PALL Life Sciences

AcroPak™ 500, 1000 & 1500 Sterile Capsules with Supor® Membrane

Description

AcroPak Capsules with Supor Membrane are specifically designed for the most critical applications where a double layer of membrane is required. With identical double layer configuration of Supor membrane, these capsules offer retention of *B. diminuta*[1,2] and Mycoplasma species[3]. With a built-in prefilter, AcroPak Capsules save time and money by increasing throughput[2]. In addition to the high throughput nature of the patented Supor membrane, these capsules are manufactured using fusion technology. This minimizes the number of structural components and eliminates the potentially harmful extractables that may be released from uncured sealing adhesives.

Ordering Information

Prod. No.	Product	Pore Size	EFA
12991	AcroPak 500 (sterile)[2]	0.8/0.2 µm	500 cm²
12992	AcroPak 1000 (sterile)[2]	0.8/0.2 µm	1000 cm²
12675	AcroPak 1500 (sterile)[2]	0.8/0.2 µm	1500 cm²
12993	AcroPak 500 (sterile)[2]	0.8/0.45 µm	500 cm²
12994	AcroPak 1000 (sterile)[2]	0.8/0.45 µm	1000 cm²
12995	AcroPak 500 (sterile)[1]	0.2/0.2 µm	500 cm²
12996	AcroPak 1000 (sterile)[1]	0.2/0.2 µm	1000 cm²
12686	AcroPak 1500 (sterile)[1]	0.2/0.2 µm	1500 cm²
12997	AcroPak 500 (sterile)[3]	0.1/0.1 µm	500 cm²
12999	AcroPak 1000 (sterile)[3]	0.1/0.1 µm	1000 cm²

[1] formerly CritiCap™ capsules
[2] formerly SuporCap™ capsules
[3] formerly CritiCap-M capsules

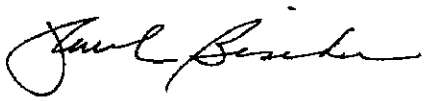
Certification

Pall Life Sciences certifies that this lot meets or exceeds the specifications listed below.

Part Number:

Lot Number:

Date:



Paul Bischer, Manufacturing Quality Assurance Manager

Specifications

Materials of Construction
Filter Media: Supor (hydrophilic polyethersulfone)
Capsule Construction: Polypropylene
Filling Bell: Polycarbonate (no filling bell on 12675 or 12686)
Sealing Methods: Thermal Bonding
Diameter: 6.9 cm (2.7 in)

Minimum Bubble Point
(60% isopropanol/40% water):
0.1 µm ≥ 2.4 bar (35 psi)

(Water):
0.2 µm ≥ 3.5 bar (51 psi)
0.45 µm ≥ 1.7 bar (24 psi)

Forward Flow
(in water):
0.1/0.1 (500 cm²) < 2.0 cc/min. at 3.4 bar (50 psi)
0.1/0.1 (1000 cm²) < 4.0 cc/min. at 3.4 bar (50 psi)
0.2/0.2 (500 cm²) < 1.5 cc/min. at 3.1 bar (45 psi)
0.2/0.2 (1000 cm²) < 3.0 cc/min. at 3.1 bar (45 psi)
0.2/0.2 (1500 cm²) <3.5 cc/min. at 3.1 bar (45psi)

Specifications (cont.)

Typical Water Flow Rates
0.1/0.1 (500 cm²) 0.2 Lpm/0.1 bar (0.2 Lpm/psi)
0.1/0.1 (1000 cm²) 0.4 Lpm/0.1 bar (0.3 Lpm/psi)
0.2/0.2 (500 cm²) 0.6 Lpm/0.1 bar (0.4 Lpm/psi)
0.2/0.2 (1000 cm²) 1.1 Lpm/0.1 bar (0.8 Lpm/psi)
0.2/0.2 (1500 cm²) 1.6 Lpm/0.1 bar (1.1 Lpm/psi)
0.8/0.2 (500 cm²) 1.1 Lpm/0.1 bar (0.8 Lpm/psi)
0.8/0.2 (1000 cm²) 1.6 Lpm/0.1 bar (1.1 Lpm/psi)
0.8/0.2 (1500 cm²) 2.2 Lpm/0.1 bar (1.5 Lpm/psi)
0.8/0.45 (500 cm²) 1.3 Lpm/0.1 bar (0.9 Lpm/psi)
0.8/0.45 (1000 cm²) 2.5 Lpm/0.1 bar (1.7 Lpm/psi)

Bacterial Retention
AcroPak™ 500 & 1000 Capsules with Supor® Membrane, 0.1 µm: lot samples retain 10^7/cm² of *A. laidlawii* per modified ASTM F838-83. AcroPak 500, 1000 & 1500 Capsules with Supor Membrane, 0.2 µm: lot samples retain 10^7/cm² of *B. diminuta* per modified ASTM F838-83.

