BioNTech Manufacturing GmbH

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BIONTECH
Manufacturing

Prelimenary Certificate of Compliance

(No.:CoC-EJ0553-01)

Product:	BNT162b2
Lot/Batch No.:	EJ0553
Date of Manufacture	25 Sep 2020

Batch size:	[redacted]
Packaging:	GC-Vial 2 mL (195 vials/tray)
Strength/Potency:	30 µg BNT162b2 per dose (0.3 mL) (after dilution of DP with sterile isotonic Sodium Chloride solution (0.9% NaCl))
Volume per vial:	0.45 ml
Dosage Form:	Concentrate for solution for i.m. injection
Retest date/Expiry date:	28 Feb 2021
Destination	All countries that accepted Emergency Use Application
Authorization	New version will be issued when authorization is received

Name and Address of Manufacturer:	BioNTech Manufacturing GmbH An der Goldgrube 12 D-55131 Mainz
Manufacturing authorization number:	DE_RP_01_MIA_2020_0065

Remarks:
Filling date 01 Oct 2020.

Certification Statement:
I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging in full compliance with the GMP requirements of the local Regulatory Authority and with the specification as defined in the global EUA package from 24 Nov 2020. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

02. DEZ. 2020

Date, Signature of the Qualified Person [redacted]

Batch certification and release

Product:	BNT 162b2	**Batch:**	EJ0553
IMPD/IND/IND incl. Version	Global EUA Package	**Valid from:**	EUA package approved on 24 Nov 2020

Review by the QP (external documentation)	
Batch Record incl. Review of the Drug Substance manufacturing and quality control is present:	☒ yes ☐ no
CoA for Drug Substance is issued and all results are in specification as defined in the valid IMPD/IND:	☒ yes ☐ no
CoC for Drug Substance is issued and is compliant with the valid IMPD/IND:	☒ yes ☐ no
Batch Record incl. Review of the Drug Product Bulk manufacturing is present:	☒ yes ☐ no
CoC of the Drug Product Bulk is issued and is compliant with the valid IMPD/IND:	☒ yes ☐ no
CoA for Drug Product bulk (for applicable tests) is issued	☒ yes ☐ no
Batch Record incl. Review of the filling of Drug Product Bulk in vials is present:	☒ yes ☐ no
CoA for the Drug Product is issued and all results are in specification as defined in the valid IMPD/IND:	☒ yes ☐ no
CoC of the Drug Product in vials is issued and is compliant with the valid IMPD/IND:	☒ yes ☐ no
Batch Record incl. Review of the labeling of Drug Product in vials is present:	☒ yes ☐ no
CoC of the Drug Product in vials labeled is issued and is compliant with the IMPD/IND:	☒ yes ☐ no
All Deviations and OoS are reviewed and closed and are not critical for the release of the batch:	☒ yes ☐ no
Changes/CAPA are reviewed and are not critical for the release of the batch:	☒ yes ☐ no
Detection of further errors during the batch record review:	☐ yes ☒ no
Remarks: All documentation and specifications have been checked against the global EUA package besides the IND/IMPD as stated above. The geanology for this batch is attached to this documentation (see attachment 1). The NIBCS-Certificate for this batch has been received (see attachment 2) Only one major deviation has been reported by the Drug Product Filling Site [redacted]	
The deviation is closed and has been reviewed. The assessment of the deviation came to the conclusion that there is no impact on safety and quality of the batch. All affected vials have been removed and [redacted]	

02. DEZ. 2020 [redacted]
Date, Name and Signature of the QP

Product:	BNT 162b2	**Batch:**	EJ0553
IMPD/IND/IND incl. Version	Global EUA Package	**Valid from:**	EUA package approved on 24 Nov 2020

Release by the QP (BNT)	
Release of the batch:	☐ yes ☐ no
CoC is created and signed:	☐ yes ☐ no
CoC is attached to this document:	☐ yes ☐ no
Batch has been added to the register (LIS-070.025A)	☐ yes ☐ no
The responsible department (e.g. SCM) is informed about the certification	☐ yes ☐ no
Remarks: Klicken oder tippen Sie hier, um Text einzugeben.	
Klicken oder tippen Sie hier, um Text einzugeben.	
Date, Name and Signature of the QP	

