

Spectrum Laboratories manufactures hollow fiber filtration modules in an ISO Class 7 (US Fed. 209 E Class 10,000) clean room according to cGMP and ISO 9001:2000 standards. Each module has 100% lot traceability for materials and fabrication and is individually tested using a modified pressure hold test to assure membrane integrity. All of the hollow fiber filtration modules are made "Animal By-Product Free" and meet USP Class VI certification.

A. MATERIALS OF CONSTRUCTION

Disposable Hollow Fiber Modules

Following is a list of the major components used in the manufacturing of the disposable hollow fiber modules (1 of 4 membrane types):

Membrane Fiber:	1. Polysulfone (PS)	Housing:	Polysulfone
	2. Polysulfone with 0.9% NaCl* and 0.9% H ₂ O ₂ *(PS Wet)	Potting:	Polyurethane (Polycin* and Vorite*) or Epoxy
	3. Polyethersulfone (PES)	Netting (if present):	Polypropylene
	4. Mixed Cellulose Ester* with Glycerin* (ME)	Gasket (if present):	Silicone

*An MSDS on the raw material which comprise the module is available upon request.

B. MODULE PREPARATION

Spectrum recommends the following module flushing and wetting protocols based on the membrane type.

Polysulfone (PS), Dry

In order to achieve maximum flux capacity, the hydrophobic membrane must be completely pre-wetted with alcohol.

1. Flush the module with 100% isopropanol or 70% ethanol until a filtrate volume of 2 ml/cm² of surface area is reached. (Modules \geq 1 m² surface area can be rinsed until filtrate volume equals 1 ml/cm² of surface area.) To conserve alcohol, the filtrate can be directed into the retentate reservoir. OR, the module can be filled with alcohol for 2 hours to thoroughly wet out the pores.
2. Drain the alcohol from retentate and filtrate sides of module (and system).
3. Rinse out remaining alcohol with DI water or buffer at 2-5 psi until a filtrate volume of 2 ml/cm² of surface area is reached. (Modules \geq 1 m² surface area can be rinsed until filtrate volume equals 1 ml/cm² of surface area.)
4. Drain water from module and perform integrity test.

Polysulfone (PS), Wet

Hydrophobic polysulfone modules are available pre-wetted for your convenience. The pre-wetted ultrafiltration modules are packaged in DI water containing 0.9% hydrogen peroxide and 0.9% sodium chloride as a preservative.

1. Drain excess preservative solution from retentate and filtrate sides of module.
2. Rinse out remaining solution with DI water or buffer at 2-5 psi until a filtrate volume of 2 ml/cm² of surface area is reached. (Modules \geq 1 m² surface area can be rinsed until filtrate volume equals 1 ml/cm² of surface area.)
3. Drain module and perform module integrity test.

Mixed Cellulose Ester (ME)

Microfiltration modules made with hydrophilic mixed cellulose ester (ME) membrane contains glycerin as a humectant to preserve the membrane durability. Glycerine is water soluble and readily rinses out.

1. Rinse out glycerine with DI water or buffer at 2-5 psi until a filtrate volume of 2 ml/cm² of surface area is reached. (Modules \geq 1 m² surface area can be rinsed until filtrate volume equals 1 ml/cm² of surface area.) OR, the membrane can be rinsed with 25-35% isopropanol or ethanol under the same conditions. After which, the alcohol must be thoroughly rinsed out with DI water or buffer, again under the same conditions.
2. Drain module and perform module integrity test.

Polyethersulfone (PES)

Microfiltration modules made with hydrophilic PES are provided dry and without preservative. PES modules are ready for use out of the package. However, Spectrum strongly recommends integrity testing prior to use.

1. Wet out the module with DI water or buffer at 2-5 psi until a filtrate volume of 2 ml/cm² of surface area is reached. (Modules \geq 1 m² surface area can be rinsed until filtrate volume equals 1 ml/cm² of surface area.)
2. Drain module and perform module integrity test.

C. MODULE INTEGRITY TESTING

All hollow fiber modules are integrity tested prior to shipment. However, Spectrum strongly recommends an integrity test be performed prior to use.

The following pressure hold test is recommended to verify the integrity of a wetted module:

1. Close the filtrate side of the wetted module and system.
2. Use air or nitrogen gas to pressurize the retentate side of the module and system up to 5 psig (up to 10 psig for large modules).
3. If pressure drops greater than 0.5 psi/min, then the system connections may be leaking. Tighten all connections, pressurize to 5 psig and check for pressure drop again.
4. After assuring system integrity, open the filtrate line.
5. If the pressure drop is less than 0.5 psi/min, the membrane is integral. Release pressure before use.
6. If the pressure drop is more than 0.5 psi/min, the module is either not integral or not completely wetted.
7. Re-wet the module with water (2 ml/cm² surface area), drain and pressurize retentate side to 5 psig.
8. If the pressure drop is more than 0.5 psi/min again, then the module is not integral and should not be used.

D. MODULE STERILIZATION & SANITIZATION

Spectrum recommends only hollow fiber modules not subjected / exposed to prior sterilization procedures should be subjected / exposed to one of the following methods. Modules previously irradiated, exposed to ethylene oxide (ETO) or steam autoclaved cannot be subsequently re-subjected / re-exposed to any of these methods.

Chemical Sanitization

The following sanitization methods are recommended for use with hollow fiber modules:

1. Exposure to 0.5 N sodium hydroxide for 30 min – 45 min (PS & PES only).
2. Exposure to 70% ethanol, circulating for 60 min (PS & PES only).
3. Exposure to 500 ppm sodium hypochlorite for 20 min.
4. Exposure to 1.0% hydrogen peroxide, sodium benzoate, sodium azide or formaldehyde for 20 minutes.

