BNM Capsule Filters

Nylon 6,6 Membrane





Designed for sterilizing filtration

Optimized for retention

Final filtration of USP Purified Water and WFI, buffers

Bioburden reduction in SVPs and LVPs

Broad solvent compatibility

Applications

- ♦ Buffers and Feedstocks
- ♦ WFI Water
- **♦** Solvents

- SVPs
- ♠ LVPs
- ♦ Vaccines

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 it's broad compatibility and low level of extractables.

BNM Capsule Filters - Filtration Area

| Media | | Capsule Length | | | | |
|--------------------|---|--|--|--|--|--|
| Media 2" | 2" | 5″ | 10" | 20" | 30" | |
| Nylon 6,6 Membrane | 1.0 ft ² (930cm ²) | 3.0 ft ² (2788cm ²) | 7.0 ft ² (6503cm ²) | 14.0 ft ² (13006cm ²) | 21.0 ft ² (19509cm ²) | |

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 ft 2 (930 cm 2) 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.

| Pore Size | 0.10 μm | 0.22 μm | 0.45 μm | 0.65 μm |
|-----------|---------|---------|---------|---------|
| GPM | 0.14 | 0.25 | 0.43 | 0.60 |
| LPM | 0.53 | 0.95 | 1.63 | 2.27 |

^{*} For approximate flow rates for 5" through 30" capsules, refer to the appropriate cartridge data sheet

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) |

Integrity Test Specifications

| Pore Size | Test Pressure | (cc/m | Max [nin -wate | Diffusior er wette | | rane) |
|-----------|------------------|-------|--------------------|-----------------------|-----|-------|
| | (psi) | 2" | 5" | 10" | 20" | 30" |
| 0.10 | 48 | 4.3 | 12.9 | 30 | 60 | 90 |
| 0.22 | 35 | 4.3 | 12.9 | 30 | 60 | 90 |
| 0.45 | 20 | 4.3 | 12.9 | 30 | 60 | 90 |
| 0.65 | 15 | 4.3 | 12.9 | 30 | 60 | 90 |

Integrity Test Specifications - Bubble Point

| Pore Size | Bubble Point (water wetted membrane) | |
|-----------|---|--|
| 0.10 μm | ** | |
| 0.22 μm | 50 psig (3.5 barg) | |
| 0.45 μm | 25 psig (1.7 barg) | |
| 0.65 μm | 19 psig (1.3 barg) | |

^{**} 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

Biopharmaceutical grade NM capsule 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.

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.

.....BNM capsules are not to be used in steam. Pre-SterilizedBNM capsules are offered in both non- and pre-sterilized forms.

USP Biosafety and FDA Compliance

The materials used to construct biopharmaceutical grade NM 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. BNM 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 biopharmaceutical grade capsule filters are below current USP limits as specified for water for injection.

Extractables

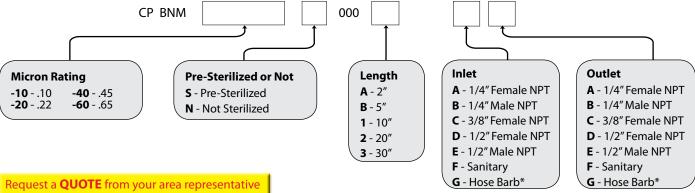
Biopharmaceutical grade filters typically exhibit low levels of nonvolatile residues.

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.

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.





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Hose Barb Diameter Ranges*

| | Minimum | Maximum |
|------------------------|----------------|-----------------|
| Outer Diameters | 11/32" (8.6mm) | 9/16" (14.0mm) |
| Inner Diameters | 5/32" (4.0mm) | 13/32" (10.5mm) |