



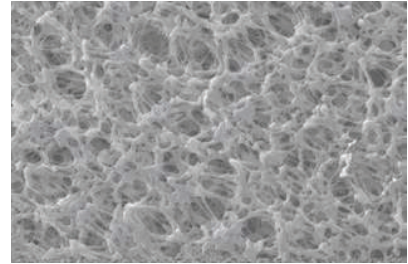
Membrane Characteristics

Filtration through a membrane means that the filter material will stop particles larger than the pore size rating. This enables an absolute pore size rating for the membranes for which they are clearly classified. Bacterial retention claims can be made based on the pore size of the membrane.

Hydrophilic – Hydrophobic Membranes

Hydrophilic membranes have permeability of aqueous solutions and once wetted, they stop gasses. This means that aqueous solutions pass through hydrophilic membranes but gas is stopped when the membrane is wet until the applied pressure exceeds the “bubble point”, at which time the air will evacuate the pore, the liquid is expelled, and the gas will go through. Dry hydrophilic membrane allows gas to pass through. Our HI-FLO PES membranes are hydrophilic membranes.

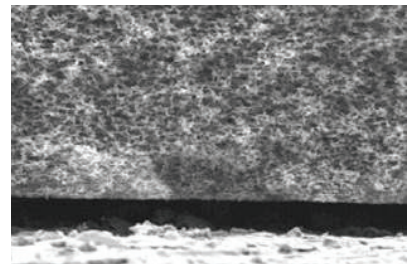
- Hydrophobic membranes have permeability to the gas, but they stop aqueous solutions. In other words, they do the opposite job when compared to hydrophilic membranes. This means that gas will pass through these membranes, but aqueous solutions will be stopped. If air or gas can reach the hydrophobic membrane, it will go through, but if the contact with the hydrophobic membrane is not possible, then the gas will not pass through. The pressure at which aqueous solutions will pass through a hydrophobic membrane is called the water breakthrough (WBT) or water intrusion pressure (WIP). PTFE membranes are hydrophobic membranes. PES membranes are hydrophilic membranes.



Membrane outside wall

Pore size

Pore size is determined by the size of the particle that is expected to be retained with a defined with a high degree of efficiency. Pore size is typically stated in micrometers or microns (μm), and should clearly be designated as either nominal or absolute. Nominal pore size is the ability to retain a majority (60% - 98%) of particles having a specific dimension. Retention efficiency is also depending on such process conditions as concentration, operating pressure etc. Rating parameters can vary among manufacturers. When the pore size, or retention, is “nominal”, it should be stated at a particle size and a percent, i.e., 99.97% retention of 0.3 μm particles. Absolute pore size is the ability to retain the 100% of particles of a specific dimension under defined test conditions (particle size, challenge pressure, concentration, detection method).



Membrane cross section

Pore Size	Challenge Organism:
0.1 micron	Acholeplasma laidlawii
0.2 micron	Brevundimonas diminuta
0.45 micron	Serratia marcescens
0.8 micron	Lactobacillus species
1.2 micron	Candida albicans

The above table shows proper pore size of hydrophilic membranes to be used to retain the corresponding bacteria. Hydrophobic membranes are about ten times more efficient in retaining bacteria in air than they are in liquids using the same pore size.

FILTRATION GUIDE

Chemical compatibility

This is the ability of the membrane to resist to chemicals without mechanical or chemical damage from chemical exposure. Information about the liquid used with a specific filter material should be outlined before application to determine compatibility, GVS Life Sciences can assist customers in choosing the proper filter (and housing) materials.

Extractables

Extractables are contaminants (typically chemicals) that elute from the filter which might affect quality of the effluent. Wetting agents (surfactants), manufacturing or sterilization residuals are the main cause of undesired extractables. Typical problems caused by extractables are found in the following applications:

- HPLC analysis (strange result)
- Cell culture (cytotoxicity)
- Microbiological analysis (affects the microorganism)
- Environmental analysis (contaminants)

Flushing of the line prior to use can reduce Extractables and their adverse effects.

Binding

This is the property of substances to be filtered having affinity with membranes. This could be a positive effect in some circumstances, but most of the time it can create adverse effects. Particularly it could lead to loss of active components of the liquid to be filtered reducing its beneficial effect. Our PES HI-FLO membrane is low protein binding.

Thermal Stability

This characteristic allows unchanged performance at elevated temperatures. Some membranes can only be sterilized by EtO. Others can be gamma, beta or e-beam sterilized, as well as EtO. Others can be also steam sterilized with no adverse affects. Membrane performance is sometimes reduced at temperature higher than 25°C, and high temperatures can also reduce chemical stability. PTFE membrane is widely stable (any type of sterilization) if the product is designed properly. PES membrane is suggested for EtO and irradiation (no steam sterilization).

Biosafety

These tests are conducted in compliance with ISO-10993 and USP class VI, see specifications Tests that are conducted are: Cytotoxicity – Sensitization – Irritation intracutaneous reactivity – Systemic toxicity (acute) – Hemocompatibility (Hemolysis).

Pyrogenicity

Pyrogens are chemicals on the filter media and other components that are caused by the waste of dead bacteria. When introduced to a patient, they can elevate the patient's temperature, and can cause complications – even death. Filters that are pyrogenic can make solutions pyrogenic.

They cannot be removed by sterilization, so it is very important that non-pyrogenic filter media and components are used in the production of medical filter devices. The test to determine the pyrogenicity is the LAL test (Limulus Amebocyte Lysate test).

