FibraFlow Tangential Flow Filtration

GVS provides comprehensive solutions on tangential flow filtration

TFFS PS 010 003 010 80N

1 2 3 4 5 6

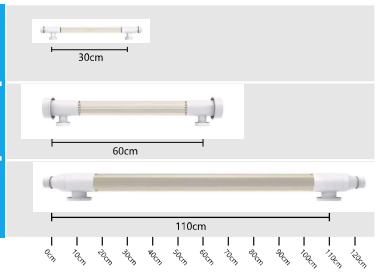
1 Material of hollow fiber membrane

PS	PES(Modified polyethersulfone)

2 MWCO

010M	0.1μm
020M	0.2μm
045M	0.45μm

3 Passageway length

03	
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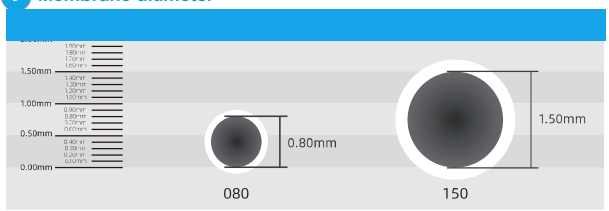
5 Membrane diameter



6 Specification

N	common filters
A	autoclavable filter
SU	single-use filter, irradiated

4 Housing specifications

Code	Scale	Inner diameter (mm)	Membrane area (m^2)	Passageway length (cm)	Housing length (cm)	Interface specifications Inlet/Return Port Through Port
01	small scale	3	0.00067	27	32.2	4mm male luer head
			0.0014	56	62.2	4mm female luer head
02		9	0.017	27	31.8	TC25(1/2") TC25(1/2")
			0.035	56	61.8	
03		19	0.10	27	33.3	TC25(1/2") TC25(1/2")
			0.20	56	63.3	
04	middle scale	32	0.24	27	31.2	TC50(1-1/2") TC25(1/2")
			0.50	56	61.2	
05		51	0.53	27	35.5	TC50(1-1/2") TC25(1/2")
			1.1	56	65.5	
06	production	76	2.7	53	67.9	TC64(2") TC50(1-1/2")
			5.1	101	117.9	
07		108	5.0	50	70.9	TC64(2") TC50(1-1/2")
			10	101	121.1	

Hollow Fiber Filter

Common applications:

- Lysate clarification
- Upstream cell perfusion culture
- Inclusion body clarification and renaturation
- Nanoparticle Diafiltration and Separation
- Liposome concentration and diafiltration
- Cell concentration, clarification, diafiltration
- Purification, concentration, diafiltration of proteins and nucleic acids
- Virus purification, concentration, diafiltration

The production raw materials of this product meet the requirements of EMEA/410/01.

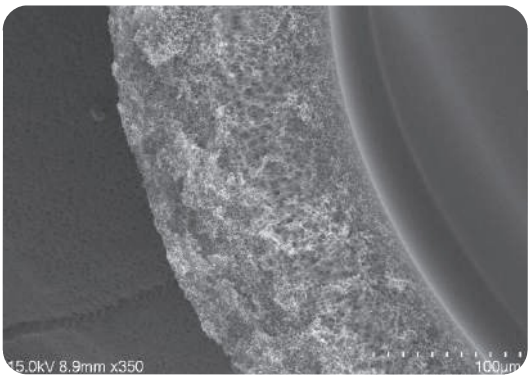
The technical parameters of this product meet the following regulatory requirements:

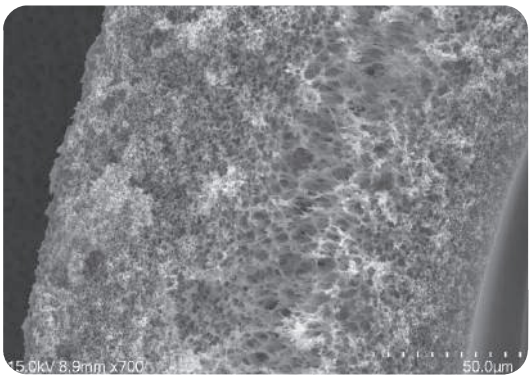
- Biological Reactivity Test, In Vivo per USP<88>Class VI
- 21CFR177 Indirect Food Additives
- L929 MEM Elution test - ISO 10993-5(Cytotoxicity)
- Hemolysis - Rabbit Blood (direct contact) - ISO 10993-4

