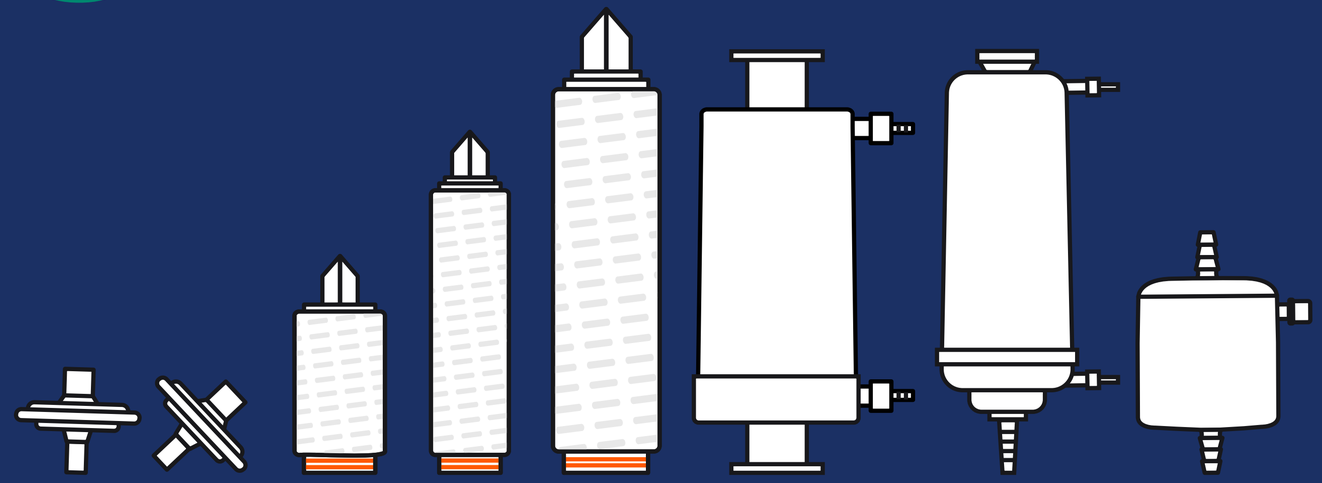
Buffer filter selection guidelines



cytiva

Introduction

In biotech drug manufacturing, a significant proportion of filtration costs are attributable to filters utilized for removing fine contaminants and low levels of bioburden from buffers and wash fluids.

For those engaged in the development of new or running of established filter-intensive manufacturing processes, buffer filtration costs can be well-managed via the implementation of robust, highly efficient filters that reliably yield a premium quality filtrate.

Cytiva is able to supply technologically innovative buffer filters designed to help with the successful and cost-effective protection of processes from microbial and particulate contamination.

Key end-user requirements

Process safety

Buffers may contain low levels of bioburden and extraneous particulates. The removal of these by filtration is important to ensure that a buffer can support unit operations that may become compromised by potentially process limiting contaminants. A risk-based approach to filter selection can help determine what type of microbial removal rating will offer the appropriate level of safety.

Process efficiency and filter sizing

Because buffers are typically prepared using highly soluble powdered raw materials with purified water or water for injection, when compared with other feeds such as complex growth media or product containing fluids with a high or varied particulate load, they are not usually challenging to filter.

The size of a buffer filter required for a target process volume over a fixed time period can often be determined by calculation, referring principally to the filter's water flow versus differential pressure performance claim. Pilot testing may be employed subsequently or in parallel; however the process of filter sizing for buffers can be considered fairly straightforward in comparison with hard to filter feeds. Unlike buffers, these may require repeated testing with a number of filter and feed samples to confidently predict a filter's behavior.

Process compatibility

The variety of applications for buffers in bioprocessing means that a population of buffers used in a single facility may cover a broad pH range. It is important that filters designed for buffer filtration are shown to have extensive fluid compatibility, helping the end user to utilize a single filter type to serve all of their buffer filtration requirements.

Vendor qualification

It is useful that any filters deemed sufficiently compatible are supported by rigorous qualification studies performed by the manufacturer. A review of a filter's materials of construction and performance claims along with a filter supplier's generic validation documents, product release, and other quality criteria is advised. This helps the end user initially determine if a product is likely to be suitable for filtering their range of buffer feeds in keeping with current good manufacturing (cGMP) standards.

Meeting key end-user requirements

Process safety

Sterilizing grade filters or dedicated bioburden control filters are effective at delivering a sterile effluent or reducing bacterial loads in process feeds to acceptably low levels.

A sterilizing grade filter, per filter vendor specification, is a filter which when challenged with 10^7 colony forming units (cfu) *B. diminuta* per cm^2 membrane area, produces a sterile effluent. A dedicated bioburden reduction filter is a filter that can reliably deliver a high titer reduction when challenged with similarly large bacterial load.