Genealogy of the Batch EJ0553

Manufacturing Step	Batch Number	Manufacturing site	Manufacturing date/ Batch Size
DNA Plasmid linearized	CPF-L001 (Axis batch 20-SM-000123) Item Number: SM-001372 Material Description: PF-07305883 [pST4-1525] Linearized Plasmid 1g/L	St. Louis Laboratories Pfizer Inc. 875 Chesterfield Parkway West Chesterfield, MO 63017	18 Aug 2020 Date of inspection: 19–20 Aug 2019 [redacted] Date of inspection: 27–29 Aug 2019 Agency: Spanish Agency AEMPS (EMA). [redacted]
Drug Substance	Batch 20Y513C501 AXIS360 Batch 20-DS-00043 Item Number DS-001477 Material Description: PF-07305885 DS	Andover Manufacturing facility (ACMF), Pfizer Inc., 1 Burtt Road Andover, MA 01810 USA	10 Sep 2020 [redacted] [redacted] Jan 2019 [redacted] 03 May 2019 [redacted]
Drug Product compounded	BCV4/L07	Polymun Scientific GmbH Donaustr. 99, 3400 Klosterneuburg Austria	30 Sep 2020 [redacted] Polymun Scientific Immunbiologische Forschung GmbH Donaustraße 99 A-3400 Klosterneuburg Date of inspection: 07 JUN 2018, BASG / AGES MEA Austria (EMA, certificate number 482009-0011) Y Date of inspection: 18 APR 2017, BASG / AGES MEA Austria (EMA, certificate number 482009-0012)
Drug Product in vials	EJ0553 (1950 unlabeled clinical vials have been preciously releases as EJ0553Z)	Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs Belgium	25 Sep 2020 (fill date 01 Oct 2020) [redacted] Primary Packaging Secondary Packaging [redacted] Date of inspection: 09–16 Nov 2017 [redacted] Date of inspection: 14–15 Jul 2020 Agency: Belgian Federal Agency for Medicines and Health Products (EMA, certificate number BE/GMP/2020/034) Date of inspection: 25–27 Feb 2019 [redacted]

Medicines & Healthcare products Regulatory Agency

Amendment 2 to FOR-070-025A

02. DEZ. 2020

NIBSC Confidence in Biological Medicines

UK CERTIFICATE OF COMPLIANCE FOR IMMUNOLOGICAL PRODUCTS

Finished Product
Examined under Regulation 174A of the Human Medicines Regulations 2012 (as added thereto by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020)

NIBSC Release Certificate Number:	202000603
Trade name / Product Name:	Covid-19 mRNA Vaccine BNT162b2
Batch number appearing on package and other identification numbers associated with this batch:	EJ0553
Type of container:	Vial
Total number of containers in this batch:	[redacted]
Nominal dose per container:	5
Date of start of period of validity:	25th September 2020
Date of expiry:	28th February 2021
Name and address of Manufacturer:	BioNTech Manufacturing GmbH Pfizer Global Manufacturing Belgium NV, Rijksweg 12, B-2870 Puurs, Belgium

This batch has been examined using documented procedures forming part of a quality system accredited to ISO/IEC 17025. NIBSC is a UKAS accredited testing laboratory No. 1470. All tests may not be accredited. Tests may include those for which accreditation is claimed under the bounds of our flexible scope of accreditation.

This examination is based on the review of the manufacturer's protocol and, where appropriate, laboratory tests.

This batch is in compliance with the manufacturing specifications provided.

