Date: 18 Aug 21

Subject: Electronic Protocol Signature Page

License No.: 2229
Company Name: Pharmacia & Upjohn Company LLC for BioNTech Manufacturing GmbH

Pharmacia & Upjohn Company LLC for BioNTech Manufacturing GmbH hereby submits the following lot as an electronic submission by Electronic Submissions Gateway (ESG). All tests conducted on this lot are reported and pass specifications as required.

**COVID-19 Vaccine, mRNA**

<table>
<thead>
<tr>
<th>STN</th>
<th>Lot Number</th>
<th>Lot Type</th>
<th>Filename</th>
</tr>
</thead>
<tbody>
<tr>
<td>125742_0</td>
<td>FE3592</td>
<td>FC</td>
<td>20219002.PC1</td>
</tr>
</tbody>
</table>

Sample Status
- Sample Not Required
- Sample Submitted with Protocol
- Sample Previous Submitted: 16-Aug-2021

Virus Verification

<table>
<thead>
<tr>
<th>Software Name: Symantec Web Security Service</th>
<th>Version: 7.2.1</th>
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<tbody>
<tr>
<td>Company Name: Symantec</td>
<td></td>
</tr>
<tr>
<td>Date of Definitions: 16-Aug-2021</td>
<td>Date of Scan: 16-Aug-2021</td>
</tr>
</tbody>
</table>

I certify that the submission is virus-free.
The approximate file size of this submission is 1.25MB.

Comments:
The following corrections were made:
1) The reason for submission designation included on the top right of page 1 of the protocol.
2) The proper name of the product stated on the electronic protocol signature.
3) Inclusion of cc: STN 125742-0/2229/FC on page 7 & 13 of the protocol

Signature of Authorized Official
Printed Name and Title of Signatory Title

REASON: I approve this document.

(b)(6) 18 Aug 2021 08:57:050-0400
cc: STN 125742-0/2229/FC
Lot Number: FE3592
License Name of Product: COVID-19 mRNA Vaccine (nucleoside modified)

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: 30-Jun-2021 Expiration Date: 30-Nov-2021

Fill Information

<table>
<thead>
<tr>
<th>Container Type:</th>
<th>Via 1</th>
<th>Volume per container:</th>
<th>0.45mL</th>
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</thead>
<tbody>
<tr>
<td>Approved Storage Period:</td>
<td>6 months</td>
<td>Storage Temperature:</td>
<td>-90°C to -60°C</td>
</tr>
</tbody>
</table>

(b) (4)

Number of containers manufactured:

(b) (4)

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.

REASON: I approve this document.

Signature: _______________ Date: _______________
Title: (b) (6) Electronic Protocol # - 20219002.PCI
Lot Number: FE3592

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

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

Date of Manufacture: 30-Jun-2021  
Date of Expiry: 30-Nov-2021

Date of Fill: 30-Jun-2021

Product Information:

<table>
<thead>
<tr>
<th>Component Description</th>
<th>Batch Number</th>
<th>Date of Manuf.</th>
<th>Manufacture Site</th>
<th>Quantity</th>
<th>Target Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>BNT162b2 Drug Substance</td>
<td>(b) (4)</td>
<td>(b) (4)</td>
<td>Pfizer (b) (4)</td>
<td>(b) (4)</td>
<td></td>
</tr>
<tr>
<td>BNT162b2 Drug Substance</td>
<td></td>
<td></td>
<td>Pfizer (b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LNP Fabrication</td>
<td>(b) (4)</td>
<td></td>
<td>Pharmacia &amp; Upjohn Company LLC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formulated Bulk Batch</td>
<td>30-Jun-2021</td>
<td></td>
<td>Pharmacia &amp; Upjohn Company LLC</td>
<td></td>
<td></td>
</tr>
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</table>
Table 1. Filled Vaccine Quality Control Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Test Method</th>
<th>Specification</th>
<th>Date of Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Appearance (Visual)</td>
<td>White to off-white suspension</td>
<td>(b) (4)</td>
<td>MEETS TEST</td>
</tr>
<tr>
<td>Appearance (Visible Particulates)</td>
<td>Appearance (Particles)</td>
<td>May contain white to off-white opaque amorphous particles</td>
<td>(b) (4)</td>
<td>MEETS TEST</td>
</tr>
<tr>
<td>Subvisible Particles</td>
<td>Subvisible Particulate Matter</td>
<td></td>
<td>(b) (4)</td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td></td>
<td></td>
<td>(b) (4)</td>
<td>6.9 - 7.9</td>
</tr>
<tr>
<td>Osmolality</td>
<td>Osmometry</td>
<td></td>
<td>(b) (4)</td>
<td>mOsmol/kg</td>
</tr>
<tr>
<td>LNP Size</td>
<td>Dynamic Light Scattering (DLS)</td>
<td></td>
<td>(b) (4)</td>
<td>nm</td>
</tr>
<tr>
<td>LNP Polydispersity</td>
<td>Dynamic Light Scattering (DLS)</td>
<td></td>
<td>(b) (4)</td>
<td></td>
</tr>
<tr>
<td>RNA Encapsulation</td>
<td>Fluorescence assay</td>
<td></td>
<td>(b) (4)</td>
<td>%</td>
</tr>
<tr>
<td>RNA content</td>
<td>Fluorescence assay</td>
<td></td>
<td>(b) (4)</td>
<td>mg/mL</td>
</tr>
<tr>
<td>ALC-0315 content</td>
<td>HPLC-CAD</td>
<td></td>
<td>(b) (4)</td>
<td>mg/mL</td>
</tr>
<tr>
<td>ALC-0159 content</td>
<td>HPLC-CAD</td>
<td></td>
<td>(b) (4)</td>
<td>mg/mL</td>
</tr>
<tr>
<td>DSPC content</td>
<td>HPLC-CAD</td>
<td></td>
<td>(b) (4)</td>
<td>mg/mL</td>
</tr>
<tr>
<td>Cholesterol content</td>
<td>HPLC-CAD</td>
<td></td>
<td>(b) (4)</td>
<td>mg/mL</td>
</tr>
<tr>
<td>Vial content</td>
<td>Container Content</td>
<td></td>
<td>(b) (4)</td>
<td>mL</td>
</tr>
<tr>
<td>Lipid identities</td>
<td>HPLC-CAD</td>
<td>Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)</td>
<td></td>
<td>Positive</td>
</tr>
</tbody>
</table>
cc: STN 125742-0/2229/FC