In buffer filtration applications sterilizing grade filters are often used to maintain low levels of bioburden rather than to achieve sterility. If a sterile filtrate is not expected, a bioburden control filter with a more open pore structure and/or a reduced number of membrane layers, and consequently a higher flow rate, can also meet an end-users safety objectives with greater efficiency (Fig. 1).

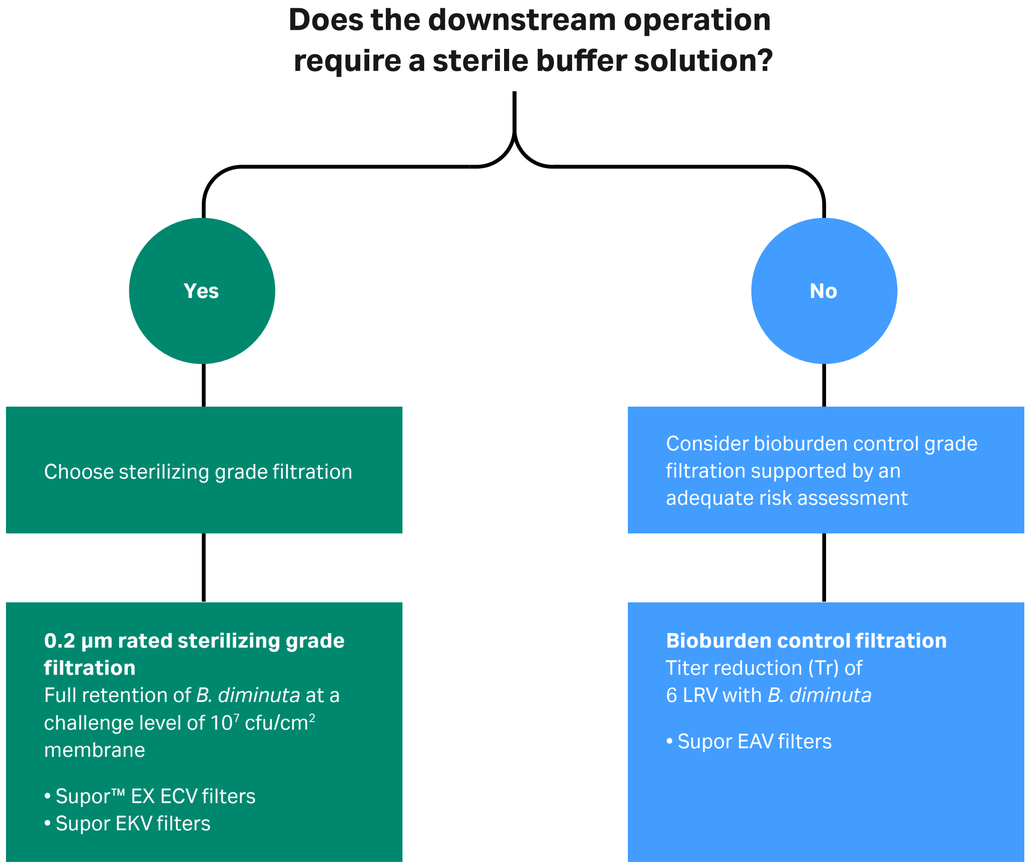


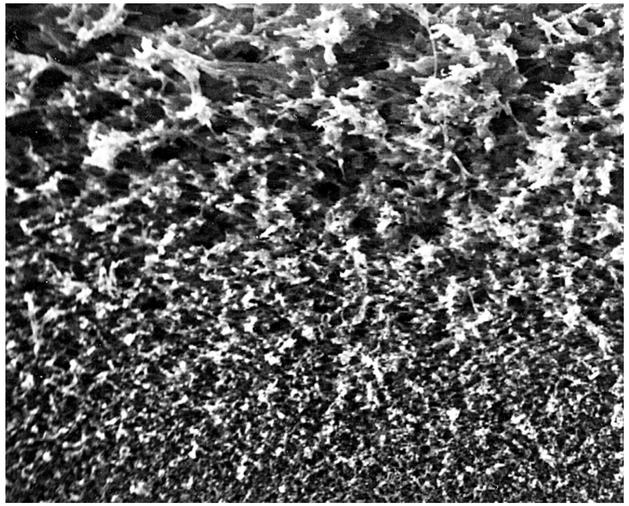
Fig 1. Fully validated filter products for buffer filtration in bioprocessing.

Process efficiency and filter sizing

Each of the described filters have a unique media orientation resulting in different liquid flow versus flow differential pressure profiles. Common to each is a highly asymmetric polyethersulfone (PES) membrane technology and in 127 mm (5 in.) to 762 mm (30 in.) filters laid-over pleat membrane geometry for efficient use of filter membrane capacity. These characteristics deliver outstanding flow rate performance in buffer filtration applications, resulting in compact, efficient filter systems.

The following configurations of filters for buffer filtration are available to process volumes ranging from mL to 1000s of liters in stainless steel or single-use systems.

Cytiva's sterilizing grade filters, with approaching double the clean water flow rate of alternate vendors, can allow for effective process protection with a 50% reduction in buffer filter footprint.



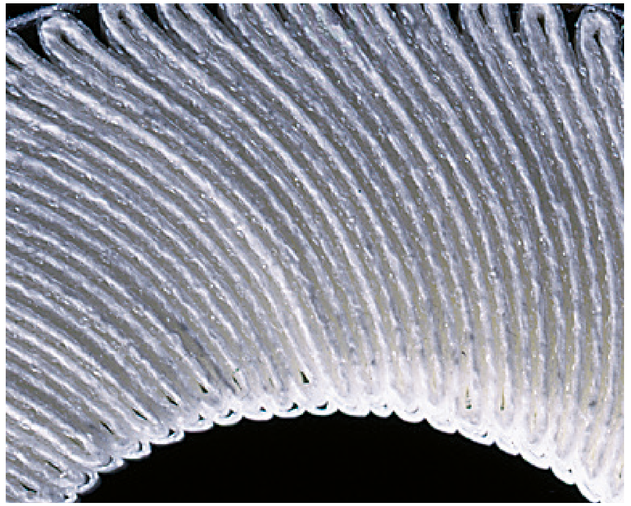


Fig 2. Highly asymmetric membrane and laid-over pleat construction used in Supor filters for buffer filtration.

Table 1. Available configurations of Supor filters

	Filter capsules							Filter cartridges	
									
Element size	Flat sheet	2–6 in.				5 in.	10–30 in.		5–40 in.
Device name	Mini Kleenpak™ 20 filter capsules	Mini Kleenpak filter capsules	Kleenpak filter capsules			Kleenpak Nova filter capsules		AB-style filter cartridges	
Purpose	For process development, validation, and manufacturing						For manufacturing		
Part number prefix	KM5-	KA02-	KA1-	KA2-	KA3-	NP5L-	NP/T 6-8	AB05	AB1-4
Supor EAV membrane	×				×		×	×	×
Supor EKV membrane	×	×	×	×	×	×	×	×	×
Supor ECV membrane		×					×	×	×

Please refer to appendix for individual device product specifications, supporting use in biopharmaceutical applications

To benefit from the process efficiency of Supor filters it is important that the filters are appropriately sized with consideration to process volume and filtration time.

Refer to the following sizing charts to identify which filter configurations we can recommend for buffer filtration volumes up to 10 000 liters.

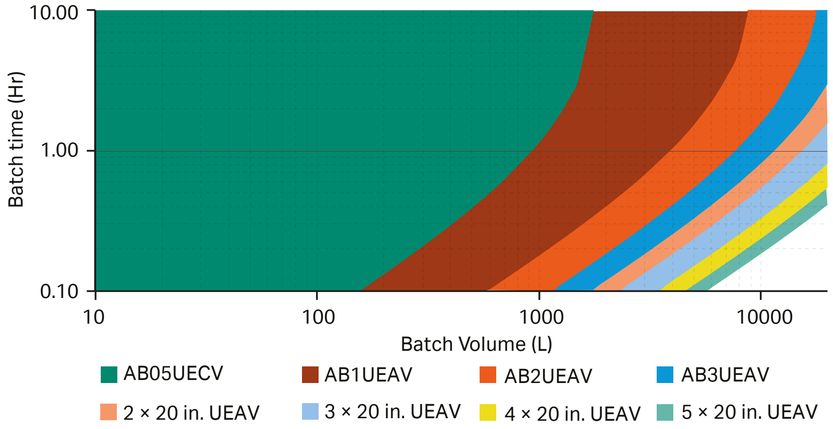


Fig 3. Sizing chart for Supor EAV filters.

Guideline

Based on configurations available, Supor EAV filters are best suited to the bioburden control filtration of buffer volumes of > 250 L.

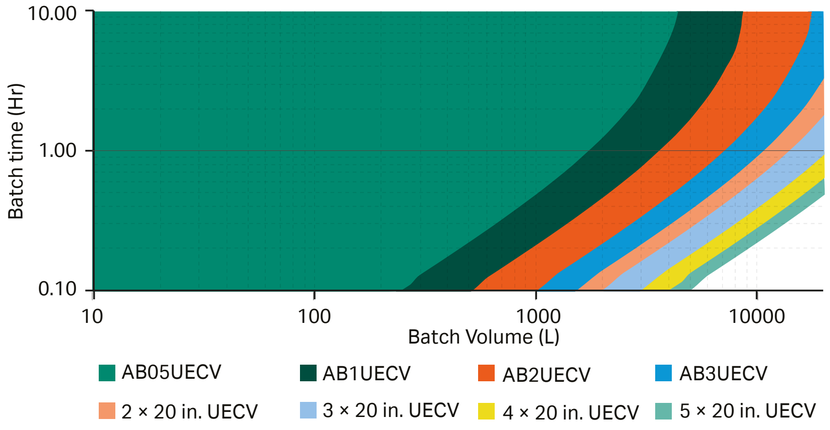


Fig 4. Sizing chart for Supor EX ECV filters.

Guideline

Based on configurations available, Supor EX ECV filters are best suited to the sterile filtration of buffer volumes of > 250 L. Performance benefits are most significant at volumes > 1000 L.

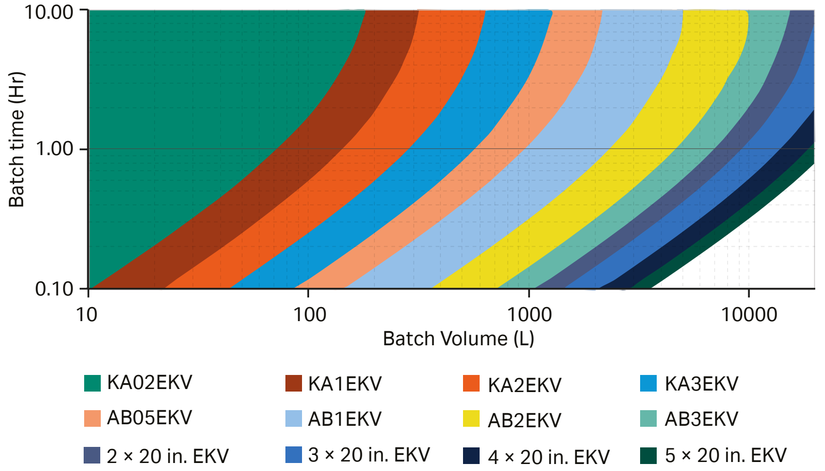


Fig 5. Sizing chart for Supor EKV filters.

Guideline

Based on configurations available, Supor EKV filters are best suited to the sterile filtration of buffers in single-use systems and secondarily in large scale manufacturing facilities.

These charts are for reference purposes, please contact your Cytiva representative for further assistance with filter sizing.

Meeting end-user qualification requirements

Process compatibility

Table 2 supports the use of Supor filters in a range of buffer applications. This table is for guidance purposes; where necessary or for critical applications, ensure process specific testing following appropriate risk assessment.

For the listed fluids:

A = Generally resistant for most applications at ambient temperature

A* = Generally assumed resistance based on similar limited data

B = Limited resistance. May require evaluation.

C = Not recommended

ND = No data available

Table 2

		Filter media	Hardware	Standard O-ring
	Fluid	**Supor PES (EKV, EAV, ECV)**	**Polypropylene**	**Silicone**
Acid	Phosphoric acid (100 mM)	A*	A	B
	Formic acid (1.0 M) (e.g viral inactivation titrant down)	A	A	B
	Formic acid (50%; 11.8 M)	A	A	A*
	Citric acid - 630.4 kg/3000 L water	A	A	A
	Acetic acid (1 M)	A	A	A
	Acetic acid (75 mM)	A	A	A
	Hydrochloric acid (6 M)	A	A	A
	Sodium acetate (100 mM)	A*	A	ND
	Sodium acetate (50 mM), 600 mM NaCl	A*	A	ND
	Sodium acetate (10 mM), 5% sorbitol	A*	A	ND
	Sodium acetate (1.0 M)	A*	A	C
	Sodium acetate (50 mM), 100 mM NaCl	A*	A	C
Weak base	Sodium carbonate - 318 kg/3000 L water	ND	A	A
	Tris/HCl (10 mM), 2 M NaCl	A	A	A
	Tris (25 mM), 5 mM EDTA, 3.0 M NaCl	A	A	A
	Tris (500 mM)	A	A	A*

	Fluid	Filter media Supor PES (EKV, EAV, ECV)	Hardware Polypropylene	Standard O-ring Silicone
Base	NaOH (1 N)	A	A	A
	NaOH (0.5 N)	A	A	A
	NaOH (2 N)	A	A	A*
	NaOH (0.1 N)	A	A	A
	Tris (25 mM), 100 mM NaCl	A	A	A*
	Tris base (2 M)	A	A	A*
	Tris (25 mM), 0.5 M arginine	A	A	A*
	Urea (6 M)	B	A	A
	Sodium phosphate (0.4 M)	A*	A	ND
	Sodium phosphate (10 mM), 0.1 N NaOH	A*	A	ND
	Sodium phosphate (100 mM)	A*	A	ND
	Sodium phosphate (10 mM), 145 mM NaCl	A*	A	ND
	Sodium phosphate (50 mM), 100 mM NaCl	A*	A	ND
	Ammonium acetate (2.5 M)	A	A	A
	Ammonium sulfate (3.8 M), 0.01 M Tris	A	A	A
	Potassium phosphate (2 M)	A*	A*	A*
	MES (50 mM)	ND	ND	ND

	Fluid	Filter media Supor PES (EKV, EAV, ECV)	Hardware Polypropylene	Standard O-ring Silicone
Solvent	Benzyl alcohol 100%	C**	A	A
	Benzyl alcohol (2%), 50 mM sodium citrate	ND	A	A
	Ethanol (70%)	A	A	A
	Propylene glycol (25%), 0.2 M arg HCl, 0.5 M Sodium phosphate	A*	A*	ND
	Propylene glycol (25%) A A A	ND	ND	ND
	Triton (600 L/3000 L water)	A*	A	A*
	Triton (0.1%) A A A	ND	ND	ND
	Tween 20 ND A ND	ND	ND	ND
	Tween 80 (100%)	C	A	A*
	Tween 80 (1%)	B	A	A*
Neutral	EDTA (0.1 M) (ethylenediaminetetraacetic acid)	A*	A*	A
	Mannitol (3%), 25 mM histidine, 1.6 mM glycine	A*	A*	A*
	Sodium chloride - 5 M A A A	ND	ND	ND
Amino acid	Glycine (0.1 M)	A*	A*	A*

** Recommend Fluorodyne™ II (DFL), special purpose nylon (NRP), or Emflon™ II filters for these applications

Quality in process

Supor filters recommended for buffer filtration have been qualified to meet the biopharmaceutical end-user's acceptance criteria around documentation, quality, and assurance of supply, reference Table 3.

Table 3. Quality standards met by Supor filters

	Criteria		Supor EAV Filters Bioburden Control	Supor ECV Filters Sterilizing Grade	Supor EKV Filters Sterilizing Grade
Quality Standards, per Pharmaceutical Certificate of Test	Biological Reactivity *In Vivo* (USP <88>)		The filter components have met the specifications for biological tests (including the acute systemic injection test, intracutaneous test, and implantation test) listed in the current revision of the United States Pharmacopeia (USP) for Class VI - 121°C plastics.		
	Lot release tests	Bacterial retention		Lot samples are subject to bacterial challenge testing in correlation with current revision of ASTM 838, post-sterilization in conformance with the applicable requirements of the FDA Guideline Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice (September 2004)	
		Integrity testing in manufacturing	Integrity test performed on lot samples	100% integrity test of filter elements used in finished product, during manufacture	
		Bacterial Endotoxin (USP <85>)	Lot samples meet current requirement under USP Water for Injection, 0.25 EU/mL, when an aliquot from a soak solution is tested using Limulus Amoebocyte Lysate (LAL) reagent in accordance with USP <85> Bacterial Endotoxins Test.		
		pH Shift (USP <791>)	Lot samples meet internal specifications after flushing, upstream versus downstream differential not to exceed +/- 0.5 pH units, when tested in accordance with USP <791> pH.		
		Particulate Matter and Fiber Release (USP <788>)	Lot samples meet with adequate safety margin after flushing. Current limits under USP <788> Particulate Matter in Injections with effluent counts determined microscopically. Counts serve to document conformance with the requirements for a non-fiber-releasing filter per Title 21 of the U.S. Code of Federal Regulations (CFR) parts 211.72 and 210.3 (b) (6).		
		Water Conductivity (USP <645>)	Lot samples meets the current USP limits under Purified Water after flushing when tested in accordance with USP <645> Water Conductivity.		
		Total Organic Carbon (TOC) (USP <643>)	Lot samples meets the current USP limits under Purified Water after flushing when tested in accordance with USP <643> Total Organic Carbon.		
	Manufacturing locations		Pall Puerto Rico, Pall UK	Pall UK	Pall Puerto Rico, Pall UK
Additional quality criteria	Quality systems		These Cytiva filters are manufactured in a controlled environment under quality management systems that are certified to ISO9001, for Quality Management, ISO 14001 for Environment Management, and ISO 22301 for Business Continuity Management.		
	Sterilization validation		For pre-sterilized product (only), the gamma-irradiation sterilization process (25-35 kGy) has been validated to ANSI/AAMI		
	FDA compliance		These filters may be used in conformance with cGMP in Manufacturing, Processing, Packing or Holding of Drugs (21CFR210) and cGMP for Finished Pharmaceuticals (21CFR211.72).		

Criteria	Supor EAV Filters Bioburden Control	Supor ECV Filters Sterilizing Grade	Supor EKV Filters Sterilizing Grade
Drug master file	Information on these filters has been submitted to the U.S. Food and Drug Administration in a Drug Master File. Letters of Authorization are available on request.		
TSE BSE Safety (EMA/410/01 rev3)	Animal Derived Ingredients: • Some resins used to manufacture the filter components contain trace levels of stearates, which may be derived from bovine tallow. • Tallow derivatives are not considered specified BSE risk materials according to the current revision of Title 21, of the U.S. Code of Federal Regulations, part 189.5. Furthermore, the CPMP's Note for Guidance (EMA410/01) gives specific consideration to tallow derivatives and states they are unlikely to be infectious due to the rigorous processing steps used (an example of which is trans esterification, or hydrolysis, at not less than 200°C under pressure for not less than 20 minutes). The raw materials we purchase have been processed with these steps.		
Compliance with international regulations	Products comply with the following regulations and legislative requirements: • REACH (19-7/2006/EC) • Restriction of Hazardous Substances (RoHS) (2002/95/EC and amendments including the recast directive 2011/65/EU) • Conflict Minerals (Dodd-Frank Wall Street Reform and Consumer Protection Act)		
Material safety	Documentation regarding material safety is available, covering exclusion of: • Melamine • Bisphenol A (BPA) • Latex • Phthalates		
Explosive atmospheres "ATEX" directive 94/9/EC	Capsule designs have been reviewed for compliance equipment group II, category 2 for dust and gas.		

Summary

The content in this guide offers information to support the selection of microbially rated filters for the effective management of buffer filtration costs, whether they are being considered for use in a new process or as part of a process optimization.

In either case, it is recognized that any decision to implement a new or change of filter would typically involve a risk based approach to filter specification, depending on the purpose of the filter or quality criteria for the filtrate.

Where necessary, Cytiva is able to assist with a risk-based methodology for the qualification of new or change out of installed buffer filters and can provide highly experienced technical support.

Appendix

Table 4. Specifications of available pharmaceutical-grade configurations of Supor EAV filters

Supor EAV Filters **Physical properties and performance claims**					
Part number prefix	KM5	KA02EAV	KA3EAV	NP/T 6-8UEAV	AB1-4UEAV
					
Removal rating	0.2 µm				
Retention claim	Validated titer reduction of *B. diminuta* at 10^6 TR (6 LRV), correlated to an integrity test value				
Device type	Filter Capsules			Filter artridges	
Filter element size	Flat sheet	2 in. element	6 in. element	10–30 in. element	10–40 in. element
Device name	Mini Kleenpak 20 filter capsule	Mini Kleenpak filter capsules	Kleenpak filter	Kleenpak Nova filter capsules	AB filter cartridges
Purpose	Validated for filter sizing, process validation, or GMP manufacture				

Supor EAV Filters **Physical properties and performance claims**					
Part number prefix	KM5	KA02EAV	KA3EAV	NP/T 6-8UEAV	AB1-4UEAV
Filter membrane	Polyethersulphone, single layer				
Filter cage	Polypropylene				
Filter core	Polypropylene				
Filter end caps	Polypropylene				
Capsule shell bowl	Polypropylene				N/A
Capsule shell head	Polypropylene			Polypropylene with TiO_2 whitener	N/A
Sealing	Thermal bonding, without adhesives				
Effective filter area (cm²)	20	260	2100 (per 254 mm/ 10 in. element)	10600 (per 254 mm/ 10 in. element)	10600 (per 254 mm/ 10 in. element)
Flow at 100 mbard (L/min)	0.08	0.35	6.1 (per 254 mm/ 10 in. element)	20 (per 254 mm/ 10 in. element)	20 (per 254 mm/ 10 in. element)

Supor EAV Filters
Physical properties and performance claims

Part number prefix	KM5	KA02EAV	KA3EAV	NP/T 6-8UEAV	AB1-4UEAV
Steam sterilization	N/A				10 × 1 hr at 125ºC
Autoclave sterilization (slow exhaust)	N/A	3 × 30 minutes at 135°C	10 × 60 minutes at 125°C	1 × 60 minutes at 135°C	10 × 1 hr at 125°C
Gamma sterilization (non-irradiated, non-sterilized filter capsules only)	50 kGy				N/A
Maximum operating temperature	N/A	40°C			80°C

Physical properties and performance claims

Part number prefix	KM5	KA02EAV	KA3EAV	NP/T 6-8UEAV	AB1-4UEAV
Maximum operating pressure and temperature	1.4 bar at 21.7ºC (20 psi at 71 ºF)	4.1 bar (60 psi) at 38°C	5.2 bar (75 psi) at 20°C, 4.0 bar (58 psi) at 40°C	3 bar (43.5 psi) at 40°C	5.5 bard (80 psid) at 40°C, 3 bard (43 psi) at 80°C
Typical NVR extractables, 4 hr extraction in water following autoclave or gamma-sterilization	N/A	< 2 mg	< 10 mg (per 254 mm/ 10 in element)	< 50 mg (per 254 mm/10 in. element)	

Supor EAV Filters
Physical properties and performance claims

Part number prefix	KM5	KA02EAV	KA3EAV	NP/T 6-8UEAV	AB1-4UEAV
Identification, packaging, and storage					
Identification marking on product	Part number and lot number hot-stamped	Part number and lot number hot-stamped		Part number and lot number laser marked	Part number and lot number laser marked/hot-stamped
Outer box packaging	Cardboard box with supporting inserts				
Packaging with-in box	Double-bagged easy-to-open oriented polyamide (OPA) over polyethylene (PE)				Single-bagged, easy-to-open OPA/PE
Additional protection	N/A	Vent/drain and inlet/outlet caps on pre-sterilized product			N/A
Additional product marking information	Pre-sterilized product packaging displays a red dot product				N/A
Shelf-life	5 years	5 years, non-sterile, 3 years pre-sterilized product			5 years
Storage	Store in original packaging out of direct sunlight in dry place between 2 and 30°C, only consider product in undamaged packing suitable for use				

Key documents	
Product datasheets	Please visit cytiva.com
Validation guide	Please refer to your local Cytiva sales office or account manager
Instructions for use	Available at cytivalifesciences.com/support/instructions-for-use
Pharmaceutical "Certificate of Test" (P-cert)	Supplied with every box

Table 5. Specifications of available configurations of pharmaceutical-grade Supor EX ECV Filters

Supor EX ECV Filters Physical properties and performance claims					
Part number prefix	KA02ECV	NP5LUECV	NP/T 6-8UECV	AB05UECV	AB1-4UECV
					
Removal rating	0.2 µm, sterilizing grade				
Retention claim	Retentive for *B. dim* at challenge level of 10^7 cfu/cm^2 membrane per ASTM 838-15, correlated to forward flow IT test value, after sterilization methods of gamma, steam, autoclave				
Device type	Filter Disc	Filter Capsules		Filter Cartridges	
Filter element	2 in. element	5 in. element	10–30 in. element	5 in. element	10–40 in. element
Device name	Mini Kleenpak filter capsules	Kleenpak Nova filter capsules		AB-style filter cartridges	
Purpose	For sizing only	Validated for filter sizing, process validation, or manufacturing			
Filter membrane	Polyethersulphone, double layer				
Filter cage	Polypropylene				

Supor EX ECV Filters
Physical properties and performance claims

Part number prefix	KA02ECV	NP5LUECV	NP/T 6-8UECV	AB05UECV	AB1-4UECV
Filter core	Polypropylene				
Filter end caps	Polypropylene				
Capsule shell bowl	Polypropylene			N/A	
Capsule shell head	Polypropylene	Polypropylene with TiO_2 whitener		N/A	
Effective filter area (cm^2)	220	5200	10400 (per 254mm/ 10 in. element)	5200	10400 (per 254 mm/ 10 in. element)
Flow at 100 mbar DP (L/min)	N/A	8.5	17 (per 254 mm/ 10 in. element)	8.5	17 (per 254 mm/ 10 in. element)
Steam sterilization	N/A			5 × 60 minute cycles at 125°C, 1 x 60 minute cycle at 135°C	
Autoclave sterilization	N/A	3 × 60 minute cycles at 125°C		5 × 60 minute cycles at 125°C	
Gamma sterilization (non-irradiated, filter capsules only)	N/A	N/A	50 kGy		N/A

Supor EX ECV Filters
Physical properties and performance claims

Part number prefix	KA02ECV	NP5LUECV	NP/T 6-8UECV	AB05UECV	AB1-4UECV
Max operating pressure and temperature	N/A	3 bar (43.5 psi) at 40°C		5.0 bar (72.5 psi) at 40°C, 3.0 bar (43.5 psi) at 80°C	
NVR extract-ables, 24 hour, in water following autoclave or gamma-sterilization	N/A	N/A	< 150 mg per 254 mm/10 in. assembly		N/A

Identification, packaging, and storage

Identification Marking on product stamped	Part number hot stamped	Lot number and part-number laser marked	Lot number and part number laser marked/hot-stamped filter cartridge
Outer box packaging	Cardboard box, with supporting inserts		
Packaging within box	Double-bagged, in easy to open PEI		Single- bagged, easy to open PEI
Additional protection	Vent/drain and inlet/outlet caps on pre-sterilized product		N/A
Shelf-life	5 years, non-sterile, 3 years pre-sterilized product		5 years
Storage	Store in original packaging out of direct sunlight in dry place between 2 and 30°C, only consider product in undamaged packing suitable for use		

Key documents	
Product datasheets	Please visit cytiva.com
Validation guide	Please refer to your local Cytiva sales office or account manager
Instructions for use	Available at cytivalifesciences.com/support/instructions-for-use
Pharmaceutical “Certificate of Test” (P-cert)	Supplied with every box

Table 6. Specifications of available configurations of pharmaceutical-grade Supor EKV Filters

Supor EKV Filters **Physical properties and performance claims**									
Part number prefix	KM5EKV	KA02EKV	KA1EKV	KA2EKV	KA3EKV	NP5LEKV	NP/T 6-8EKV	AB05EKV	AB1-4EKV
									
Removal rating	0.2 µm, sterilizing grade								
Retention claim	Retentive for *B. dim* at challenge level of 107 cfu/cm^2 membrane per ASTM 838-15, correlated to forward flow IT test value, after sterilization methods of gamma, steam, autoclave								
Device type	Filter Capsules							Filter Cartridges	
Filter element	Flat sheet	2 in. element	3–6 in. filter elements			5 in. element	10–30 in. element	5 in. element	10–40 in. element
Device name	Mini Kleenpak 20 capsules	Mini Kleenpak filter capsules	Kleenpak filter capsules			Kleenpak Nova filter capsules		AB-style filter cartridges	
Purpose	Validated for filter sizing, process validation, or manufacturing								
Filter membrane	Polyethersulfone, two layers								
Filter cage	Polypropylene								
Filter core	Polypropylene								

Supor EKV Filters
Physical properties and performance claims

Part number prefix	KM5EKV	KA02EKV	KA1EKV	KA2EKV	KA3EKV	NP5LEKV	NP/T 6-8EKV	AB05EKV	AB1-4EKV
Filter end caps	Polypropylene								
Capsule shell bowl	Polypropylene							N/A	
Capsule shell head	Polypropylene					Polypropylene with TiO_2 whitener		N/A	
Effective filter area (cm^2)	20	200	380	790	1500	2300	6000 (per 254 mm/ 10 in. element)	2300	6000 (per 254 mm/ 10 in. element)
Flow at 100 mbard (L/min)	0.04	0.35	0.8	1.5	3	5.5	13 (per 254 mm/ 10 in. element)	5.5	13 (per 254 mm/ 10 in. element)
Steam sterilization	N/A							30 × 60 minutes at 125°C, 5 × 60 minutes at 142°C	
Autoclave sterilization	N/A	3 × 60 minutes at 135°C	5 × 60 minutes at 125°C			1 × 60 minutes at 135°C		30 × 60 minutes at 125°C	
Gamma sterilization (non-irradiated, non-sterilized filter capsules only)	50 kGy							N/A	
Maximum operating temperature	21.7ºC	40°C						80°C	

Supor EKV Filters
Physical properties and performance claims

Part number prefix	KM5EKV	KA02EKV	KA1EKV	KA2EKV	KA3EKV	NP5LEKV	NP/T 6-8EKV	AB05EKV	AB1-4EKV
Maximum operating pressure and temperature	1.4 bar at 21.7°C (20 psi at 71°F)	4.1 bar (60 psi) at 40°C	5.2 bar (75 psi) at 20°C, 4.0 bar (58 psi) at 40°C			3 bar (43.5 psi) at 40°C		5.5 bard (80 psi) at 40°C 4.0 bard (58 psi) at 80°C	
Typical NVR extractables 4 hours in water following autoclave or gamma-sterilization	N/A	< 5 mg			< 10 mg	< 25 mg per 254 mm/10 in. assembly			
Identification marking on product	Part number and lot number hot-stamped	Part number and lot number hot-stamped				Part number and lot number laser marked		Part number and lot number laser marked/hot-stamped filter cartridge	
Outer box packaging	Cardboard box, with supporting inserts								
Packaging within box	Double-bagged, in easy to open oriented polyamide (OPA) over polyethylene (PE)							Single- bagged, easy to open OPA/PE	
Additional ID information		Pre-sterilized product packaging displays a red dot						N/A	N/A
Shelf-life	5 years	5 years for non-sterile, 3 years for pre-sterilized sterile product						5 years	
Storage	Store in original packaging out of direct sunlight in dry place between 2 and 30°C, only consider product in undamaged packing for use								

Key documents	
Product datasheets	Please visit cytiva.com
Validation guide	Please refer to your local Cytiva sales office or account manager
Instructions for use	Available at cytivalifesciences.com/support/instructions-for-use
Pharmaceutical “Certificate of Test” (P-cert)	Supplied with every box

cytiva.com

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

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