CERTIFICATE OF QUALITY ASSURANCE

Pharmaceutical Grade Polyethersulfone Membrane Filter Cartridges

PRODUCT IDENTIFICATION
Model Number: PPS*20N00001S5
Lot Number: XXXXX-XX

PHYSICAL CHARACTERISTICS
Pore Size Rating: 0.22 Micron
Adapter Style: 2-222 / Flat
Nominal Length: 10 inches
Nominal Outer Diameter: 2.75”
Nominal Inner Diameter: 1.25”

MATERIALS OF CONSTRUCTION
Filter Media: Polyethersulfine Membrane Dual layered
Support Layers: Polypropylene
Cage & Core: Polypropylene
End Caps: Polypropylene
Adapters: 2-222 / Flat
Seal Elastomer: Silicone

RETENTION CHARACTERISTICS
Pharmaceutical Grade Filter Modules used in this order have been manufactured with media which characteristics include complete retention of brevundmonas diminuta at a challenge level of 10^7 organisms per cm^2 of filter media per a modified HIMA protocol. Further, representative cartridge modules have been validated to show equivalent retention characteristics.

STERILIZATION
Filtered Hot Water: ……90°C
Autoclave: ……..127°C, 30min multiple cycles
In-Line Steam: …..135°C, 30 min, multiple cycles
Chemical Sanitization: ……Industry Standard Concentration of hydrogen peroxide, paracetic acid, Sodium hypochlorite and other selected chemicals. Sanitization protocols designed to extend the useful life of Pharmaceutical Grade cartridges are available from Critical Process Filtration, Inc.

OPERATIONAL LIMITS
Max. Forw. Diff. Pressure: 50 psi (3.4 bar) at 20°C
Max. Rev. Diff. Pressure: 40 psi (2.7 bar) at 20°C

INTEGRITY TESTING
Pharmaceutical Grade Cartridge modules are factory tested for integrity before shipment.

INTEGRITY TEST SPECIFICATIONS (Per 10” inch length) (water wetted membrane)

Pore Size	Air Diffusion Rate
0.22	< 15 cc/min at 35 psi (2412)

USP BIOSAFETY
The materials used to construct Pharmaceutical Grade filters are non-toxic and meet the requirements for the MEM Elution Cytotoxicity Test and USP24 Plastic Class V1 121°C Test.

EXTRACTABLES
The levels of bacterial endotoxins in aqeous extracts from Pharmaceutical Grade Filters are typically below the USP24 limits defined in Water for Injection. Pharmaceutical Grade Filters typically exhibit low levels of non-volatile residues.

FDA COMPLIANCE
The materials used to construct Pharmaceutical Grade filters 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. PPS filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

QUALITY ASSURANCE
The Pharmaceutical Grade Filters of this batch were manufactured using current Good Manufacturing Practices under a quality management system that has met ISO 9001 standards. Each Pharaaceutical Grade Filter is assigned a lot code to ensure traceability of the data and materials used in the manufacturing process.

CRITICAL PROCESS FILTRATION, INC.

Phone: 603-880-4420
Fax: 603-880-4536
Web Site: www.criticalprocess.com
E-mail: sales@criticalprocess.com