 content	HPLC-CAD		09 Oct 20	
DSPC content	HPLC-CAD		09 Oct 20	
Cholesterol content	HPLC-CAD		09 Oct 20	
Container content for injections	Volume of injections in containers	Not less than the sum of the nominal values of [REDACTED]	27 Oct 20	Not less than the sum of the nominal values of [REDACTED]

Lot Number: EJ0553

Name of Product: COVID-19 mRNA Vaccine BNT162b2

Table 1 (Continued) Filled Vaccine Quality Control Test

Test	Test Method	Specification	Date of Test	Result
Lipid identities	HPLC-CAD	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	09 Oct 20	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR	Identity Confirmed	13 Oct 20	Confirmed
In Vitro Expression	Cell-based Flow Cytometry		13 Oct 20	
RNA Integrity	Capillary Gel Electrophoresis		09 Oct 20	
Bacterial Endotoxin	Endotoxin (LAL)		28 Oct 20	

Abbreviations: LNP = Lipid nanoparticles; CAD = charged aerosol detector; RT-PCR = reverse transcription polymerase chain reaction; FACS = fluorescence activated cell sorter; ddPCR = droplet digital PCR; qPCR = quantitative PCR; dsRNA = double stranded RNA; LAL = Limulus amoebocyte lysate; EU = endotoxin unit

Fill Vaccine Quality Control Test

Sterility

Method: Membrane Filtration

Type: Final Container

Sterility-20 mL/medium (40 vials)

Date on Test	Medium/Temperature	Date Off Test	Specification	Test Result
07 Oct 20		22 Oct 20	No Growth Detected	No Growth Detected
07 Oct 20		22 Oct 20	No Growth Detected	No Growth Detected

Lot Number: EJ0553

Name of Product: COVID-19 mRNA Vaccine BNT162b2

BNT162b2 Drug Substance

Lot Number: 20Y513C501

Manufacturing Site: Andover Clinical Manufacturing facility (ACMF), Pfizer Inc., 1 Burt Road, Andover, MA 01810, USA

Date of Manufacture: 10 Sep 20

Date of Expiry: 28 Feb 21

Storage Temperature: - 30°C to - 15°C

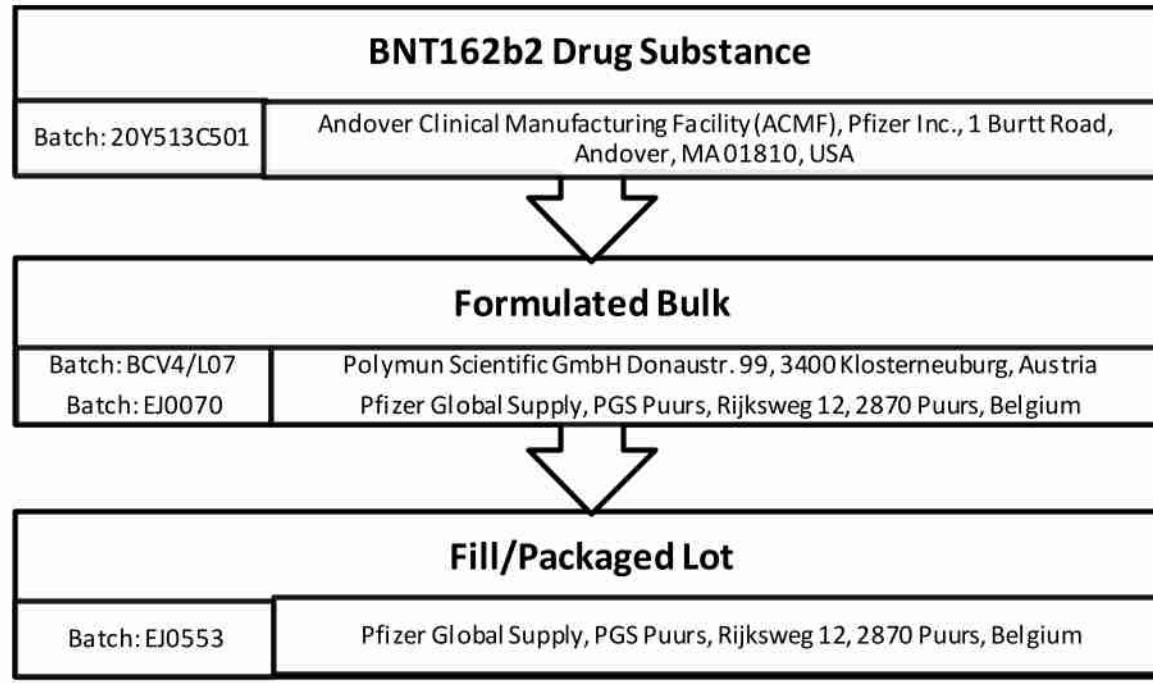
Approved Storage Period: 6 months

Consumed Quantity: [REDACTED]

Table 1. Drug Substance Quality Control Tests

Test	Test Method	Specification	Date of Test	Result
Clarity	Appearance (Clarity)	[REDACTED]	23 Sep 20	[REDACTED]
Coloration	Appearance (Coloration)		23 Sep 20	
pH	Potentiometry		22 Sep 20	
Content (RNA Concentration)	UV Spectroscopy		10 Sep 20	
Identity of Encoded RNA	RT-PCR	Identity confirmed	10 Sep 20	Confirmed
RNA Integrity	Capillary Gel Electrophoresis	[REDACTED]	10 Sep 20	[REDACTED]
5'- Cap	RP-HPLC		22 Sep 20	
Poly(A) Tail	ddPCR		22 Sep 20	
Residual DNA Template	qPCR		06 Oct 20	
Residual dsRNA	Immunoblot	[REDACTED]	09 Oct 20	[REDACTED]
Bacterial Endotoxin	Endotoxin (LAL)		11 Sep 20	
Bioburden	Bioburden		10 Sep 20	

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, NMT = Not More Than



Prepared By: [REDACTED]
 1a0df018-cfc8-4053-a93e-ef7cc9ad4eca

(Tracy Curtin - [REDACTED])

Approved By: [REDACTED]
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