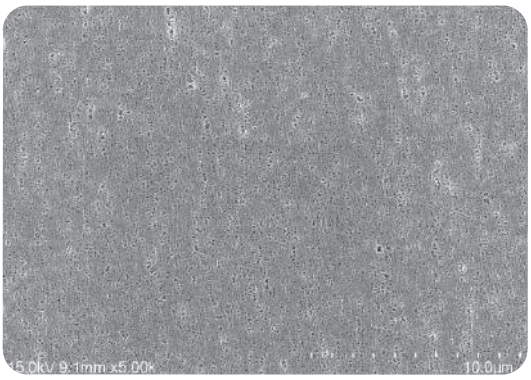
The production of this product meets the requirements of 15013485:2016 quality management system.

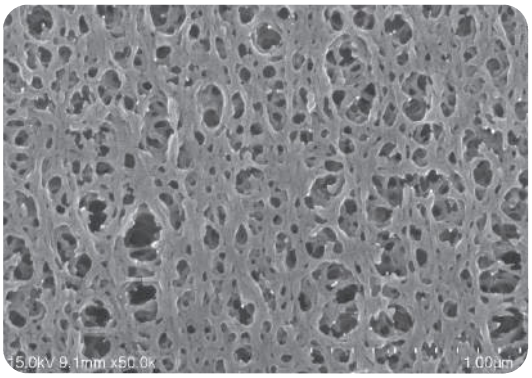
Hollow Fiber Membrane

GVS hollow fiber filter is made of modified polyethylene inkstone (mPES), which is suitable for filtration of various processes in the pharmaceutical industry (such as biopharmaceuticals, chemical drugs etc.) and the food industry. It can provide stable and reliable filtration performance.