Steam-In-Place (SIP)

Only disposable Steam-In-Place (SIP) modules can be subjected / exposed to an approved SIP cycle.

The SIP module should only be steam sterilized or autoclaved as follows:

Temperature: Minimum of 121°C to a maximum of 124°C.

Duration of SIP Treatment: Must be validated by user.

Steam Autoclaving

The following autoclave method is recommended for use with hollow fiber modules:

1. Remove and discard all pouches, as these are not autoclavable; wet the membrane (optional).
2. Loosen all sanitary connections, Luer™ fittings, clamps and flange nuts to avoid damaging the module during the autoclave cycle.
3. Wrap all open ports of the connecting tubing with autoclave paper.
4. Pre-warm the module and use pre-vacuum steps if possible.
5. Slowly ramp up the temperature of the autoclave. Use a ramp time of 15 minutes or half of the hold time of autoclave, whichever is LARGER.
6. Hold the autoclave at 121°C for 30 minutes, do not exceed 124°C.
7. Slowly ramp down the temperature of the autoclave to room temperature. Use a ramp down time of 15 minutes or half of the hold time of autoclave, whichever is LARGER. A one minute dry cycle is acceptable, though not necessary.
8. Tighten all sanitary connections, Luer™ fittings or any other clamps or connections if they are fitted in the module.

E. CHEMICAL COMPATIBILITY

This chemical resistance chart is intended for use as a guide, not as a guarantee of chemical compatibility. Variations in temperature, concentrations, durations of exposure and other factors may affect the use of the product. It is recommended to test under your own conditions. The following codes are used to rate chemical resistance:

R (Recommended); **L** (Limited Exposure); **NR** (Not Recommended); **U** (Unknown); **ME** (Mixed Cellulose Ester); **PS** (Polysulfone); **PES** (Polyethersulfone)

CHEMICAL	ME	PS/PES	CHEMICAL	ME	PS/PES	CHEMICAL	ME	PS/PES	CHEMICAL	ME	PS/PES
Acetic acid (diluted-5%)	L	R	Cyclohexane	L	L	Isopropyl Alcohol	L	R	Potassium Hydroxide (1N)	L	NR
Acetic acid (med conc-glacial)	NR	R	Cyclohexanone	NR	NR	Isopropyl Ether	L	R	Potassium Hydroxide (25%-50%)	NR	R
Acetone	NR	NR	Diacetone Alcohol	NR	NR	Lactic Acid	R	R	Propanol	R	R
Acetonitrile	NR	NR	Dichloromethane	L	L	Methyl Acetate	NR	NR	Pyridine	NR	NR
Ammonium Hydroxide (diluted)	NR	R	Dimethyl Formamide	NR	NR	Methyl Alcohol	L	L	Sodium Hydroxide (0.5N)	L	R
Ammonium Hydroxide (conc)	NR	R	Dimethylsulfoxide	NR	NR	Methyl Alcohol (98%)	L	R	Sodium Hydroxide (5%-100%)	NR	R
Amyl Acetate	NR	NR	1,4 Dioxane	NR	L	Methyl Cellosolve	L	R	Sodium Hypochlorite	R	R
Amyl Alcohol	L	L	Ethers	NR	NR	Methyl Chloride	NR	NR	Hexanol	L	R
Aniline	NR	NR	Ethyl acetate	NR	NR	Methyl Ethyl Ketone	NR	NR	Hydrochloric Acid (diluted-5%)	R	R
Benzene	NR	L	Ethyl Alcohol (15%)	R	R	Methyl Formate	NR	NR	Hydrochloric Acid (conc-25%)	NR	R
Benzyl Alcohol	NR	NR	Ethyl Alcohol (95%)	L	L	Methyl Isobutyl Ketone	NR	NR	Sulfuric Acid (diluted-5%)	L	R
Boric Acid	R	R	Ethylene Dichloride	NR	NR	Methylene Chloride	L	L	Sulfuric Acid (med conc-conc)	NR	R
Brine	R	R	Ethylene Glycol	L	R	N-methyl-2-pyrrolidone	NR	NR	Tetrahydrofuran	NR	NR
Bromoform	NR	NR	Ethylene Oxide	NR	R	Monochlorobenzene	L	NR	Toluene	R	L
Butyl Acetate	NR	NR	Formaldehyde (2%-30%)	L	R	Nitric Acid (diluted-5%)	L	R	Trichloroacetic Acid (25%)	NR	R
Butyl Alcohol	L	R	Formic Acid (25%-50%)	NR	R	Nitric Acid (med conc-25%)	NR	R	Trichlorobenzene	NR	NR
Butyl Cellosolve	NR	NR	Glycerine/Glycerol	R	R	Nitropropane	NR	NR	Trichloroethane	L	L
Butylaldehyde	NR	NR	Hydrochloric Acid (37%)	NR	R	Pentane	R	R	Trichloroethylene	R	R
Carbon Tetrachloride	NR	NR	Hydrofluoric Acid (25%)	NR	L	Perchloric Acid (25%)	NR	NR	Triethylamine	NR	NR
Cellosolve	NR	R	Hydrogen Peroxide (30%)	R	R	Perchloroethylene	NR	NR	Urea	R	R
Chloroacetic Acid	NR	NR	Iodine Solutions	NR	NR	Petroleum Ether	R	R	Urea (6N)	NR	NR
Chloroform	L	L	Isobutyl Alcohol	R	R	Phenol (0.5%)	R	R	Water	R	R
Chromic Acid	NR	NR	Isopropanol	L	R	Phenol (10%)	NR	L	Xylene	NR	NR
Cresol	NR	NR	Isopropyl Acetate	NR	NR	Phosphoric Acid (25%)	NR	R			

For additional product literature and technical information, please go to our website at www.spectrumlabs.com.



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