

# Emflon™ II membrane

IN MINI KLEENPAK™ 20 CAPSULES

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

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

Mini Kleenpak™ 20 capsules with Emflon II membrane deliver gamma-compatible sterilizing-grade air filtration for use on small scale process gas and vent applications. With a comprehensive validation and quality package, Mini Kleenpak 20 capsules with Emflon II membrane are designed for use from clinical development through to licensed drug manufacture.

## 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 or autoclavable for maximum convenience
- Integrity-testable using the bubble point test

## High quality standards

- Validated in liquids with *Brevundimonas diminuta* (ATCC 19146) at a challenge level of  $10^7$  organisms/cm<sup>2</sup> of filter area
- 100% integrity-tested during manufacturing
- Filters supplied with a pharmaceutical certificate of test
- Comprehensive validation guide available
- Manufactured under a quality management system certified to ISO 9001:2015



Fig 1. Mini Kleenpak 20 capsules.

## Biological tests

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

## Effluent quality tests <sup>(1)</sup>

- Meets cleanliness per USP particulates in injectables
- Non-fiber-releasing per 21CFR 211.72 and 21CFR 210.3(b)(6)
- Non-pyrogenic per USP bacterial endotoxins (< 0.25 EU/mL)

<sup>(1)</sup> Per lot samples on rinse-up flush aliquots

# Technical specifications

## Materials of construction

Membrane	Polyvinylidene fluoride (PVDF)
Capsule	Polypropylene

## Dimensions (nominal)

Housing diameter	68 mm (2.7 in.)
Inlet/outlet hose barb length	83 mm (3.3 in.)
Nominal effective filtration area	20 cm <sup>2</sup> (0.022 ft <sup>2</sup> )

## Operating conditions <sup>(2)</sup>

Maximum operating temperature and pressure	2.0 bar (29 psi) at 20°C
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<sup>(2)</sup> In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction.

## Sterilization <sup>(3)</sup>

Gamma-irradiation	Maximum 50 kGy
Autoclav	131°C, 3 × 60 minute cycles

Warning: pre-sterilized Mini Kleenpak 20 capsules (as supplied on some single-use systems) should not be re-sterilized. Contact Cytiva in regards to re-sterilizing gamma-irradiated Mini Kleenpak 20 capsules. The capsules must not be sterilized *in situ* by passing steam under pressure. Do not autoclave after use if heat labile chemical contaminants are present on the filter.

<sup>(3)</sup> The figures are maximum allowable figures determined by testing under controlled laboratory conditions to the length of time indicated. Actual operating conditions may affect the filter's long term response to sterilization. Filters should be qualified for each process application.

# Typical air flow rates <sup>(4)</sup>

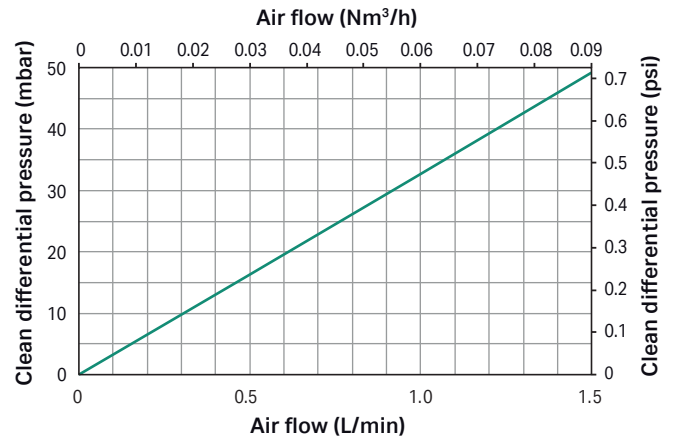


Fig 2. Vent conditions for Mini Kleenpak 20 capsules.

<sup>(4)</sup> For gases other than air or nitrogen, contact us.

# Ordering information

Product	Quantity per box	Product code
Mini Kleenpak 20 filter capsule with 0.2 µm Emflon II membrane and ¼ to ½ in. (6 to 13 mm) hose barb connections, supplied non-sterile, gamma-irradiatable/autoclavable	3	KM5V002P2G
	100	KM5V002P2G100

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