Lot Number: FE3592

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

Table 1 (Continued) Filled Vaccine Quality Control Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Test Method</th>
<th>Specification</th>
<th>Date of Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identity of encoded RNA sequence</td>
<td>RT-PCR</td>
<td>Identity confirmed</td>
<td>(b) (4)</td>
<td>Positive</td>
</tr>
<tr>
<td>In Vitro Expression</td>
<td>Cell-based Flow Cytometry</td>
<td>% Cells Positive</td>
<td>(b) (4)</td>
<td></td>
</tr>
<tr>
<td>RNA Integrity</td>
<td>Capillary Gel Electrophoresis</td>
<td>% intact RNA</td>
<td>(b) (4)</td>
<td></td>
</tr>
<tr>
<td>Bacterial Endotoxin</td>
<td>Endotoxin (LAL)</td>
<td>EU/mL</td>
<td>(b) (4)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: LNP = Lipid nanoparticles; CAD = charged aerosol detector; RT-PCR = reverse transcription polymerase chain reaction; LAL = Limulus amebocyte lysate; EU = endotoxin unit

Filled Vaccine Quality Control Tests (cont.)

Sterility

Method: (b) (4)  
Type: Final Container

<table>
<thead>
<tr>
<th>Date On Test</th>
<th>Medium/Temperature</th>
<th>Date Off Test</th>
<th>Specification</th>
<th>Test Result</th>
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</thead>
<tbody>
<tr>
<td>(b) (4)</td>
<td>(b) (4)</td>
<td></td>
<td>No growth observed</td>
<td>No growth observed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No growth observed</td>
<td>No growth observed</td>
</tr>
</tbody>
</table>

DocUUID: 62ef52b2-1b0d-4987-b89c-36af069cc96f
Lot Number: FE3592

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

Filled Vaccine Quality Control Tests (Continued)

<table>
<thead>
<tr>
<th>Lipid Identity</th>
<th>Specification</th>
<th>Limit</th>
<th>Result</th>
<th>Pass</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALC-0315 content</td>
<td>Standard Retention Times (RT)</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALC-0159 content</td>
<td>Sample Retention Time</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DSPC content</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Cholesterol content</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Lot Number: FE3592

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

### Filled Vaccine Quality Control Tests (Continued)

**RNA encapsulation and content test**

<table>
<thead>
<tr>
<th>Test date</th>
<th>(b) (4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test method</td>
<td>TM8940A</td>
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<tr>
<td>Specification: RNA Encapsulation</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>Specification: Content RNA Content</td>
<td>(b) (4) mg/mL</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample/Control</th>
<th>Acceptance Criteria</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>R² for Standard A</td>
<td>(b) (4)</td>
<td></td>
</tr>
<tr>
<td>R² for Standard B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total RNA (mg/mL)</td>
<td></td>
<td>(b) (4)</td>
</tr>
<tr>
<td>Encapsulated RNA (mg/mL)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

cc: STN 125742-0/2229/FC
Lot Number: FE3592
License Name of Product: COVID-19 mRNA Vaccine (nucleoside modified)

Filled Vaccine Quality Control Tests (Continued)