Endotoxin
< 0.25 EU/mL using Limulus Amebocyte Lysate (LAL) test.

Biosafety
Passes USP Class VI - 121 °C Plastics Tests

Maximum Operating Pressure
4.1 bar (60 psi) at ambient temperature

Maximum Operating Temperature
60 °C (140 °F) @ 2.1 bar (30 psi)

Sterilization
Sterilized by gamma irradiation; if desired, autoclave once only prior to use at 121-123 °C (250 - 253 °F) at 1.0 bar (15psi) for a maximum of 20 minutes.

NOTE: The polypropylene resin in this capsule does not contain radiation stabilizers or colorants. It turns a light yellow color after gamma irradiation. This color is normal and indicates that the sterilization process has occurred.

NOTE: The measurements above were made with DI water as filtrate. Operating characteristics may vary depending upon solution being filtered.

Instructions for Use

1. All AcroPak Capsules with Supor Membrane are supplied presterilized by gamma irradiation (15 - 30 kGy). They can be resterilized by autoclaving **one time only** prior to use.
2. Vent valves should be loosened during the autoclave cycle. Securely wrap both ports with suitable paper prior to autoclave sterilization. Close vent valves after sterilization cycle is complete with just enough force to tighten snugly.
   CAUTION: DO NOT OVER-TIGHTEN OR VENTS MAY BREAK. LEAKAGE FROM THE VENTS MAY DEVELOP IF VENT VALVES ARE OVER TIGHTENED.
3. Prewet capsules with DI water prior to autoclaving and autoclave on a liquid type cycle with a slow exhaust.
4. We recommend that you perform an integrity test after the filter unit is sterilized, and prior to and following filtration, by either the bubble point or forward flow method.
5. AcroPak 500 & 1000 Capsules with Supor Membrane come with removable filling bells for sterile filtration into media bottles or similar receiving vessels. For in-line applications, remove the filling bell by grasping the capsule in one hand and the filling bell in the other; then, with a firm twisting and pulling motion, separate the two parts.
6. Aseptic conditions are required for proper functioning of these products.
7. Securely clamp tubing to upstream hose barb connections.
8. For single use only.

Integrity Testing

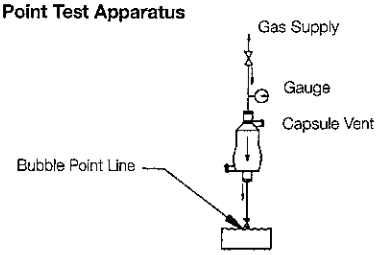
Bubble Point Method

Procedure:

1. Flush the sterile capsule for 2 - 3 minutes at 0.34 bar (5 psi) with sterile water.
2. Assemble test apparatus as shown in the bubble point apparatus diagram.
3. Turn on gas supply.
4. Pressurize the filter assembly to 0.34 bar (5 psi); hold for 1/2 minute and watch for bubbles. Continuous bubbling at 0.34 bar (5 psi) indicates either loss of integrity in the system or that the membrane is not completely wetted. Rewet the filter and proceed from step 2.
5. If no rapid continuous bubbling is observed at the bubble point line, increase the pressure at a rate of 1.4 bar (20 psi)/minute up to 4.1 bar (60 psi). DO NOT EXCEED THE MAXIMUM OPERATING PRESSURE DURING BUBBLE POINT TEST PROCEDURE! A rapid continuous stream of bubbles indicates actual bubble point pressure. A bubble point at the minimum appropriate pressure value stated in the Specifications section indicates an acceptable filter.

Integrity Testing (cont.)

Bubble Point Test Apparatus



Forward Flow Method

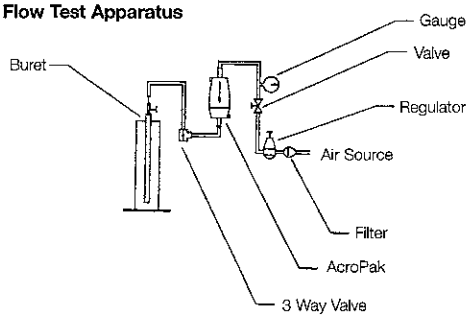
Required Materials:

1. Sterile water at ambient temperature (approx. 21 °C [70 °F])
2. Dry filtered compressed air ≥ 4.1 bar (60 psi)
3. Regulator, relieving
4. Pressure gauge 0 - 4.1 bar (60 psi) minimum, calibrated
5. Stop watch, calibrated
6. 25 cc burette
7. 2L (2.0 L) graduated cylinder, calibrated
8. Sterilized hose and fittings to connect pressure to upstream (inlet) of filter and downstream (outlet) of the filter to the tip of the burette (safety rated to the test pressure)
9. A sterilized three-way valve

