AcroPak™ 20 filters with 0.2 µm hydrophilic membranes

Instructions for Use

Introduction

Intended use

Cytiva Lab Filtration products are designed for professional laboratory applications only. These products are not approved for use in medical, clinical, surgical or other patient protection applications. They are also not suitable for use in Biopharmaceutical manufacturing or production.

Important

Employment of the products in applications not specified, or failure to follow all instructions contained in this Instructions for Use, can result in personal injury, damage to property or the product, or improper functioning of the product.

Background

Description

Ideal for filtering aqueous solutions, cell culture media and serum.

AcroPak™ 20 filters are designed to add convenience to small- and medium-volume filtration. Their unique design generates twice the effective filtration area and double the throughput and flow rate of conventional metal 47 mm reusable filter holders. They are disposable, which reduces the labor required for disassembly, cleaning, replacement of filtration membranes, reassembly, and integrity testing of reusable stainless steel filter holders. Use of the AcroPak 20 filters can significantly reduce the costs of repeat testing when scaling up your filtration system. The AcroPak 20 filters have the added benefit of being available sterile and non-sterile, non-pyrogenic, and integrity testable by the bubble point method.

Applications

AcroPak 20 with Fluorodyne™ II membrane

- Small batch sterile filtration of solutions containing dilute preservatives, proteins, or other critical components.

AcroPak 20 with Supor™ membrane

- Small batch sterile filtration of biologicals, culture media, and other difficult-to-filter fluids.

Instructions for use

Note: *Do not exceed the maximum operating parameters listed in the Specifications, on page 2.*

Note: *The AcroPak 20 filters are designed for single use only.*

Step	Action
1	Assemble filtration apparatus as shown in the figures below.

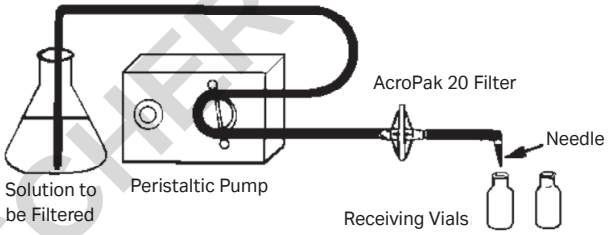


Fig 1. Filtration via peristaltic pump

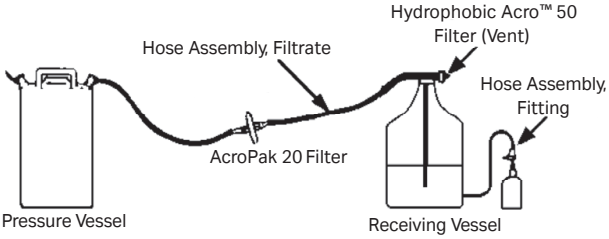


Fig 2. Small batch filtration

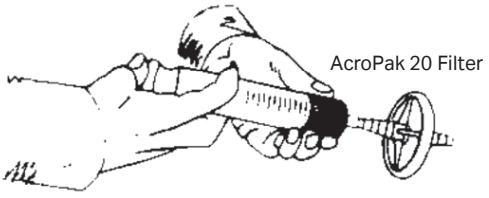


Fig 3. Syringe volume filtration

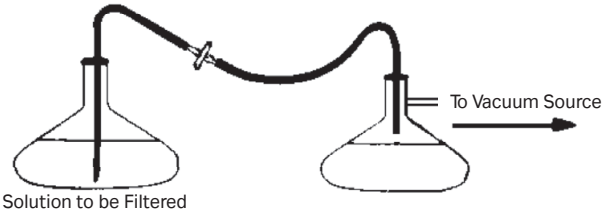


Fig 4. Vacuum filtration

Integrity testing

Filter integrity confirmation is recommended before and after filtration using standard techniques. See Specifications, on page 2 for appropriate bubble point in water.

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Wetting procedure – (pre-use)

To make sure the test is valid, all membrane pores must be fully wetted with liquid prior to applying air test pressure. The flushing procedure below is designed to make sure wetting is adequate.

Step	Action
1	Orient the filter vertically with the outlet port pointed up and the inlet port (side with the bleed valve) pointed down.
2	Starting with low pressure (< 0.3 bar, 30 kPa, 5 psi), carefully initiate liquid flow.
3	Gradually increase liquid pressure to a minimum of 1.0 bar (100 kPa, 15 psi) and pass a minimum of 50 mL of wetting solution through the filter.
4	Release the liquid pressure and disconnect the flow source.

Bubble point test – (pre-use)

Filter must be fully wetted.

Step	Action
1	Apply a compressed air source to the filter on the inlet side and increase the pressure to one psi below the recommended minimum bubble point listed in *Specifications, on page 2*.
2	Wait 30 seconds and place the filter outlet under water (either directly or via a connected length of tubing). Any evidence of air flow (bubbles) indicates a bubble point failure. Integral filters must show no visible bubbling. ***Note:*** *Exceeding the minimum bubble point specification during pre-use testing may result in reduced liquid flow due to air blockage.*
3	After the test, carefully relieve the pressure before disassembling the equipment.