Identity of encoded RNA sequence test

<table>
<thead>
<tr>
<th>Test method</th>
<th>RT-PCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test date</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>Specification</td>
<td>Identity confirmed</td>
</tr>
<tr>
<td>Result</td>
<td>Positive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample/Control</th>
<th>Lot number</th>
<th>Replicate</th>
<th>Ct value</th>
<th>Acceptance criteria</th>
<th>Pass/Fail</th>
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<tbody>
<tr>
<td>DP Sample</td>
<td>FE3592</td>
<td>1</td>
<td>(b) (4)</td>
<td></td>
<td>Pass</td>
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<td></td>
<td></td>
<td>2</td>
<td></td>
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<tr>
<td></td>
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<td>3</td>
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<tr>
<td>Positive PCR Control</td>
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<tr>
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<td>Positive Control</td>
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<td>Pass</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
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<td></td>
</tr>
<tr>
<td>Negative PCR Control</td>
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<td>1</td>
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<td></td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative Control</td>
<td>NA</td>
<td>1</td>
<td></td>
<td></td>
<td>Pass</td>
</tr>
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<tr>
<td></td>
<td></td>
<td>3</td>
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</table>
cc: STN 125742-0/2229/FC

Lot Number: FE3592

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

Filled Vaccine Quality Control Tests (Continued)

In Vitro Expression Assay

<table>
<thead>
<tr>
<th>Test date</th>
<th>LAB-38621</th>
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<tbody>
<tr>
<td>Test method</td>
<td>LAB-38621</td>
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</table>

<table>
<thead>
<tr>
<th>Specification</th>
<th>Acceptance Criteria</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (4) cells positive</td>
<td>(b) (4)</td>
<td>(b) (4)</td>
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<tr>
<td>Positive Control lot number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% cell viability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average Number of Cells Counted for Sample</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Result (% positive cells)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
cc: STN 125742-0/2229/FC

Lot Number: FE3592

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

Filled Vaccine Quality Control Tests (Continued)

Limulus Amebocyte Lysate Test

(b) (4)

Calculations or additional comments
N/A
Lot Number: FE3592

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

BNT162b2 Drug Substance

Lot Number: (b) (4)

Date of Manufacture: (b) (4)  Date of Expiry: (b) (4)

Storage Temperature: -25°C to -15°C  Approved Storage Period: (b) (4) months

Consumed Quantity: (b) (4)

Table 1. Drug Substance Quality Control Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Test Method</th>
<th>Specification</th>
<th>Date of Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarity</td>
<td>Appearance (Clarity)</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coloration</td>
<td>Appearance (Coloration)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>(b) (4)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Content (RNA Concentration)</td>
<td>UV Spectroscopy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identity of Encoded RNA Sequence</td>
<td>RT-PCR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RNA Integrity</td>
<td>Capillary Gel Electrophoresis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5'- Cap</td>
<td>RP-HPLC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poly(A) Tail</td>
<td>ddPCR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residual DNA Template</td>
<td>qPCR</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Residual dsRNA</td>
<td>Immunoblot</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacterial Endotoxin</td>
<td>Endotoxin (LAL)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bioburden</td>
<td>Bioburden</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: NTU = Nephelometric Turbidity; ddPCR = droplet digital PCR; qPCR = quantitative PCR; dsRNA = double stranded RNA; LAL = Limulus amebocyte lysate; EU = endotoxin unit; CFU = colony forming unit
License Name of Product: COVID-19 mRNA Vaccine (nucleoside modified)

BNT162b2 Drug Substance

Lot Number: (b) (4)

Date of Manufacture: (b) (4)  
Date of Expiry: (b) (4)

Storage Temperature: -25°C to -15°C  
Approved Storage Period: 6 months

Consumed Quantity: (b) (4)

### Table 1. Drug Substance Quality Control Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Test Method</th>
<th>Specification</th>
<th>Date of Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarity</td>
<td>Appearance (Clarity)</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coloration</td>
<td>Appearance (Coloration)</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>(b) (4)</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Content (RNA Concentration)</td>
<td>UV Spectroscopy</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identity of Encoded RNA Sequence</td>
<td>RT-PCR</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RNA Integrity</td>
<td>Capillary Gel Electrophoresis</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5'-Cap</td>
<td>RP-HPLC</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poly(A) Tail</td>
<td>ddPCR</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residual DNA Template</td>
<td>qPCR</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residual dsRNA</td>
<td>Immunoblot</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacterial Endotoxin</td>
<td>Endotoxin (LAL)</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bioburden</td>
<td>Bioburden</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:** NTU = Nephelometric Turbidity chain reaction; ddPCR = droplet digital PCR; qPCR = quantitative PCR; dsRNA = double stranded RNA; LAL = Limulus amebocyte lysate; EU = endotoxin unit; CFU = colony forming unit
Genealogy Flowchart

Prepared By:

(b) (6)  
18 Aug 2021 10:58:042-0400

REASON: I approve this document.

Approved By:

(b) (6)  
18 Aug 2021 08:57:050-0400

REASON: I approve this document.
SAMPLE INFORMATION

(b) (4), (b) (6)