



**Reason for Submission
For Release**

cc: STN 125742-36/2229/FC

Lot Number: FW1330

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: 26-Jan-2022

Expiration Date: 30-Sep-2022

Fill Information

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

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

(b) (6)
Signature: _____
Title: (b) (6)
Electronic Protocol # - 20229001.P0

Date: 24-FEB-2022

cc: STN 125742-36/2229/FC

Lot Number: FW1330

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

Formulation: Tris/Sucrose

Manufacturing Site: Pharmacia & Upjohn Company LLC, 7000 Portage Rd., Kalamazoo, MI 49001 USA

Date of Manufacture: 26-Jan-2022

Date of Expiry: 30-Sep-2022

Date of Fill: 28-Jan-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)
LNP Production and Bulk Drug Product Formulation	(b) (4)		Pharmacia & Upjohn Company LLC	(b) (4)
Drug Product Fill/Inspection	(b) (4)		Pharmacia & Upjohn Company LLC	(b) (4)
Drug Product Packaging	FW1330		Pharmacia & Upjohn Company LLC	(b) (4)