



081-TEST

Quality of Vaccines and Blood Products

**EU OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE  
FOR IMMUNOLOGICAL PRODUCTS**

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE – Finished Product

Examined under Article 114 of Directive 2001/83/EC as amended by Directive 2004/27/EC (Immunological Medicinal Products) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Trade name	COMIRNATY ✓
International Non-proprietary Name / Ph.Eur. name / Common name	Pandemic COVID-19 Vaccine (mRNA)
Batch numbers appearing on the package and other identification numbers associated with this batch <sup>1</sup>	FL7649 ✓
Type of container	Vial
Total number of containers in this batch	683.388
Number of doses per container	6 doses
Date of start of period of validity	15 September 2021
Date of expiry	28 February 2022 ✓
Marketing Authorisation number (member state / EU) issued by	EU/1/20/1528
Name and address of manufacturer	Pfizer Manufacturing Belgium NV / 2870 Puurs, Belgium
Name and address of marketing authorisation holder if different	BioNTech Manufacturing GmbH An der Goldgrube 12 55131 Mainz, Germany

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard.

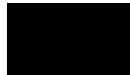
This examination is based on the relevant EU OCABR guideline for this product.

**This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released.**

Signature	Digitally signed by [Redacted]
Date of issue	Date: 2021.10.20 19:01:37 +02'00' ← LIMS
Name and function of signatory	[Redacted] Quality of Vaccines and Blood Products Service

Certificate number: BE/21/2030 ← LIMS

<sup>1</sup> Such as batch number of final bulk



**Pfizer Manufacturing Belgium NV**  
PGS Puurs  
Rijksweg 12  
2870 Puurs

Date: 19-Oct-2021

Sciensano  
Quality of Vaccines and Blood Products  
Juliette Wytsmanstraat 14  
B1050 Brussels  
Belgium

Please consider this as an official request for Official Control Authority Batch Release (OCABR) and WHO release for the following product:

Trade Name:	COMIRNATY
Type of Container:	Vial
Storage Conditions:	-90°C to -60°C
Marketing Authorisation Holder:	BioNTech Manufacturing GmbH, An der Goldgrube 12, 55131 Mainz, Germany
Batch Number:	FL7649
Date of Filling:	27-Sep-2021
Expiry Date:	28-Feb-2022
Total Quantity:*	683388
Site of Manufacture:	Pfizer Manufacturing Belgium NV, PGS Puurs, Rijksweg 12, 2870 Puurs, Belgium

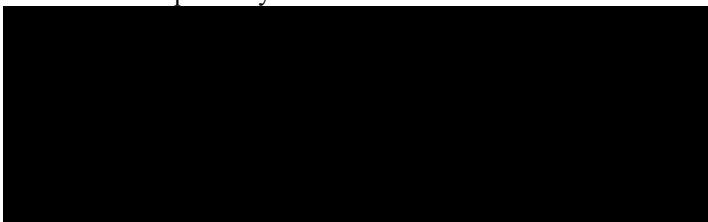
\*No deviations were raised in context of yield for the batch. Therefore, there were no exceedance of the yield limits

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. The OMCL performing OCABR has been notified of all relevant approved variations that have an impact on product specifications or on data supplied in section 3 of this protocol as described in the EU administrative procedure for OCABR.

In addition, certification by qualified person that the above COMIRNATY batch was manufactured following all national requirements and complies with WHO good manufacturing practices for pharmaceutical products: main principles; WHO good manufacturing practices for biological products; and WHO Guidelines for independent lot release of vaccines by regulatory authorities.

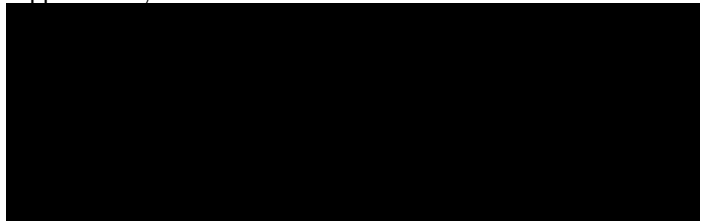
- WHO Technical Report Series, No. 986, Annex 2.
- WHO Technical Report Series, No. 999, Annex 2.
- WHO Technical Report Series, No. 978, Annex 2

Prepared By:



QP Delegate

Approved By:



QP Delegate

**REASON FOR SUBMISSION:**

For Release

**Lot Number:** FL7649**Trade Name of Product:** COMIRNATY**Licensed Name of Product:** COMIRNATY**Marketing Authorisation Holder Name and Address:** BioNTech Manufacturing GmbH, An der Goldgrube 12, 55131 Mainz, Germany**Manufacturing Site:** Pfizer Manufacturing Belgium NV, PGS Puurs, Rijksweg 12, 2870 Puurs, Belgium**Marketing Authorisation Number:** EU/1/20/1528**Date of Manufacture:** 15-Sep-2021**Date of Expiry:** 28-Feb-2022**Date of Fill:** 27-Sep-2021**Product Information:****Drug Substance Target Concentration:** [REDACTED]

