MILLIPORE

DATA SHEET

Durapore® CBR 0.2 µm Bioburden Reduction Filters

- *For fine filtration of deionized water, in vitro diagnostics, oral suspensions, bulk pharmaceutical solutions, and for media prefiltration*
- *Superior membrane for filtration processes requiring high throughputs and flow rates*
- *Controlled low bioburden for lower overall filtration costs and improved process economics*
- *Ideal for LVP bulk pharmaceutical product filtration*

Superior filters for controlled low bioburden levels in biopharmaceutical fluids

A trusted name in the industry for over 25 years, hydrophilic Durapore 0.2 µm polyvinylidene fluoride (PVDF) membrane offers consistent and reliable performance for bioburden reduction and particle removal. Hydrophilic Durapore CBR devices are ideal for clean processes due to low extractables, broad chemical compatibility and its non-fiber releasing properties.

Hydrophilic Durapore CBR 0.2 µm Bioburden Reduction filters are recommended for applications requiring bioburden reduction and small particle removal across a wide range of pharmaceutical and biological liquids and intermediate bulk pharmaceutical products. Typical applications for the Durapore CBR 0.2 µm filters include the filtration of diagnostics, diluents, bulk pharmaceutical products, serum, tissue culture media and media additives.

High Throughput Flow Rates

Durapore CBR 0.2 µm hydrophilic cartridge filters provide high throughput and flow rates with minimal differential pressure. Cartridges are robust, strong, resilient and are designed to withstand multiple steam-in-place cycles. Each Durapore CBR cartridge filter is integrity tested during the manufacturing process.

Code 7 and Code 0 connections are availabe to suit your application and housing needs.

Membrane Type

- Durapore 0.2 µm hydrophilic

Filter Format

- Cartridge filters

Recommended Applications

- Cell culture media
- Large volume parenterals (LVP's)
- Pharmaceutical bulk chemical solutions
- Bioprocessed protein solutions
- Biologicals
- Diagnostics
- Purified water
- Blood and serum fractions

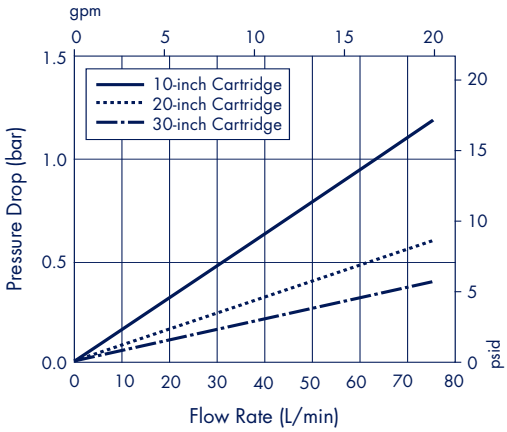
Specifications

	Cartridges (per 10-inch element)
Nominal Dimensions	
Outside diameter:	6.9 cm (2.7 in.)
Filtration Area	0.69 m^2 (7.4 ft^2)
Materials of Construction	
Filter membrane:	Hydrophilic PVDF
Film edge:	Polypropylene
Supports:	Polypropylene
Structural components:*	Polypropylene
O-rings:	Fluorocarbon rubber or silicone
Maximum Differential Pressure	
Forward:	5.5 bar (80 psid) at 25 °C, 1.75 bar (25 psid) at 80 °C, 345 mbar (5 psid) at 135 °C
Reverse:	3.4 bar (50 psid) at 25 °C, intermittent
Bubble Point at 23 °C	≥ 3100 mbar (45.0 psig) air with water
Air Diffusion	Through a water wet membrane at ambient temperature, at 2.8 bar (40 psig): ≤ 13.3 cc/min per 10-inch cartridge
Bacterial Retention	Samples of the Durapore membrane used in these cartridges are tested for bacterial retention and meet the criteria for sterilizing grade performance as defined by the ASTM® test method using *Brevundimonas diminuta* at a minimum challenge concentration of 1 x 10^7 CFU/cm^2.
Extractables	After 24 hour soak in 1 liter 18 megohm/cm water at controlled room temperature: ≤ 25 mg per 10-inch cartridge
Downstream Cleanliness/ Effluent Particle Level	After a 50 gallon flush at 2 gpm: ≤ 10 particles per liter (particle diameter ≥ 1.0 µm) per 10-inch cartridge
Resistivity Recovery	Effluent quality after a 15 gallon flush with > 16.5 megohm/cm water at 25 °C and at 1 gpm per 10-inch cartridge: ≥ 15 megohm/cm
Good Manufacturing Practices	These products are manufactured in a Millipore facility which adheres to FDA Good Manufacturing Practices.
Non-Fiber Releasing	Durapore membrane meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).
Component Material Toxicity	Component materials were tested and meet the criteria for the USP <88> Reactivity Tests for Class VI Plastics. This filter meets the requirements of the USP <88> Safety Test utilizing a 0.9% sodium chloride extraction.
Indirect Food Additive	The Durapore membrane used in these products meets the FDA Indirect Food Additive requirements cited in 21 CFR 177.2910. All other component materials also meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.

*Outer sleeve, core and end caps

Typical Clean Water Flow Rates

0.2 µm Hydrophilic Durapore (CVDI) Cartridge Filters



Regulatory Compliance

Filters with hydrophilic Durapore membrane are designed, developed, and manufactured in accordance with a Quality Management System approved by an accredited registering body to an ISO® 9000 Quality Systems Standard. A detailed Certificate of Quality is available on request. Each cartridge filter is integrity tested during manufacturing and is supported by a Validation Guide. For traceability and easy identification, each filter is labeled with the product name and identifying characteristics.

Ordering Information

Cartridge Filters

C	V	D	I			T	P	

Cartridge Filter

Membrane Type
V = Durapore

Pore Size
DI = 0.2 µm

Cartridge Code
0 = (2-222) O-ring
7 = (2-226) O-ring with locking tab and spear

Cartridge Length
1 = 10-inch
2 = 20-inch
3 = 30-inch
4 = 40-inch

Packaging Code
TP = 1/pk

O-ring Material
E = Fluorocarbon rubber
S = Silicone

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To Place an Order or Receive Technical Assistance

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