Bubble point test (post-use only)

Step	Action
1	Orient the filter vertically with the inlet port (side with the bleed valve) pointed up and the outlet port pointed down (reverse of initial wetting procedure).
2	Introduce water into the filter to displace the remaining fluid after filtration. Avoid introduction of air. Air bubbles can be displaced by opening the upstream bleed valve during liquid flow.
3	Gradually increase liquid pressure to a minimum of 1.0 bar (100 kPa, 15 psi) and pass a minimum of 50 mL of wetting solution through the filter.
4	Apply a compressed air source to the filter on the inlet side and increase the pressure to one psi below the recommended minimum bubble point listed in *Specifications, on page 2*.
5	Wait 30 seconds and place the filter outlet under water (either directly or via a connected length of tubing). Any evidence of airflow (bubbles) indicates a bubble point failure. Integral filters must show no visible bubbling.
6	After the test, carefully relieve the pressure before disassembling the equipment. ***Note:*** *Alternate testing methodology can be used as determined appropriate by the filter user.* ***Note:*** *Testing of small area filters such as AcroPak 20 using automated filter integrity test instruments requires modified protocols. For further information and recommendations, contact your local Cytiva representative.*

Specifications

Parameter	Specification
Materials of construction	Filter media: Fluorodyne II membrane (hydrophilic PVDF) Supor membrane (hydrophilic polyethersulfone) Supor EKV membrane (hydrophilic polyethersulfone) Housing, vent plug, and filter support: Polypropelene Sealing technology: Thermal bonding Filling bell: Polycarbonate
Effective filtration area	20 cm^2
Dimensions (nominal)	Housing length: 8.3 cm (3.3 in.) Housing diameter: 6.7 cm (2.7 in.)
Inlet and outlet connections	6.4 to 12.7 mm (¼ to ½ in.) diameter stepped hose barb with female luer slip interior and filling bell outlet
Maximum operating pressure and temperature	4.1 bar (410 kPa, 60 psi) at 21°C to 24°C (70 to 75 °F) 1.0 bar (100 kPa, 15 psi) at 60°C (140 °F)
Recommended integrity test	Minimum bubble point - water 12201: 3.2 bar (320 kPa, 46 psi) 12202 and 12203: 3.5 bar (350 kPa, 51 psi) 12247: 3.32 bar (332 kPa, 48 psi)
Typical water flow rate in mL/min at 0.1 bar (10 kPa) [mL/min/psi]	12201: 26 [18] 12202 and 12203: 40 [28] 12247: check Cytiva website for product details
Typical hold-up volume	≤ 2.5 mL
Bacterial retention	Lot samples retain a minimum 10^7 cfu/cm^2 of *B. diminuta* per modified ASTM F838, current revision
Endotoxin	< 0.25 EU/mL using Limulus Amebocyte Lysate (LAL) test

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Parameter	Specification
Autoclave stability	12202 and 12203: can withstand one autoclave cycle at 131°C (268 °F) for 30 min 12200, 12201, 12246 and 12247: autoclave once at 125°C (257 °F) for 60 minutes; water wet capsule prior to autoclaving
Sterilization	PN 12201, 12203 and 12247 sterilized by gamma irradiation and individually packaged

Chemical compatibility

Chemical compatibility data can be obtained by contacting Cytiva.

Ordering information

Part number	Description	Pkg
12201	AcroPak 20 with Fluorodyne II membrane, 0.2 µm, 20 cm^2 EFA, sterile	3/pkg
12202	AcroPak 20 with Supor membrane, 0.8/0.2 µm, 20 cm^2 EFA, non-sterile	3/pkg
12203	AcroPak 20 with Supor membrane, 0.8/0.2 µm, 20 cm^2 EFA, sterile	3/pkg
12247	AcroPak 20 with Supor EKV membrane, 0.2 µm, 20 cm^2 EFA, sterile	3/pkg

Complementary products

Part number	Description	Pkg
12069	AcroPak 200 capsule with Fluorodyne II membrane, 0.2 µm, 200 cm^2 EFA, sterile	3/pkg
12941	AcroPak 200 capsule with Supor membrane, 0.8/0.2 µm, 200 cm^2 EFA, sterile	3/pkg
12991	AcroPak 500 capsule with Supor membrane, 0.8/0.2 µm, 500 cm^2 EFA, sterile	1/pkg
12992	AcroPak 1000 capsule with Supor membrane, 0.8/0.2 µm, 1000 cm^2 EFA, sterile	1/pkg
12675	AcroPak 1500 capsule with Supor membrane, 0.8/0.2 µm, 1500 cm^2 EFA, sterile	1/pkg

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