Procedure:

1. Note flow arrow on housing label. Flow of liquids and gases must always match the direction of the arrow to assure downstream sterility. Check to make sure vents are closed before proceeding.
2. Flush the capsule with approximately 2L of sterile water minimum (one minute at 0.14 bar [2 psi]). [1]
3. Connect the air pressure source assembly to the filter inlet as in the diagram.
4. Gradually increase the pressure to 0.55 bar (8 psi). Aseptically remove the downstream cap. Residual water will drip out the downstream end.
5. Allow two minutes for fluid drainage and pressure stabilization.
6. Aseptically connect filter outlet to sterile valves and burette with hose open to atmosphere. Carefully avoid blocking downstream lines with draining fluids.
7. Open burette line, close vent line. With stopwatch determine volume of air passing through the filter per minute. [2]
8. Reopen vent and repeat. Values below 0.5 cc/min. (0.5 cc displaced in burette) indicates basic system integrity.
9. A value above 0.5 cc/min. probably indicates that the filter membrane is not completely wet. Rewet the capsule following steps 2-9. [3]
10. Once basic system integrity is assured, open the downstream valve and slowly increase pressure to the value stated in the Specifications section. It takes about 1-2 minutes to reach pressure. More fluid will be expelled downstream.
11. At the recommended pressure, allow 1 minute for the system to drain, by positioning the 3 way valve to the open position. Change the 3 way valve to the open burette position which will close the vent line. Determine volume of air for one minute. Volume at the appropriate cc/min value stated in the product specification section indicates an acceptable integral capsule filter. Volumes above these stated cc/min values indicate incomplete wetting or possible integrity failure (repeat steps 10 and 11).

Forward Flow Test Apparatus



[1]Oth er wetting fluids may be used. Contact Pall Life Sciences Technical Services for recommendations.

[2]A ny measurement consistent with basic gas laws may be used (i.e., flow, pressure decay, pressure increase, volumetric, etc.). Contact Pall Life Sciences Laboratory Technical Services for other recommendations.

[3]A lternate-wetting procedure: Fill upstream side with water and allow to soak 2-3 minutes. Drain water and allow to sit for 5-10 minutes. Resume test with Step No. 3 of Test Procedure.

Complementary Products

Prod No.	Description	Packaging
12941	AcroPak™ 200 Capsule with Supor® Membrane, 0.8/0.2 µm, 200 cm² EFA, sterile (formerly SpiralCap® PF)	3/pkg
12202	AcroPak 20 Filter with Supor Membrane, 0.8/0.2 µm, 20 cm² EFA, non sterile (formerly Acro® 50 Filter)	3/pkg
12203	AcroPak 20 Filter with Supor Membrane, 0.8/0.2 µm, 20 cm² EFA, sterile (formerly Acro 50 Filter)	3/pkg

Warning:

Employment of the products in applications not specified, or failure to follow all instructions contained in this product information insert, may result in improper functioning of the product, personal injury, or damage to property or the product. See Statement of Warranty in our most recent catalog.

Pall Life Sciences
600 South Wagner Road
Ann Arbor, MI 48103-9019 USA

For ordering or technical information:
Tel: 734-665-0651
800-521-1520 (in USA)
Fax: 734-913-6114

Visit Pall Life Sciences on the Internet:
www.pall.com/Lab or
e-mail us at: Lab@pall.com

Offices:
Australia, Lane Cove, NSW, 2-9428 2333
Austria, Wien, 043-1-49 192 0
Canada, Ontario, 905-542-0330
Canada, Québec, 514-337-2744
China, P.R., Beijing, 10-6464-9156
France, St. Germain-en-Laye, 01 30 61 39 92
Germany, Dreieich, 06103-307 333
India, Mumbai, 91-22-5956050
Ireland, Co. Dublin, 1-2846177
Italy, Milano, 02-47-79-61
Japan, Tokyo, 3-3495-8319
Korea, Seoul, 2-569-9161
Poland, Warzawa, 22 835 8383
Russia, Moscow, 095-490-68-07
Singapore, 65-546-5056
Spain, Madrid, 91-657-9876
Sweden, Lund, 46-0-46 15 84 00
Switzerland, Basel, 061-638 39 00
Taiwan, Taipei, 2-2545-5991
United Kingdom, Portsmouth, 023 92 302600

Pall, PALL, Acro, AcroPak, CritiCap, SpiralCap, Supor, and SuporCap are trademarks of Pall Corporation. ® indicates a registered trademark in the USA.

©Copyright 2002, Pall Corporation, 04/02

PN 82836K