## LOT GENEALOGY

Component Description	Batch Number	Date of Manuf.	Manufacture Site	Quantity
Working Cell Bank	DW8970	07-May-2020	St. Louis Laboratories Pfizer Inc.	N/A
DNA Plasmid linearised	CPF-L022	13-Apr-2021	St. Louis Laboratories Pfizer Inc.	39.223 kg
BNT162b2 Drug Substance	21Y513C6101	21-May-2021	Pfizer ACMF	162.115 L
LNP Fabrication and Bulk Drug Product Formulation	FL1681	15-Sep-2021	Pfizer Puurs	328.10 kg
Drug Product Fill/Packaging	FL7649	15-Sep-2021	Pfizer Puurs	701572

**Lot Number:** FL7649

**Licensed Name of Product:** COMIRNATY

FILL INFORMATION

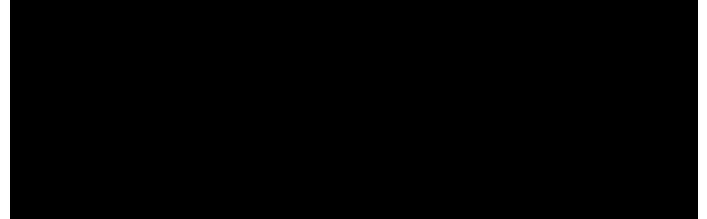
<b>Container Type:</b>	Vial	<b>Volume per container:</b>	0.45mL
<b>Approved Storage Period:</b>	6 months	<b>Storage Temperature:</b>	-90°C to -60°C
<b>Number of containers for release:</b>	683388	<b>Number of Doses per container:</b>	6
<b>Volume of single human dose:</b>	30 µg/Dose	<b>Start Date of period of Validity:</b>	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.

In addition, the OMCL performing OCABR has been notified of all relevant approved variations that have an impact on product specifications or on data supplied in section 3 of this protocol as described in the EU administrative procedure for OCABR.

**Prepared By:**

**Approved By:**



**Lot Number:** FL7649

**Licensed Name of Product:** COMIRNATY





**Table 1. Filled Vaccine Quality Control Tests**

Test	Test Method	Specification	Date of Test	Result
Appearance	Appearance (Visual)		01-Oct-2021	MEETS TEST
Appearance (Visible Particulates)	Appearance (Particles)		01-Oct-2021	MEETS TEST
Subvisible Particles	Subvisible Particulate Matter		06-Oct-2021	67 Particles $\geq$ 10 $\mu$ m per container
			06-Oct-2021	0 Particles $\geq$ 25 $\mu$ m per container
pH	Potentiometry		04-Oct-2021	7.6
Osmolality	Osmometry		06-Oct-2021	572 mOsm/kg
LNP Size	Dynamic Light Scattering (DLS)		05-Oct-2021	█ ← LIMS
LNP Polydispersity	Dynamic Light Scattering (DLS)		05-Oct-2021	█ ← LIMS
RNA Encapsulation	Fluorescence assay		05-Oct-2021	█
RNA content	Fluorescence assay		05-Oct-2021	0.48 mg/n ← LIMS
ALC-0315 content	HPLC-CAD		06-Oct-2021	6.69 mg/mL ← LIMS
ALC-0159 content	HPLC-CAD		06-Oct-2021	0.83 mg/mL ← LIMS
DSPC content	HPLC-CAD		06-Oct-2021	1.42 mg/mL ← LIMS
Cholesterol content	HPLC-CAD		06-Oct-2021	2.89 mg/mL ← LIMS
Container content for injections	Vial Content (Volume)		01-Oct-2021	✓ Not less than 0.406 mL
Lipid identities	HPLC-CAD		06-Oct-2021	✓ MEETS TEST

Lot Number: FL7649

Licensed Name of Product: COMIRNATY

Table 1 (Continued) Filled Vaccine Quality Control Tests

Test	Test Method	Specification	Date of Test	Result
Identity of encoded RNA sequence	RT-PCR	[REDACTED]	06-Oct-2021	Identity confirmed 
In Vitro Expression	Cell-based Flow Cytometry		08-Oct-2021	64 % 
RNA Integrity	Capillary Gel Electrophoresis		30-Sep-2021	62 % 
Bacterial Endotoxin	Endotoxin (LAL)		05-Oct-2021	<5.00 EU/mL 

**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

Filled Vaccine Quality Control Tests (cont.) 

