# 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: | $-90^{\circ} \mathrm{C}$ to $-60^{\circ} \mathrm{C}$ |
| Number of containers manufactured: | (b) (4) | Number of Doses per <br> container: | 10 |
| Number of containers for release: | (b) (4) | $30 \mu \mathrm{~g} /$ Dose | Start Date of period of <br> Validity: |
| Volume of single human dose: | Date of <br> Manufacture |  |  |

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

Signature: $\qquad$
$\qquad$ Date: 24-FES-2022
Title: Manager, Quáality Operatigns
Electronic Protocol \#-20229001.P0
ce: $\operatorname{STN} 125742-36 / 2229 / \mathrm{FC}$

Lot Number: FW1330
License Name of Prodact: 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) | 10 -Oct-2021 | Pfizer Andover | (b) (4) |
| LNP Production and Bulk <br> Drug Product Formulation | (b) (4) | 26 -Jan-2022 | Pharmacia \& Upjohn <br> Company LLC | (b) (4) |
| Drug Product Fill/Inspection | (b) (4) | 26-Jan-2022 | Pharmacia \& Upiohn <br> Company LLC | (b) (4) |
| Drug Product Packaging | FW1330 | 26-Jan-2022 | Pharmacia \& Upjohn <br> Company LLC | (b) (4) |

