Biopharmaceutical grade NM capsules are designed to be used for sterilizing grade filtration. The Nylon 6,6 membrane is optimized for retention. BNM capsule filter elements are 100% integrity tested during production.

BNM capsules see broad service in bioburden management for filling operations as well as for buffers, feedstocks, purified water, WFI, and other media.

Additional applications for BNM capsule filters include filtration of solvents, alcohols and other excipients. Nylon is particularly suited for the filtration of solvents because of its broad compatibility and low level of extractables.

### Construction Materials

- **Housing**: Polypropylene
- **Filtration Media**: Nylon 6,6 Membrane
- **Media Support**: Polypropylene
- **End Caps**: Polypropylene
- **Center Core**: Polypropylene
- **Outer Support Cage**: Polypropylene
- **Sealing Method**: Thermal Bonding

### Maximum Operating Parameters

- **Liquid Operational Pressure**: 80 psi (5.5 bar) at 20 °C (68 °F)
- **Gases Operational Pressure**: 60 psi (4.1 bar) at 20 °C (68 °F)
- **Operating Temperature**: 43 °C (110 °F) at 30 psi (2.1 bar) in water
- **Forward Differential Pressure**: 50 psid (3.4 bard) at 20 °C (68 °F)
- **Reverse Differential Pressure**: 40 psid (2.7 bard) at 20 °C (68 °F)
- **Recommended Changeout Pressure**: 35 psid (2.4 bard)

### Flow Rate / Filtration Area

The following table represents typical water flow at a one psi (69 mbar) pressure differential across a single 2 inch capsule 1.0 ft² (930 cm²) of media with 1/2” FNPT ports. The test fluid is water at ambient temperature. Higher pressure drops are acceptable, but as flows increase the pressure drop of the housing becomes more apparent.

<table>
<thead>
<tr>
<th>Pore Size</th>
<th>0.10 μm</th>
<th>0.22 μm</th>
<th>0.45 μm</th>
<th>0.65 μm</th>
</tr>
</thead>
<tbody>
<tr>
<td>GPM</td>
<td>0.14</td>
<td>0.25</td>
<td>0.43</td>
<td>0.60</td>
</tr>
<tr>
<td>LPM</td>
<td>0.53</td>
<td>0.95</td>
<td>1.63</td>
<td>2.27</td>
</tr>
</tbody>
</table>

* For approximate flow rates for 5” through 30” capsules, refer to the appropriate cartridge data sheet

### BNM Capsule Filters - Filtration Area

<table>
<thead>
<tr>
<th>Media</th>
<th>2”</th>
<th>5”</th>
<th>10”</th>
<th>20”</th>
<th>30”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nylon 6,6 Membrane</td>
<td>1.0 ft² (930cm²)</td>
<td>3.0 ft² (2788cm²)</td>
<td>7.0 ft² (6503cm²)</td>
<td>14.0 ft² (13006cm²)</td>
<td>21.0 ft² (19509cm²)</td>
</tr>
</tbody>
</table>

* For approximate flow rates for 5” through 30” capsules, refer to the appropriate cartridge data sheet

### Applications

- Buffers and Feedstocks
- WFI Water
- Solvents
- SVPs
- LVPs
- Vaccines

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Additional applications for BNM capsule filters include filtration of solvents, alcohols and other excipients. Nylon is particularly suited for the filtration of solvents because of its broad compatibility and low level of extractables.
Integrity Test Specifications

<table>
<thead>
<tr>
<th>Pore Size</th>
<th>Test Pressure (psi)</th>
<th>Max Diffusion Rate (cc/min - water wetted membrane)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2°</td>
</tr>
<tr>
<td>0.10</td>
<td>48</td>
<td>4.3</td>
</tr>
<tr>
<td>0.22</td>
<td>35</td>
<td>4.3</td>
</tr>
<tr>
<td>0.45</td>
<td>20</td>
<td>4.3</td>
</tr>
<tr>
<td>0.65</td>
<td>15</td>
<td>4.3</td>
</tr>
</tbody>
</table>

Integrity Test Specifications - Bubble Point

<table>
<thead>
<tr>
<th>Pore Size</th>
<th>Bubble Point (water wetted membrane)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.10 μm</td>
<td>**</td>
</tr>
<tr>
<td>0.22 μm</td>
<td>50 psig (3.5 barg)</td>
</tr>
<tr>
<td>0.45 μm</td>
<td>25 psig (1.7 barg)</td>
</tr>
<tr>
<td>0.65 μm</td>
<td>19 psig (1.3 barg)</td>
</tr>
</tbody>
</table>

** Test pressure exceeds operational limits of capsule filters. Use the diffusion test method.

Quality Assurance and Standards

Critical Process Filtration uses state-of-the-art computer controlled equipment to consistently produce high quality products as well as significantly reduce hand operations that can compromise quality. All manufacturing and testing is continuously monitored in real time so that data can be quickly and easily analyzed to facilitate improvements in both quality and cost.

The Critical Process Filtration manufacturing and quality systems meet rigorous ISO 9001:2008 standards. Each operation, including assembly, testing, cleaning, drying and packaging, is done in an appropriately rated clean room. Manufacturing is controlled using a sophisticated manufacturing system that networks work stations, manufacturing centers and inspection points. During the manufacturing and inspection processes, data is collected in real time to allow continuous quality monitoring and full traceability of all materials and processes.

Each capsule assembly is integrity tested before release.

Ordering Information

Capsule order number example: Biopharmaceutical Grade Nylon 6,6 Membrane, 0.22 Micron Rating, Pre-Sterilized, 10" Length, Sanitary Inlet, Sanitary Outlet = CPBNM-20S0001FF.

![Integrity Test Specifications](image)

![Integrity Test Specifications - Bubble Point](image)

![Quality Assurance and Standards](image)

![Ordering Information](image)

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