



# 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: FP1430

Date Generated: 09-Dec-2021

Product Name: BNT162 Tris/Sucrose, 10 mcg/0.2 mL Suspension for Intramuscular Injection (PF07302048  
0.1mg/ml 10x1.3ml GVL PU BNT)

Material Number: F000054450

Date of Manufacture: 22/10/2021

Expiration Date: 31/03/2022

Importing Country: All countries that accepted Emergency Use Application

REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
<b>COMPOSITION AND STRENGTH</b>		
<b>Appearance (Visual)</b> Appearance	White to off-white suspension	MEETS TEST
<b>Appearance (Particles)</b> Visible Particulates	May contain white to off-white opaque, amorphous particles	MEETS TEST
<b>Subvisible Particulate Matter</b> Subvisible particles	Particles $\geq 10 \mu\text{m}$ : $\leq 6000$ per container Particles $\geq 25 \mu\text{m}$ : $\leq 600$ per container	11 Particles $\geq 10 \mu\text{m}$ per container 0 Particles $\geq 25 \mu\text{m}$ per container
<b>Potentiometry</b> pH	7.4 +/- 0.5	7.5
<b>Osmometry</b> Osmolality	320 +/- 80 mOsmol/kg	358 mOsmol/kg
<b>Dynamic Light Scattering (DLS)</b> LNP Size LNP Polydispersity	56 - 101 nm $\leq 0.3$	68 nm 0.2
<b>Fluorescence assay</b> RNA Encapsulation RNA Content	$\geq 85\%$ 0.100 +/- 0.026 mg/mL	97 % 0.087 mg/mL
<b>HPLC-CAD</b> ALC-0315 Content ALC-0159 Content DSPC content Cholesterol content	0.90 – 1.85 mg/mL 0.11 – 0.24 mg/mL 0.18 – 0.41 mg/mL 0.36 – 0.78 mg/mL	1.25mg/mL 0.17 mg/mL 0.30 mg/mL 0.58 mg/mL
<b>Container content</b> Vial content (volume)	Not less than 1.222 mL	$\geq 1.222$ mL
<b>IDENTITY</b>		
<b>HPLC-CAD</b> Lipid identities	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)	MEETS TEST
<b>RT-PCR</b> Identity of encoded RNA sequence	Identity confirmed	MEETS TEST

REGISTERED TESTS	ACCEPTANCE CRITERIA	RESULT
<b>POTENCY</b>		
Cell-based Flow Cytometry In Vitro Expression	≥ 30% cells positive	66 %
<b>PURITY</b>		
Capillary Gel Electrophoresis RNA Integrity	≥ 58% intact RNA	65 %
<b>ADVENTITIOUS AGENTS</b>		
Endotoxin (LAL) Bacterial endotoxin	≤ 12.5 EU/mL	<5.00 U/mL
Sterility Sterility	No growth detected	NO GROWTH DETECTED

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.

**Prepared by:**

Name: Tine Verlinde

Title: QP Trainee

Signature: 

Date: 09/12/2021

**Approved by:**

Name: 

Title: QP delegate

Signature: 

Date: 10/12/2021

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