



**Pfizer Global Supply**  
Rijksweg 12,  
2870 Puurs,  
Belgium

Date: 21-Dec-2020

Paul-Ehrlich-Institut  
Section 2/1 Viral Vaccines  
Federal Institute for Vaccines and Biomedicines  
Paul-Ehrlich-Str. 51-59  
63225 Langen/Germany

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

Trade Name:	COMIRNATY
Type of Container:	Vial
Storage Conditions:	5.1.1c
Marketing Authorisation Holder:	BioNTech Manufacturing GmbH, An der Goldgrube 12, 55131 Mainz, Germany
Batch Number:	5.1.1c
Date of Filling:	5.1.1c
Expiry Date:	5.1.1c
Total Quantity:	280 020
Site of Manufacture:	5.1.1c

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.

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.

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5.1.2e 21 Dec 2020 16:29:029-0500

**REASON:** I approve this document as author.

Prepared By: 1a0df018-cfc8-4053-a93e-ef7cc9ad4eca

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**REASON FOR SUBMISSION:**  
For Release

**Lot Number:** 5.1.1c  
**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:** 5.1.1c  
**Marketing Authorisation Number:** EU/1/20/1528

**Date of Manufacture:** 13-Nov-2020  
**Date of Fill:** 20-Nov-2020

**Date of Expiry:** 5.1.1c

**Product Information:**

LOT GENEALOGY

Component Description	Batch Number	Date of Manuf.	Manufacture Site	Quantity	Target Concentration
Working Cell Bank					
DNA Plasmid linearized					
BNT162b2 Drug Substance			5.1.1c		
LNP Fabrication and Bulk Drug Product Formulation					
Drug Product Fill/Packaging					

FILL INFORMATION

<b>Container Type:</b>	Vial	<b>Volume per container:</b>	0.45mL
<b>Approved Storage Period:</b>		<b>Storage Temperature:</b>	
<b>Number of containers for release:</b>	5.1.1c	<b>Number of Doses per container:</b>	5.1.1c
<b>Volume of single human dose:</b>		<b>Start Date of period of Validity:</b>	

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:** \_\_\_\_\_

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REASON: I approve this document.

Lot Number: 5.1.1c

Licensed Name of Product: COMIRNATY

Table 1. Filled Vaccine Quality Control Tests

Test	Test Method	Specification	Date of Test	Result
Appearance		5.1.1c		
Appearance (Visible Particulates)				
Subvisible Particles				
pH				
Osmolality				
LNP Size				
LNP Polydispersity				
RNA Encapsulation				
RNA content				
ALC-0315 content				
ALC-0159 content				
DSPC content				
Cholesterol content				
Container content for injections				

Lot Number: 5.1.1c

Licensed Name of Product: COMIRNATY

Table 1 (Continued) Filled Vaccine Quality Control Tests

Test	Test Method	Specification	Date of Test	Result
Lipid identities				
Identity of encoded RNA sequence		5.1.1c		
In Vitro Expression				
RNA Integrity				
Bacterial Endotoxin				

**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
			5.1.1c	

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

Fill Weight (g)	Acceptance Criteria	Pump #1	Pump #2	Pump #3	Pump #4	Pump #5	Pump #6	Pump #7	Pump #8
Minimum									
Maximum					5.1.1c				
Median									

Lot Number: 5.1.1c

Licensed Name of Product: COMIRNATY

**BNT162b2 LNP Fabrication & Drug Product Formulation**

Lot Number: 5.1.1c

Manufacturing Site: 5.1.1c

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

Test	Test Method	Specification	Date of Test	Result
pH of Citrate Buffer		5.1.1c		
pH of Phosphate Buffered Saline (PBS)				
RNA Content (Post bio burden reduction filtration prior to PBS addition)				

Lot Number: 5.1.1c

Licensed Name of Product: COMIRNATY

**BNT162b2 Drug Substance**

Lot Number: 5.1.1c

Manufacturing Site: Andover Clinical Manufacturing Facility (ACMF), Pfizer Inc, 1 Burtt Rd., Andover, MA 01810 USA

Date of Manufacture: 24-Sep-2020

Date of Expiry: 5.1.1c

Storage Temperature: 5.1.1c

Approved Storage Period: 5.1.1c

Consumed Quantity: 30968 g

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

Test	Test Method	Specification	Date of Test	Result
RNA Content(UFDF Pool Pre-Dilution)		5.1.1c		
RNA Content(UFDF Pool Post Dilution)				

