

Millipore Express® SHC Hydrophilic Cartridge Filter

0.5/0.2µm Rated

Catalogue Number: CHGE02TS3

Lot Number: C9MN39769

Good Manufacturing Practices

This product was manufactured in a Millipore facility which adheres to Good Manufacturing Practices.

ISO® 9001 Quality Standard

This product was manufactured in a Millipore facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard.

100% Integrity Testing in Manufacturing

Each filter cartridge must pass the Millipore Integrity Test correlated to the *Brevundimonas diminuta* ASTM® F838 bacterial challenge test.

Validated Production Process

This product was fabricated using a validated manufacturing process. Principles of statistical process control and determinations of process capability have been applied to critical variables in the cartridge fabrication process. In process controls are used to assure stability of the process.

Alcohol Reference Test

Sterilizing-grade (0.2µm) hydrophilic Millipore Express SHC membrane is certified to a bubble point equal to or greater than 18.5 (1275 mbar) in a 70%/30% IPA/water mixture with nitrogen at 23° C.

Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

Bacterial Retention

Samples were quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration of 1×10^7 CFU/cm² using ASTM F838 methodology.

USP Bacterial Endotoxins

A cartridge aqueous extraction contains less than 0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.

Integrity

Samples tested on an automated integrity tester exhibited a water bubble point equal to or greater than 58.0 psig (4000 mbar) with air at 23° C.

Samples exhibited an air diffusional flow rate of less than or equal to 56.3 cc/min. per 20-inch cartridge at 40 psig (2758 mbar) in water at 23° C.

Thermal and Hydraulic Stress

Samples were steamed at 135° C for 30 minutes and maintained integrity after a forward stress to 100 psid (6895 mbar) and a reverse stress to 30 psid (2068 mbar).

Flow Rate and Pressure Drop

Cartridge samples met a maximum pressure drop of 2.9 psid (200 mbar) at 4 gpm (7.6 L/min) per 20-inch cartridge with clean water at 23° C.

USP Oxidizable Substances

Effluent meets the requirements for USP Sterile Water for Injection after a water flush of 4 liter per autoclaved 20-inch cartridge.

TOC/Conductivity

Samples exhibited less than 500 ppb TOC per USP <643> and less than 1.3 µS/cm per USP <645> after autoclaving and a WFI water flush of 40 liters per 20-inch cartridge at 25° C.

Quality Performance Criteria

This product was designed and manufactured to meet the following specifications.

Multiple Sterilization Cycles

Cartridge integrity was validated for the following in-line steam cycles.

25 forward cycles, 30 min., 135° C at ≤ 5 psid (340 mbar) or 22 forward cycles, 30 min., 135° C at ≤ 5 psid (340 mbar) and 3 reverse cycles, 30 min., 135° C at < 1 psid (69 mbar) or 3 forward cycles, 30 min., 135° C at less than or equal to 1.5 psid (1000 mbar)

Maximum Differential Pressure

Forward: 100 psid (6895 mbar) at 25° C
25 psid (1700 mbar) at 80° C
1.5 psid (1000 mbar) at 135° C

Reverse: 30 psid (2068 mbar) at 25° C
< 1 psid (69 mbar) at 135° C

Toxicity

Component materials were tested and meet the criteria for the USP <88> Biological Reactivity Tests for Class VI Plastics.

This product meets the requirements of the USP <88> Safety Test utilizing a 0.9% Sodium Chloride extraction.

This product is non-cytotoxic per USP Cytotoxicity MEM Elution test.

Indirect Food Additive

All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.182.

Non-Fiber Releasing

This product was manufactured with a Millipore Express SHC membrane which meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).



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