Name: [redacted]

Function of Signatory: Head of Division

Signed: [redacted]

Date of Issue: 2nd December 2020

(Form: R174A Version: 1)

National Institute for Biological Standards and Control,
Potters Bar,Hertfordshire, EN6 3QG,United KingdomT +44(0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

Certificate of Analysis

PFIZER MANUFACTURING BELGIUM NV
RIJKSWEG 12
B-2870 PUURS (BELGIUM)
TEL: +32 (0)3 890.92.11
FAX: +32 (0)3 889.65.32

Batch Number: EJ0553

Date Generated: 30/11/2020

Product Name: COVID-19 mRNA Vaccine BNT162b2 (PF07302048 VAC 195X0.45ML GVL US)

Material Number: F000049855

Date of Manufacture: 25/09/2020

Expiration Date: 28/02/2021

Importing Country: All countries that accepted Emergency Use Application

REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
COMPOSITION AND STRENGTH		
Appearance (Visual)[a] Appearance	White to off-white suspension	White to off-white suspension
Appearance (Particles)[a] Visible Particulates	May contain white to off-white opaque, amorphous particles	Essentially free from visible particulates
Subvisible Particulate Matter[a] Subvisible particles	Particles ≥10 µm: ≤ 6000 per container Particles ≥ 25 µm: ≤ 600 per container	[redacted]
Potentiometry[a] pH	7.4 +/- 0.5	[redacted]
Osmometry[a] Osmolality	[redacted]	[redacted]
Dynamic Light Scattering (DLS)[a] LNP Size LNP Polydispersity		
Fluorescence assay[a] RNA Encapsulation RNA Content		
HPLC-CAD[a] ALC-0315 Content ALC-0159 Content DSPC content Cholesterol content		
Volume of injections in containers[a] Container content for injections	Not less than the sum of the nominal values of [redacted]	Not less than the sum of the nominal values of [redacted]
IDENTITY		
HPLC-CAD[a] Lipid identities	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
RT-PCR[a] Identity of encoded RNA sequence	Identity confirmed	Confirmed

POTENCY		
Cell-based Flow Cytometry[a] In Vitro Expression[b]	[redacted]	[redacted]
PURITY		
Capillary Gel Electrophoresis[a] RNA Integrity	[redacted]	[redacted]
ADVENTITIOUS AGENTS		
Endotoxin (LAL) Bacterial endotoxins	≤ 12.5 EU/mL	[redacted]
Sterility Sterility	No growth detected	No growth detected

a. Testing performed by ARD (Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC, Andover, US).
b. [redacted] is the test included in EUA regulatory filing section P.5.2.4.2.

I HEREBY CERTIFY THAT THE ABOVE INFORMATION IS AUTHENTIC AND ACCURATE.

QUALITY ASSURANCE REVIEW: THE BATCH DOCUMENTATION FOR THE ABOVE LISTED LOT OF PRODUCT HAS BEEN REVIEWED AND ALL ASPECTS WERE FOUND ACCEPTABLE. ALL DEVIATIONS HAVE BEEN THOROUGHLY REVIEWED AND APPROVED. THE RESULTS OF ALL IN-PROCESS TESTING MEET THE REQUIREMENTS. THE BATCH HAS ALSO BEEN TESTED AND CONFORMS TO ALL EUA SPECIFICATIONS AND INTERNAL CONTROL TARGETS. ALL BATCH DOCUMENTATION IS RETAINED AT PFIZER MANUFACTURING BELGIUM NV AND AVAILABLE FOR REVIEW.

MANUFACTURING/PACKAGING REVIEW: THE BATCH DOCUMENTATION FOR THE ABOVE LISTED LOT OF PRODUCT HAS BEEN REVIEWED AND ALL ASPECTS OF THE MANUFACTURING AND PACKAGING WERE JUDGED ACCEPTABLE AND CONSISTENT WITH THE REQUIREMENTS OUTLINED IN THE EUA AND MASTER MANUFACTURING DOCUMENTS. ALL MANUFACTURING DEVIATIONS HAVE BEEN THOROUGHLY REVIEWED AND APPROVED.

ALL ACTIVITIES ARE PERFORMED BY QUALIFIED PEOPLE, UNDER THE SUPERVISION OF THE QUALIFIED PERSON.

[redacted]