

Millipore Express® SHC Hydrophilic Cartridge Filter

0.5/0.2µm Rated

Catalogue Number: CHGE01TES

Lot Number: xxxxxxxxxx

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 *Brewandimonas 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 relative of a minimum *Brewandimonas 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 28.2 cc/min. per 10-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 2 gpm (7.6 L/min) per 10-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 2 liter per autoclaved 10-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 outgassing and a WFI water flush of 20 liters per 10-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
15 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 SHF membrane which meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).



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Jaffrey Quality Manager



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