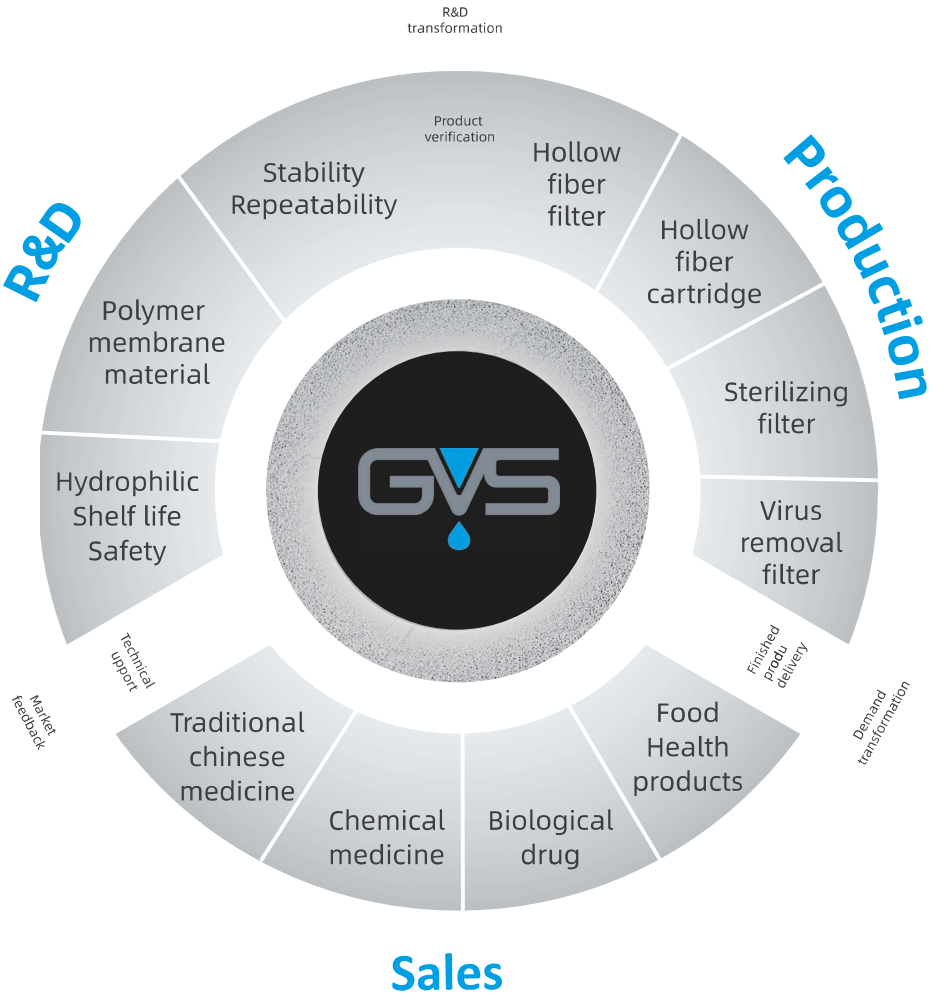






GVS hollow fiber membrane made of modified polyphenol is an asymmetric structure, the membrane layer is dense, and the outer layer is relatively open. Its unique structural design can result in lower bioburden, lower non-specific adsorption, faster filtration rate, higher throughput, and shorter filtration time, so it is very suitable for the pharmaceuti-cal and food industries.

GVS takes advantage of its professional production process in "membrane" to speed up the development of the biomedical industry



Chemical Compatibility Table

Code indication: R=recommended; L=limited exposure; NR=not recommended; U=unknown

Material / Solvent	Regenerated cellulose (RC)	Polysulfone(PS) polyethersulfone (PES)	Modified polyethersulfone (mPES)	Polypropylene (PP)	Polyvinylidene fluoride (PVDF)	Nylon (N)	Stainless steel (SS)	Polyester (P)	Fluorocarbons (F)
Ammonia (diluted)	R	R	R	R	R	R	R	U	R
Ammonia (diluted)(10%)	L	R	R	R	R	R	R	U	R
aniline	R	NR	NR	R	R	R	R	U	R
benzaldehyde	R	NR	NR	R	L	U	L	NR	R
phenol (0.5%)	R	R	R	R	R	NR	L	L	R
phenol (10%)	R	L	L	R	R	NR	L	NR	R
propanol	R	R	R	R	R	NR	R	R	R
acetone	R	NR	NR	R	L	R	R	R	R
acetic acid (5%)	R	R	R	R	R	NR	L	L	R
acetic acid (25%)	R	L	L	R	R	NR	L	NR	R
sodium hypochlorite	R	R	L	L	R	NR	NR	U	R
butanol	R	R	R	R	R	L	R	R	U
xylene	R	NR	NR	R	R	R	L	NR	R
dichloromethane	R	L	L	R	R	L	L	NR	R
dimethylformamide	L	NR	NR	R	NR	R	R	NR	U
dimethyl sulfoxide (50%)	U	L	L	U	U	U	U	U	U
glycerin	R	R	R	R	R	R	R	R	R
peracetic acid (0.1N)	U	R	R	U	U	U	U	U	U
perchloric acid(25%)	L	NR	NR	NR	R	NR	L	U	R
toluene	R	NR	NR	R	R	R	R	U	R
cresol	R	NR	NR	R	NR	NR	R	U	R
methanol	R	L	L	R	R	L	R	U	R
formaldehyde (2%)	R	R	R	R	R	R	R	R	R
formaldehyde (30%)	R	R	R	R	R	R	R	R	R
formic acid (25%)	R	R	R	R	R	NR	L	NR	R
formic acid (50%)	R	R	R	R	R	NR	L	NR	R
phosphoric acid (25%)	L	L	L	R	R	L	NR	U	R
sulfuric acid(5%)	R	R	R	R	R	L	NR	NR	R
sulfuric acid(25%)	L	R	R	R	R	NR	NR	NR	R
citric acid(2%)	U	R	R	U	U	U	U	U	U
urea	R	R	R	R	R	R	L	R	R
urea (6N)	R	NR	R	R	R	R	L	R	R
boric acid	R	R	R	R	R	L	L	R	R
hydrofluoric acid (25%)	L	L	L	NR	R	L	NR	NR	R
potassium hydroxide (1N)	R	R	R	R	R	L	L	R	R
potassium hydroxid (25%)	R	R	R	R	R	L	L	R	R
sodium hydroxide (0.1N)	R	R	R	R	R	R	L	R	R
sodium hydroxide (5%)	L	R	R	R	R	R	L	L	R
sodium hydroxide (25%)	L	R	R	R	R	R	L	NR	R
trichloroacetic acid (25%)	NR	R	R	R	R	L	NR	NR	R
trichloromethane (chloroform)	R	NR	NR	R	R	R	R	R	R
triethylamine	R	NR	NR	L	R	R	R	U	R
carbon tetrachloride	R	NR	NR	R	R	NR	L	R	U
tetrahydrofuran	R	NR	NR	R	R	R	R	R	R
diacetone alcohol	R	NR	NR	R	R	R	L	U	R
hydrogen peroxide(30%)	R	L	L	R	R	NR	L	R	R

