Item: F000051489
Title: PF-BNT 0.5MG/ML COVIDVX 25X2ML GVL EUA
Expiration Date: 31-Oct-2021
Date Of Manufacture: 29-May-2021
Specification: US EUA LIMIT

<table>
<thead>
<tr>
<th>TEST NAME</th>
<th>TEST METHOD</th>
<th>SPECIFICATION</th>
<th>UNITS</th>
<th>RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Appearance (Visual)</td>
<td>White to off-white suspension</td>
<td>None</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>None</td>
<td>Meets Test</td>
</tr>
<tr>
<td>Subvisible Particles</td>
<td>Subvisible Particulate Matter - USP &lt;787&gt;</td>
<td>(b) (4) particles/container</td>
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</tr>
<tr>
<td>pH</td>
<td>pH</td>
<td>7.4 ± 0.5</td>
<td>None mOsmol/kg</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>Osmolality</td>
<td>Osmometry – USP &lt;785&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LNP Size</td>
<td>Dynamic Light Scattering (DLS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LNP Polydispersity</td>
<td>Dynamic Light Scattering (DLS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RNA Content</td>
<td>Fluorescence assay</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RNA Encapsulation</td>
<td>Fluorescence assay</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALC-0315 Content</td>
<td>HPLC-CAD</td>
<td>Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)</td>
<td>None mg/mL</td>
<td>Positive</td>
</tr>
<tr>
<td>ALC-0159 Content</td>
<td>HPLC-CAD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DSPC Content</td>
<td>HPLC-CAD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol Content</td>
<td>HPLC-CAD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipid Identities</td>
<td>HPLC-CAD</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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### TEST NAME

- **Vial Content (Volume)**
  - **Test Method:** Container content
  - **Specification:** Not less than \( b \) \( \) \( 4 \) \( \) \ml
  - **Units:** mL
  - **Result:** \( b \) \( \) \( 4 \) Positive

- **Identity of Encoded RNA Sequence**
  - **Test Method:** RT-PCR
  - **Specification:** Identity confirmed
  - **Units:** None
  - **Result:** Positive

- **In Vitro Expression**
  - **Test Method:** Cell-based Flow Cytometry
  - **Specification:** \( b \) \( \) \( 4 \) \% cells positive
  - **Units:** \% intact RNA
  - **Result:** \( b \) \( \) \( 4 \)

- **RNA Integrity**
  - **Test Method:** Capillary Gel Electrophoresis
  - **Specification:** No growth detected
  - **Units:** None
  - **Result:** Meets Test

- **Bacterial Endotoxins**
  - **Test Method:** Endotoxin (LAL)
  - **Specification:** No growth detected
  - **Units:** EU/mL
  - **Result:** Meets Test

- **Sterility**
  - **Test Method:** Sterility
  - **Specification:** No growth detected
  - **Units:** None
  - **Result:** Meets Test

All documentation has been reviewed and found to be in compliance with the Master Production Documents and applicable Quality Agreements. The product meets specifications and was manufactured, packaged and tested under GMP conditions according to current approved control procedures.

Laura A Mroczek  
29 Jun 2021 21:11:042-0400

**REASON:** I approve this document.

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