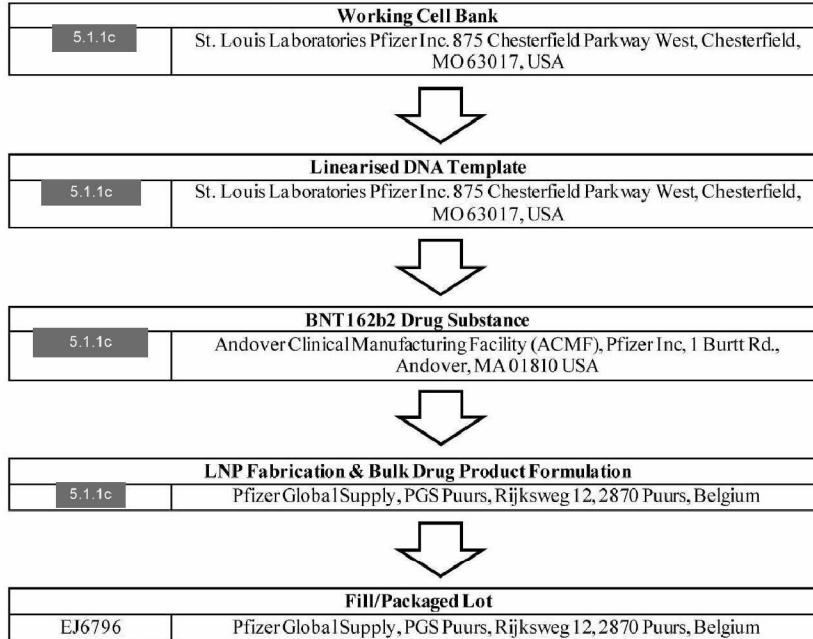
**Table 2. Drug Substance Quality Control Tests**

Test	Test Method	Specification	Date of Test	Result
Clarity		5.1.1c		
Coloration				
pH				
Content (RNA Concentration)				
Identity of Encoded RNA Sequence				
RNA Integrity				
5'- Cap				
Poly(A) Tail				
Residual DNA Template				
Residual dsRNA				
Bacterial Endotoxin				
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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**COMIRNATY Genealogy Flowchart**



Prepared By: **REASON: I approve this document as author.** [Redacted] 5.1.2e

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Approved By: [Redacted] 5.1.2e

**REASON: I approve this document.**

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## MSB

Validation Report as of: 21 Dec 2020 16:51:048-0500

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Subject CN	MSB
Subject DN	[REDACTED]msbdocs.com,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email	[REDACTED]msbdocs.com
Serial #	103155442024134641897105422308128156249
Issuer DN	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
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### Audit Trail Report

Date	User	Document	Action	Details
21 Dec 2020 22:28:037+0100	5.1.2e		Started	The custodian composed the ePak successfully. User UUID : 1a0df018-cf8-4053-a93e-ef7cc9ad4eca User Email : 5.1.2e@pfizer.com
21 Dec 2020 22:28:037+0100	5.1.2e		Request:Sent	Sign request sent to ePak recipient. User UUID : 1a0df018-cf8-4053-a93e-ef7cc9ad4eca User Email : 5.1.2e@pfizer.com
21 Dec 2020 22:28:037+0100	5.1.2e		Request:Sent	Sign request sent to ePak recipient. User UUID : aef620e9-a359-4114-9f96-1981bf4d6cd5 User Email : 5.1.2e@pfizer.com
21 Dec 2020 22:28:041+0100	5.1.2e	EJ6796 OCABR Release Request EJ6796 .pdf	DocumentViewed	Document viewed by signer. User UUID : 1a0df018-cf8-4053-a93e-ef7cc9ad4eca User Email : 5.1.2e@pfizer.com Document ULID : da0bfad0-4fc1-4844-87a4-ccafae90c8a5
21 Dec 2020 22:29:029+0100	5.1.2e	EJ6796 OCABR Release Request EJ6796 .pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document as author. I approve this document as author. User UUID : 1a0df018-cf8-4053-a93e-ef7cc9ad4eca User Email : 5.1.2e@pfizer.com Document ULID : da0bfad0-4fc1-4844-87a4-ccafae90c8a5
21 Dec 2020 22:32:005+0100	5.1.2e	EJ6796 OCABR Release Request EJ6796 .pdf	DocumentViewed	Document viewed by signer. User UUID : aef620e9-a359-4114-9f96-1981bf4d6cd5 User Email : 5.1.2e@pfizer.com Document ULID : da0bfad0-4fc1-4844-87a4-ccafae90c8a5
21 Dec 2020 22:32:039+0100	5.1.2e	EJ6796 OCABR Release Request EJ6796 .pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document. I approve this document. User UUID : aef620e9-a359-4114-9f96-1981bf4d6cd5 User Email : 5.1.2e@pfizer.com Document ULID : da0bfad0-4fc1-4844-87a4-ccafae90c8a5
21 Dec 2020 22:32:039+0100	5.1.2e		Completed	The ePak completed the workflow successfully custodian. User UUID : 1a0df018-cf8-4053-a93e-ef7cc9ad4eca User Email : 5.1.2e@pfizer.com