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petroleum ether	R	R	R	R	R	U	U	R	U
nitric acid(5%)	R	R	R	R	NR	NR	R	R	R
nitric acid (25%)	NR	R	R	R	NR	NR	R	L	R
nitric acid (6N)	NR	L	L	L	R	NR	R	R	R
acetonitrile	R	NR	NR	R	L	U	U	U	U
ether	R	NR	NR	L	L	R	R	NR	R
ethyl acetate	R	NR	NR	R	R	R	L	U	R
amyl acetate (banana oil)	R	NR	NR	R	R	L	R	L	R
ethanol	R	R	R	R	R	R	R	R	R
ethanol(15%)	R	R	R	R	R	R	R	R	R
ethanol(95%)	R	L	L	R	R	R	R	R	R
ethylene glycol	R	R	R	R	R	R	L	R	R
hydrochloric acid (5%)	R	R	R	R	R	L	NR	R	R
hydrochloric acid (25%)	NR	R	R	R	R	NR	NR	R	R
hydrochloric acid(37%)	NR	R	R	L	R	NR	NR	R	R
Isopropyl alcohol	R	R	R	R	R	NR	L	R	R
n-hexane	R	R	R	R	R	L	R	R	R

This table is for informational purposes only and is not a guarantee of chemical compatibility. Variations in temperature, concentration, exposure time and other factors may affect the performance of the product and it is recommended to test under your own conditions.

Quality compliance

GVS hollow fiber filter is designed, developed and produced under the ISO13485 quality management system certified by the authoritative organization.After the production be completed in an ISO CLASS 7 clean room, a quality certificate is issued after the products passing the inspection. Products with good quality specifications can meet the regulatory needs of biopharmaceutical customers.

- USP <88> Class VI Testing: All flow path materials have been tested confirmed to the USP <88> Class VI biocompatibility standards
- Bioburden: Bioburden of a single hollow fiber column < 1000 Colony Forming Units (CFU)
- Pyrogen: Hollow fiber filter production and assembly are carried out under strictly monitored conditions to ensure minimal endotoxin levels, but the product line cannot be guaranteed to be completely pyrogen-free
- Free of Animal Origin: Synthetic and processed materials used in fiber synthesis that do not contain any animal or derived substances
- Shipping and Packaging Verification: GVS has verified product shipping/packaging configurations to ISTA 3A (2008) requirements to ensure that sterile products are adequately protected from damage during shipping
- Product Validity: Non-sterile filters are valid for 5 years from the date of manufacture