



**Reason for Submission  
For Release**

cc: STN 125742-36/2229/FC

Lot Number: FW1333

License Name of Product: COVID-19 mRNA Vaccine (nucleoside modified)

Formulation: Tris/Sucrose

**Manufacturer Name:** Pharmacia & Upjohn, Company LLC for BioNTech Manufacturing GmbH

**Manufacturer Address:** 7000 Portage Rd., Kalamazoo, MI 49001 USA

**Trade name:** COMIRNATY

**Date of Manufacturing:** 04-Feb-2022

**Expiration Date:** 31-Oct-2022

**Fill Information**

<b>Container Type:</b>	Vial	<b>Volume per container:</b>	2.25 mL
<b>Approved Storage Period:</b>	9 months	<b>Storage Temperature:</b>	-90°C to -60°C
<b>Number of containers manufactured:</b>	(b) (4)	<b>Number of Doses per container:</b>	10
<b>Number of containers for release:</b>	(b) (4)		
<b>Volume of single human dose:</b>	30 µg/Dose	<b>Start Date of period of Validity:</b>	Date of Manufacture

All tests conducted on this lot are reported and pass specifications as required.

(b) (6)  
Signature: \_\_\_\_\_  
Title: (b) (6)  
Electronic Protocol # - 20229005.P0 ✓

Date: 19-APR-2022

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**Date of Manufacture:** 04-Feb-2022

**Date of Expiry:** 31-Oct-2022

**Date of Fill:** 05-Feb-2022

**Product Information:**

**Drug Substance Target Concentration:** (b) (4) mg/mL

**COMPONENTS**

Component Description	Batch Number	Date of Manuf.	Manufacture Site	Quantity
BNT162b2 Drug Substance	(b) (4)	(b) (4)	Pfizer Andover	(b) (4)
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LNP Fabrication and Bulk Drug Product Formulation	(b) (4)		Pharmacia & Upjohn Company LLC	(b) (4)
Drug Product Filling/Inspection	(b) (4)		Pharmacia & Upjohn Company LLC	(b) (4)
Drug Product Packaging	FW1333		Pharmacia & Upjohn Company LLC	(b) (4)