PNM capsules are designed to be used for sterilizing grade filtration. The high quality nylon membrane is optimized for retention. PNM capsule filter elements are 100% integrity tested during production.

Nylon capsules see broad service in sterile fill applications in SVPs and as bioburden management filters in LVPs. Media and service liquid filtration are other common applications for this membrane.

Additional applications for PNM capsule filters include final filtration of bulk pharmaceutical chemicals, USP Purified Water, Water for Injection (WFI), buffers, 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 with 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.
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>0.10</td>
<td>48</td>
<td>2.1 6.3 15 30 45</td>
</tr>
<tr>
<td>0.22</td>
<td>35</td>
<td>2.1 6.3 15 30 45</td>
</tr>
<tr>
<td>0.45</td>
<td>20</td>
<td>2.1 6.3 15 30 45</td>
</tr>
<tr>
<td>0.65</td>
<td>15</td>
<td>2.1 6.3 15 30 45</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.

Validation

PNM capsule filters are validated using test procedures based on ASTM Method F838-05 and HIMA protocols. The challenge level is 10³ organisms per cm² of filter media:

- 0.22 μm challenged with *Brevundimonas diminuta*;
- 0.45 μm challenged with *Serratia marcescens*;
- 0.65 μm challenged with *Saccharomyces cerevisiae*.

Critical Process Filtration can provide validation assistance.

Sanitization/Sterilization

** Autoclave ........................................ 250°F (121°C), 30 min, multiple cycles

** Chemical Sanitization ........................................

Nylon does not tolerate aggressive chemical sanitization protocols. Nylon membrane cartridges are best sanitized with 1% hydrogen peroxide or 1% hydrogen peroxide and peracetic acid. Follow the manufacturers instructions for use on nylon filter devices.

** Note ........................................ PNM capsules are not to be used in steam.

** Pre-Sterilized ........................................ PNM capsules are offered in both non- and pre-sterilized forms.

USP Biosafety and FDA Compliance

The materials used to construct pharmaceutical grade PNM capsule filters are non-toxic and meet the requirements for the MEM Elution Cytotoxicity Test and the Biological Reactivity Tests in the current version of the United States Pharmacopeia (USP) for Class VI - 121 °C Plastics. In addition, the materials meet the requirements listed by the FDA as appropriate for use in articles intended for repeated food contact as specified in Title 21 CFR sections 174.5, 177.1500, 177.1520, 177.1630, 177.2440, and 177.2600 as appropriate. PNM capsule filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters. The levels of bacterial endotoxins in aqueous extracts from pharmaceutical grade capsule filters are below current USP limits as specified for water for injection.

Extractables

Pharmaceutical grade filters typically exhibit low levels of non-volatile residues.

Total Performance

Critical Process Filtration, Inc. is a vertically integrated manufacturer of filtration products to industries in which filtration is considered a critical part of the manufacturing process. We supply a complete line of products and services to help you cost effectively satisfy all your filtration requirements from a single source.

Request a QUOTE from your area representative

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