

ChromaSorb™ Process Development Kit

Catalogue Number: CHRFA1PD09
Lot Number: C9DN90523
Membrane Lot No. 101708

Nominal Membrane Volume = 0.079ml

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

Component Materials Toxicity

Component materials were tested and meet the Criteria for the USP Class VI Biological Tests for Plastics.

Animal Origin Statement

The materials used to manufacture this product are not of animal origin.

European Pressure Equipment Directive

Millipore Corporation certifies that this product complies with the European Pressure Equipment Directive, 97/23/EC of 29 May 1997. This product has been classified under Article 3 § 3 of the Pressure Vessel Directive. It has been designed and manufactured in accordance with sound engineering practice to ensure safe use. In compliance with Article 3 § 3 of this Pressure Equipment Directive, this product does not bear the CE mark.

Quality Assurance Lot Release Criteria

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

Membrane BSA Capacity

Samples of the ChromaSorb membrane exhibited on average 50 mg/ml or greater BSA binding capacity at 0mM NaCl concentration

Membrane Extractable (TOC)

Samples of the ChromaSorb membrane demonstrate $\leq 10 \mu\text{g C} / \text{cm}^2$

Device Permeability

This product was tested for permeability and demonstrated a flow rate equal to or greater than 90 L/MH/psi

Device 100% Aerosol Integrity Test

Each ChromaSorb small scale 0.08 ml device has been aerosol tested and shown to be integral

Device Diffusion Test

This product was tested for integrity and shown by air water diffusion to have air flow less than or equal to 1.00 cc/min at 10 psid

Quality Performance Criteria

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

Device Extractable TOC

This product was tested for TOC extractable and exhibited 0.5 ppm or less of TOC after flush (post sanitization in Milli-Q® water flush at 1ml/min for 9 min)

Hydraulic Stress

This product was tested for hydraulic stress and exhibited integrity after pressurizing to 30 psid forward at 4:30° C and 5 psid reverse at 4:30° C.

Peter Eichert
Quality Manager

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