**Sterility**

**Method:** Membrane Filtration

**Type:** Final Container

**Container:** Sterility-20 mL/medium (40 vials)



Date On Test	Medium/Temperature	Date Off Test	Specification	Test Result
30-Sep-2021 	Thioglycollate 30°C-35°C	15-Oct-2021 	[REDACTED]	No growth observed
	Soybean Casein Digest 20°C-25°C			No growth observed

Table 2: Fill Vaccine In-Process Tests – **Fill Weight** Measurements

Pump	Minimum	Maximum	Mean
1	0.456 g	0.488 g	0.469 g
2	0.428 g	0.489 g	0.469 g
3	0.456 g	0.493 g	0.469 g
4	0.452 g	0.497 g	0.469 g
5	0.384 g	0.496 g	0.469 g
6	0.452 g	0.506 g	0.469 g
7	0.437 g	0.504 g	0.469 g
8	0.416 g	0.497 g	0.469 g

**Acceptance Criteria:** [REDACTED]

At least one value below limits was obtained where after corrective actions were taken as per Standard Operation Procedure (SOP) and vials were rejected during IPC Fill weight.

**Lot Number:** FL7649  
**Licensed Name of Product:** COMIRNATY

**BNT162b2 LNP Fabrication**

**LNP Lot Number:** FL1681

**Table 1: In-Process Tests (IPT-C)**

Test	Test Method	Specification	Date of Test	Result
pH of Citrate Buffer	Potentiometry		21-Sep-2021	4.0
pH of Phosphate Buffered Saline (PBS)	Potentiometry		21-Sep-2021	7.5
RNA Content (Post bioburden reduction filtration prior to PBS addition)	Fluorescence assay		12-Oct-2021	0.76 mg/mL

Lot Number: FL7649

Licensed Name of Product: COMIRNATY

**BNT162b2 Drug Substance**

**Lot Number:** 21Y513C6101

**Date of Manufacture:** 21-May-2021

**Date of Expiry:** 31-Oct-2021

**Storage Temperature:** - 25°C to - 15°C

**Approved Storage Period:** 6 months

**Consumed Quantity:** 62475 g

**Table 1. Drug Substance In-Process Tests (IPT-C)**

Test	Test Method	Specification	Date of Test	Result
RNA Content (UFDL Pool Pre Dilution)	UV Spectroscopy		20-May-2021	3.24 mg/mL
RNA Content (UFDL Pool Post Dilution)	UV Spectroscopy		20-May-2021	2.26 mg/mL

**Table 2. Drug Substance Quality Control Tests**

Test	Test Method	Specification	Date of Test	Result
Clarity	Appearance (Clarity)		28-May-2021	1 NTU
Coloration	Appearance (Coloration)		28-May-2021	<=B9
pH	Potentiometry		28-May-2021	6.9
Content (RNA Concentration)	UV Spectroscopy		25-May-2021	2.27 mg/mL
Identity of Encoded RNA Sequence	RT-PCR		25-May-2021	Confirmed
RNA Integrity	Capillary Gel Electrophoresis		25-May-2021	69 %
5'- Cap	RP-HPLC		26-May-2021	90 %
Poly(A) Tail	ddPCR		11-Jun-2021	85 %
Residual DNA Template	qPCR		26-May-2021	220 ng DNA/mg RNA
Residual dsRNA	Immunoblot		21-Jun-2021	NMT 40 pg dsRNA/µg RNA
Bacterial Endotoxin	Endotoxin (LAL)		24-May-2021	NMT 1.0 EU/mL
Bioburden	Bioburden		21-May-2021	0 CFU/10mL

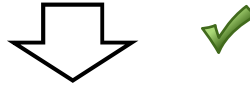
**Abbreviations:** NTU = Nephelometric Turbidity Units; B = brown; RT-PCR = reverse transcription polymerase chain reaction; ddPCR = droplet digital PCR; qPCR = quantitative PCR; dsRNA = double stranded RNA; LAL = Limulus amoebocyte lysate; EU = endotoxin unit; CFU = colony forming unit





# COMIRNATY Genealogy Flowchart

Working Cell Bank	
Batch Number	
DW8970	



Linearised DNA Template	
WCB Input(s)	Batch Number
DW8970	CPF-L022



BNT162b2 Drug Substance	
Plasmid Input(s)	Batch Number
CPF-L022	21Y513C6101



LNP Fabrication	
DS Input(s)	Batch Number
21Y513C6101	FL1681



Bulk Drug Product Formulation	
LNP Input(s)	Batch Number
FL1681	FL1681



Fill/Packaged Lot	
Formulated Bulk Input(s)	Batch Number
FL1681	FL7649



Prepared By:

Approved By:

