

Product PN CIKPS

Mod. 984

Description PES Capsule Filter

Rev. 01

Capsule Filter PES Membrane



ORDERING INFORMATION

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Product Type	Membrane Type	Membrane pore size	Application	Sterilization	Size	Fittings In/Out	Vent/Drain	Revision
CIK = Capsule Int Filter	PS = PES	0010 = 0.1 µm	B = Low Bio	N = Not Sterile	SS = 2.5"	5TC = 1.5" TC	SS = St/St	0 = Bag label
		0020 = 0.2 µm			LL = 5"	2HB = 1/2" HB	HH = HB/HB	1 = Housing label
		0045 = 0.45 µm			TE = 10"	4HB = 3/4" HB	SH = St/HB	
		0065 = 0.65 µm			TW = 20"	T2B = 1.5" TC/ 1/2" HB	HS = HB/St	
		0080 = 0.80 µm			TH = 30"	T4B = 1.5" TC/ 3/4" HB		
		0120 = 1.2 µm			FO = 40"	2BT = 1/2"HB/ 1.5 TC		
						2B4 = 1/2"HB/ 3/4"HB		
						4BT = 3/4"HB/ 1.5"TC		
						4B2 = 3/4"HB/ 1/2"HB		

INTENDED USE / APPLICATION

The PES membrane capsule utilizes single layer hydrophilic polyethersulfone membrane. It offers broad chemical compatibility, high flow rate and low extractable. Polyethersulfone is particularly suited for the filtration of products that contain substances that adsorb to the media. The lower binding characteristics of polyethersulfone make it a good choice for filtration of valuable protein solutions such as vaccines and biologicals.

- Cell Culture Media
- Large Volume Parenterals (LVP's)
- Pharmaceutical Bulk Chemical Solutions
- Diagnostics
- Blood and Serum Fractions
- Purified Water
- Beer, Wine and Spirits
- Juice & Soft Drinks
- Bottled Water

MATERIALS

- Filter Media: Polyethersulfone
- Media Support: Polypropylene
- End Caps: Polypropylene
- Inner Core: Polypropylene
- Outer Cage: Polypropylene
- Sealing Method: Thermal Bonding

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PRODUCT CHARACTERISTIC	Dimensions and filtration area: 0.6 m^2/10" Fittings: 1.5" TC, 1/2" HB, 3/4" HB, 1.5" TC/ 1/2" HB, 1.5" TC/ 3/4" HB, 1/2"HB/ 1.5 TC, 1/2"HB/ 3/4"HB, 3/4"HB/ 1.5"TC, 3/4"HB/ 1/2"HB.																											
OPERATING CONDITIONS	<table><tr><th colspan="2">Operational Limits</th></tr><tr><td>Maximum Forward Differential Pressure</td><td>Liquid:5.5 bar(80psi) at 77°F/25°C Gas:4.1 bar(60psi) at 77°F/25°C</td></tr><tr><td>Minimum Bust Pressure</td><td>8.5 bar(120psi) at 77°F/25°C</td></tr><tr><td>Maximum Forward Differential Pressure</td><td>5 bar(72psi) at 68°F/20°C</td></tr><tr><td>Maximum Reverse Differential Pressure</td><td>3.0 bar(44psi) at 68°F/20°C</td></tr><tr><td>Maximum Operating Temperature</td><td>176°F/80°C</td></tr></table>	Operational Limits		Maximum Forward Differential Pressure	Liquid:5.5 bar(80psi) at 77°F/25°C Gas:4.1 bar(60psi) at 77°F/25°C	Minimum Bust Pressure	8.5 bar(120psi) at 77°F/25°C	Maximum Forward Differential Pressure	5 bar(72psi) at 68°F/20°C	Maximum Reverse Differential Pressure	3.0 bar(44psi) at 68°F/20°C	Maximum Operating Temperature	176°F/80°C															
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SANITIZATION/ STERILIZATION	Capsules can be chemically sanitized by common sanitizing agents or hot water at 194°F/90°C for a limited time. Capsules are multi-cycle autoclavable 25 times at 257°F/125°C for 30 minutes.																											
REGULATORY COMPLIANCE	♦ The filters are constructed with polypropylene resins and filtration media in compliance with 21CFR Part 177 of the US Code of Federal Regulations and USP Class VI Biological Test for Plastic. ♦ EU10/2011 compliant. ♦ FDA food contact compliant ♦ RoHS Directive 2011/65/EU ♦ Bio-safety according to ISO 10993 ♦ Resins used to make plastic parts of cartridges are free of BSE/TSE																											
CERTIFICATE OF COMPLIANCE	All shipments shall include documentation certifying the product lot meets these specifications and must include lot data results, test method and performance specification limits.																											
PERFORMANCE REQUIREMENTS	<table><tr><th colspan="3">Water wetted membrane</th></tr><tr><th>Pore size</th><th>Min.Bubble point</th><th>Diffusive Flow/10"</th></tr><tr><td>0.04 µm</td><td>2.3 barg@22°C/IPA</td><td>≤ 25 ml/ 1.7 barg</td></tr><tr><td>0.1 µm</td><td>1.7 barg@22°C/IPA</td><td>≤ 25 ml/ 1.3 barg</td></tr><tr><td>0.2 µm</td><td>3.5 barg@22°C</td><td>≤ 25 ml/ 2.8 barg</td></tr><tr><td>0.45 µm</td><td>2.3 barg@22°C</td><td>≤ 25 ml/ 1.7 barg</td></tr><tr><td>0.65 µm</td><td>1.6 barg@22°C</td><td>≤ 25 ml/ 1.0 barg</td></tr><tr><td>0.8 µm</td><td>1.3 barg@22°C</td><td>≤ 25 ml / 0.8 barg</td></tr><tr><td>1.2 µm</td><td>0.9 barg@22°C</td><td>≤ 25 ml/ 0.6 barg</td></tr></table>	Water wetted membrane			Pore size	Min.Bubble point	Diffusive Flow/10"	0.04 µm	2.3 barg@22°C/IPA	≤ 25 ml/ 1.7 barg	0.1 µm	1.7 barg@22°C/IPA	≤ 25 ml/ 1.3 barg	0.2 µm	3.5 barg@22°C	≤ 25 ml/ 2.8 barg	0.45 µm	2.3 barg@22°C	≤ 25 ml/ 1.7 barg	0.65 µm	1.6 barg@22°C	≤ 25 ml/ 1.0 barg	0.8 µm	1.3 barg@22°C	≤ 25 ml / 0.8 barg	1.2 µm	0.9 barg@22°C	≤ 25 ml/ 0.6 barg
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VISUAL REQUIREMENTS	Visual acceptance requirements apply when inspected below conditions : Instrument inspection: with naked eye Distance: 350-400mm Sampling plan according to ISO 2859 part 1 – 1st Level inspection, single sampling plan, normal inspection. <table border="1"> <thead> <tr> <th>Specification</th><th>AQL</th></tr> </thead> <tbody> <tr> <td>Free of foreign particles</td><td rowspan="3">0.65</td></tr> <tr> <td>Free of cracks</td></tr> <tr> <td>Clear printing of labels</td></tr> </tbody> </table>	Specification	AQL	Free of foreign particles	0.65	Free of cracks	Clear printing of labels
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Free of foreign particles	0.65						
Free of cracks							
Clear printing of labels							
PACKAGING AND LABELLING	Each product and inner carton are labelled with the following traceability information : - Product code and description - Lot number - Quantity - Working conditions						
TRACEABILITY	To enable traceability of capsule, the media description, micron rating and batch number shall be engraved on the cage or end caps.						

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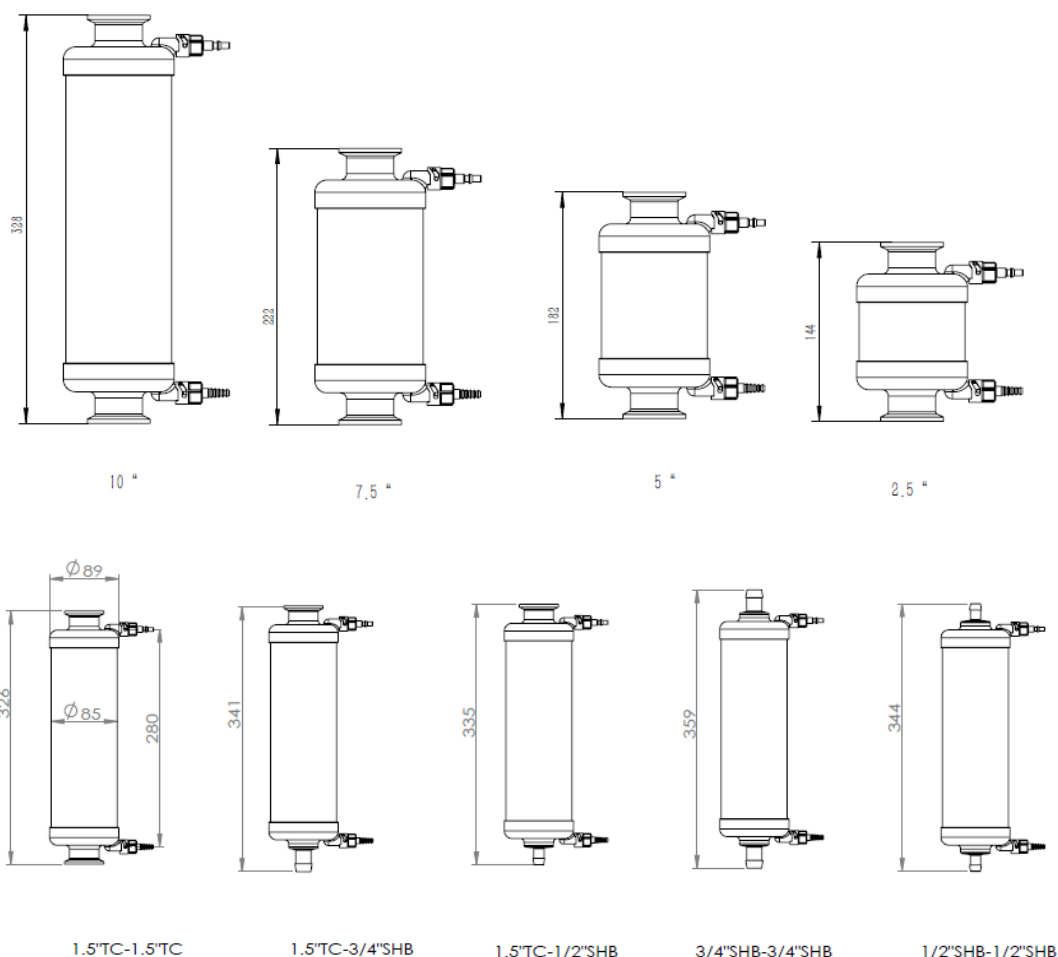
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DRAWING



STORAGE

Store the product at room temperate, in a dry place, free of dust and not exposed to direct sunlight.

NOTICE

Many factors beyond GVS control can affect the use and performance in particular application, including the conditions under which the product is used. Since these factors are uniquely within the user's knowledge and control, it is essential to do the evaluation before the user to determine whether the product is fit for the particular purpose and suitable for the user's application.

WARRANTY; LIMITED REMEDY; LIMITED LIABILITY

GVS makes no other warranties including, but not limited to, and implied warranty of merchantability or fitness for a particular purpose. Except where prohibited by law, GVS will not be liable for any indirect, special, incidental or consequential loss or damage arising from this product, regardless of the legal theory asserted.

This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

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REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
2023/3/20	01	Initial release	Rachel Zhuang/Project Engineer	Jeff Zhou/Quality Manager

Customer Approval:

We accept this material specification as a part of the agreed terms of delivery

Company name _____

Approved by: _____
(Name, Function) (Signature)

Date _____
(Company stamp)

Please send back this document signed for approval. If we will not receive this specification signed , we consider the first order placed as implicit approval.