Emflon™ II membrane

IN MINI KLEENPAK™ CAPSULES

Small-scale, gamma-compatible, sterilizing-grade air filtration

For single-use installations, from upstream to final formulation and fill, Emflon™ II membrane is the go-to gas filter for safeguarding cell cultures and drug product from adventitious bacterial and viral contamination.

Mini Kleenpak™ capsules with Emflon II membrane deliver gamma-compatible sterilizing-grade air filtration for use on process gas and vent applications. With a comprehensive validation and quality package, Mini Kleenpak capsules with Emflon II membrane are designed for use from clinical development through to licensed drug manufacture.

Fig 1. Emflon II filter capsules.

Features and benefits

- Highly-retentive Emflon II membrane for sterility assurance
- High flow rates associated with low differential pressure enable the use of small filters, leading to reduction of installation and operating costs
- Gamma-irradiatable, autoclavable or available pre-sterilized for maximum convenience
- Integrity-testable using the forward flow and bubble point test
- Choice of connection options for enhanced flexibility

High quality standards

- Validated in liquids with *brevundimonas diminuta* (ATCC 19146) at a challenge level of 10^7 organisms/cm^2 of filter area
- 100% integrity-tested during manufacturing
- Identified by a lot number and unique serial number for complete traceability of manufacturing history and for user traceability systems
- Comprehensive batch/release testing supported with a pharmaceutical certificate of test for each filter
- Validation guide available
- Manufactured under a quality management system certified to ISO 9001:2015

Biological tests

- Meets USP biological reactivity tests *in vivo*, in accordance with USP class VI plastics at 121°C

Technical specifications

Materials of construction	
Membrane	Hydrophobic polyvinylidene fluoride (PVDF)
Support and drainage layers	Polypropylene
End cap and core	Polypropylene
Outer shell	Polypropylene

Dimensions (nominal)	
Maximum diameter (including valves)	67 mm (2.6 in.)
Length with hose barb connections (Code 2)	105 mm (4.1 in.)
Length with sanitary connections (Code 8)	73 mm (2.9 in.)
Nominal filtration area	230 cm^2 (0.25 ft^2)

Sterilization [3]	
Gamma-irradiation maximum dosage (G option only)	Up to 50 kGy
Autoclave sterilization	Gamma-irradiated filters: 1 one-hour cycle at 125°C for the purpose of post-use decontamination Non gamma-irradiated filters: Up to 3 one-hour cycles at 125°C

Warning: Mini Kleenpak filters must not be steam-sterilized *in situ* by passing steam through under pressure. The figures are maximum allowable figures determined by testing under controlled laboratory conditions to the total number of hours indicated. Actual operating conditions may affect the filters long-term response to sterilization. Filters should be qualified for each process application.

Operating conditions [1]	
Maximum operating pressure	4.1 bar (60 psi) at 38°C

[1] In air/nitrogen gas service or other compatible fluids, which do not soften, swell, or adversely affect the filter or its materials of construction

Ordering information

Product	Product code
Mini Kleenpak capsule with Emflon II membrane with ¼ to ½ in. hose barb, gamma-irradiated	KA02V002P2S
Mini Kleenpak capsule with Emflon II membrane with ¼ to ½ in. hose barb, non-irradiated	KA02V002P2G
Mini Kleenpak capsule with Emflon II membrane with ½ in. sanitary flange, gamma-irradiated	KA02V002P8S
Mini Kleenpak capsule with Emflon II membrane with ½ in. sanitary flange, non-irradiated	KA02V002P8G

Typical air flow rates [2, 3]

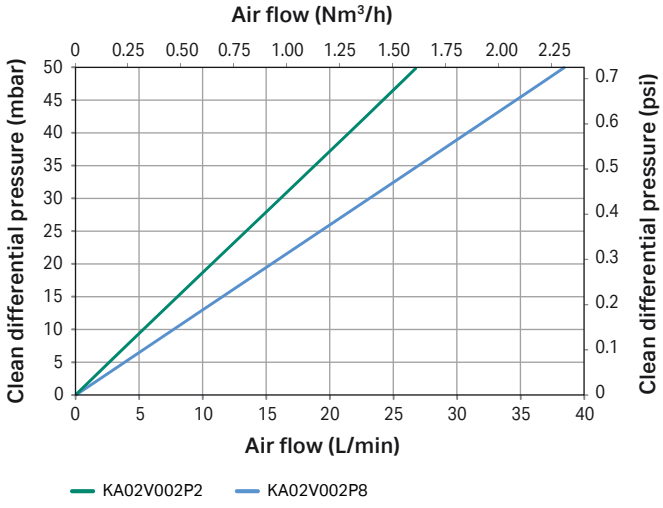

Fig 2. Vent conditions for Mini Kleenpak capsules.

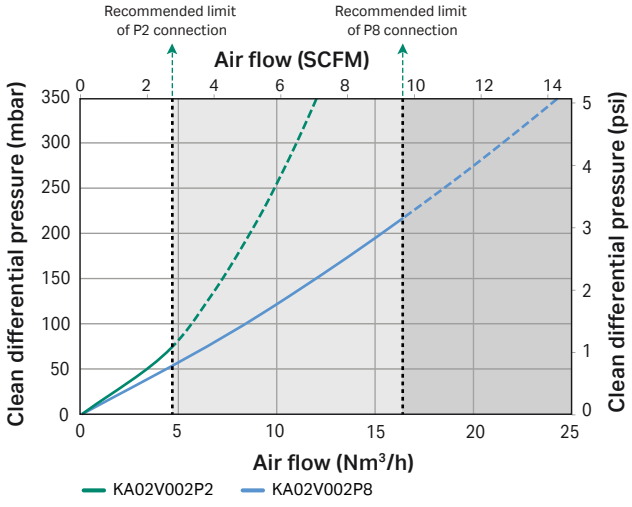

Fig 3. Operating conditions (2 bar) for Mini Kleenpak capsules.

[2] For gases other than air or nitrogen, contact your local Cytiva representative.
[3] Recommended flow limits have been based on a maximum velocity of 25 m/s through the capsule. Tubing sizes should also be considered.

cytiva.com

For local office contact information, visit cytiva.com/contact

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