PNC Capsule Filters

**Positively Charged Nylon 6,6 Membrane**

- Positively charged to enhance removal of particles smaller than the rated pore size
- Bacteria and endotoxin control in water, bulk chemicals
- Excellent throughput

**Applications**

- Dialysis water
- Medical device rinse water
- WFI water
- Endotoxin control

PNC Capsules are hydrophilic and manufactured with the highest quality charged Nylon 6,6 membrane. The capsules are sterilizing grade and the positive charge enhances its ability to remove particles smaller than its rated pore size, such as endotoxins in water streams or water based solutions. PNC capsule elements are 100% integrity tested during production.

PNC capsule filters are ideal for bacteria and endotoxin control in water systems, including WFI, rinse water for vials and other packaging, water-based bulk chemicals, and SVPs and LVPs.

PNC capsule filters are made using FDA listed Nylon 6,6 membrane layers and FDA listed polypropylene molded components. The filter materials passed all standard USP material safety tests for products used in the making of pharmaceutical products.

**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>0.18</td>
<td>0.43</td>
<td>0.79</td>
</tr>
<tr>
<td>LPM</td>
<td>0.53</td>
<td>0.68</td>
<td>1.63</td>
<td>2.99</td>
</tr>
</tbody>
</table>

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

**Construction Materials**

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

**PNC Capsule Filters - Filtration Area**

| Media | Capsule Length |
|-------|---|---|---|---|---|
| Charged Nylon 6,6 Membrane | 2” | 5” | 10” | 20” | 30” |
| 1.0 ft² (930cm²) | 3.0 ft² (2788cm²) | 7.0 ft² (6503cm²) | 14.0 ft² (13006cm²) | 21.0 ft² (19509cm²) |
PNC filters typically exhibit low levels of non-volatile residues. Extractables all materials and processes. “time” to allow continuous quality monitoring and full traceability of manufacturing and inspection processes, data is collected in “real time” so that data can be quickly and easily analyzed to facilitate quality. All manufacturing and testing is continuously monitored in real time. Critical Process Filtration can provide validation assistance.

### Integrity Test Specifications - Bubble Point

<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 μm</td>
<td>48</td>
<td>2.1 6.3 15 30 45</td>
</tr>
<tr>
<td>0.22 μm</td>
<td>35</td>
<td>2.1 6.3 15 30 45</td>
</tr>
<tr>
<td>0.45 μm</td>
<td>20</td>
<td>2.1 6.3 15 30 45</td>
</tr>
<tr>
<td>0.65 μm</td>
<td>15</td>
<td>2.1 6.3 15 30 45</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 PNC capsule assembly is integrity tested before release.

### Extractables

PNC filters typically exhibit low levels of non-volatile residues.

### Ordering Information

Capsule order number example: Pharmaceutical Grade, Charged Nylon 6,6 Membrane, 0.22 Micron Rating, Pre-Sterilized, 10” Length, Sanitary Inlet, Sanitary Outlet = CPPNC-2050001FF.

### 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>

### Validation

PNC capsules are validated using test procedures based on ASTM Method F838-05 and HIMA protocols. The challenge level is 10⁷ 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.

### Endotoxin Removal

PNC filters removed up to 99.9% of endotoxin when challenged with between 3EU/ml and 240EU/ml.

### 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 ..................................PNC capsules are not to be used in steam.

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

### USP Biosafety and FDA Compliance

The materials used to make PNC capsule filters are non-toxic and meet the requirements for the MEM Elution Cytotoxicity Test and the Biological Reactivity Tests 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. PNC 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.

### 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.

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