Bubble Point (BP)

Typically this test that is performed on hydrophilic membranes. The BP pressure is the pressure to force air through a wetted hydrophilic membrane. These tests are typically performed with water; however, this test can be conducted on hydrophobic membranes using liquids other than water that will wet the membrane. The BP is an indication of the membrane pore size, as related to actual bacterial retention. This test can also be performed on hydrophobic membranes if the correct solvent (instead of aqueous solution) is used, and is compatible with the entire product.

Water Breakthrough (WBT)

This is the test performed on hydrophobic membranes, and it is also related to the pore size of the membrane. The WBT pressure (sometimes referred to as water intrusion pressure) is the pressure it takes to force an aqueous solution through a hydrophobic membrane.



Water Flow Rate (WFR)

Typically this test is performed on hydrophilic membranes. The WFR has the aim to measure the flow of a liquid through a wetted hydrophilic membrane, at a fixed test pressure and time. This test is typically performed with water; however, it can be performed with other solutions, as long as the filter media is compatible with the liquid.

Air Flow (AF)

This is a flow rate typically related to hydrophobic membranes. It is the amount of air that passes through a fixed surface of membrane with a specific applied pressure.

Filter Efficiency (FE)

Quantity of particulate or bacteria retained compared to the total quantity of particulate or bacteria to which the filter is challenged. It is expressed in % and referred to a specific size of particles.

Effective Filtration Area (EFA)

This is the actual filtration area in a device that is subject to filtration. The sealing surfaces should be eliminated from the calculations of the device EFA.

Polymer Information

Thermoplastics and thermosets are the two basic groups of plastic materials. Thermoplastic resins can be repeatedly melted and solidified by heating and cooling so that any scrap generated in processing can be theoretically reused. No chemical change generally takes place during forming. Usually, thermoplastic polymers are supplied in the form of pellets, which often contain additives to enhance processing or to provide necessary characteristics in the finished product (e.g., color, conductivity, etc.). The temperature service range of thermoplastics is limited by their loss of physical strength and eventual melting at elevated temperatures.

Polypropylene (PP)

It is similar to polyethylene, but each unit of the chain has a methyl group attached. It is translucent, autocavable, and has no known solvent at room temperature. It is slightly more susceptible to strong oxidizing agents than conventional polyethylene because of its many branches (methyl groups, in this case). Polypropylene is noted for its excellent chemical resistance in corrosive environments. This polymer is easily welded and machined.

Typical properties:

- ◆ Clean/High Purity
- ◆ Good Dimensional Stability
- ◆ Good Organoleptic Properties
- ◆ High Clarity
- ◆ High Flow
- ◆ High Stiffness
- ◆ Homopolymer
- ◆ Low Warpage
- ◆ Narrow Molecular Weight Distribution
- ◆ Nucleated

FILTRATION GUIDE

Polyethylene (PE) Plastic

Huge family of resins obtained by polymerizing ethylene gas, and it is available in a range of flexibilities. Polyethylene can be formed by a wide variety of thermoplastic processing methods and is particularly useful where moisture resistance is required. Low-density polyethylene (LDPE) has more extensive branching, resulting in a less compact molecular structure. High-density polyethylene (HDPE) has minimal branching, which makes it more rigid and less permeable than LDPE. Linear low-density polyethylene (LLDPE) combines the toughness of low-density polyethylene with the rigidity of high-density polyethylene.

Typical properties:

- ◆ Good Processability
- ◆ Food Contact Acceptable
- ◆ Antioxidant
- ◆ High ESCR (Stress Crack Resist.)
- ◆ Low Density
- ◆ High Impact Resistance

Acrylic-based polymer

Acrylic polymer developed especially for use in the Medical Device Industry. The material is transparent and tough offer gamma and ETO sterilization resistance, and they are easy to process and weld easily to PVC. Typical applications include disposable medical diagnostic devices such as cassettes and cuvettes.

Typical properties:

- ◆ Excellent chemical resistance to fats and oils
- ◆ Excellent bonding and welding capabilities
- ◆ Excellent bonding to PVC tubing
- ◆ Good impact strength
- ◆ Good light transmission
- ◆ Good resistance to EtO, gamma and E-beam sterilization
- ◆ Superior resistance to lipids and alcohol
- ◆ Excellent ductility

Nylon

This is a group of linear polymers with repeated amide linkages along the backbone. These are produced by an amidation of diamines with dibasic acids, or polymerisation of amino acids. Nylon is strong and tough. It resists abrasion, fatigue and impact. Nylon offers excellent chemical resistance with negligible permeation rates when used with organic solvents. However, it has poor resistance to strong mineral acids, oxidizing agents and certain salts.

Typical properties:

- ◆ Good Chemical Resistance
- ◆ Good Colorability
- ◆ Good Corrosion Resistance
- ◆ Good Processability
- ◆ Good Toughness
- ◆ Good Wear Resistance
- ◆ High Rigidity
- ◆ High Strength
- ◆ Low Friction

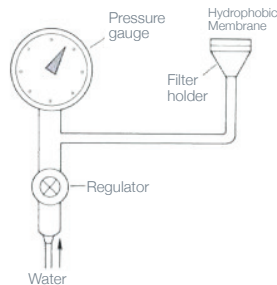
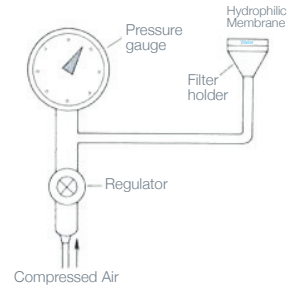


Measuring a Filter Media's Performance

GVS Filter Technology uses tests to rate the performance of its media. For any other information, feel free to contact us.

Bubble Point

Measure of the air pressure required to force liquid from the largest wetted pore of a membrane. Serves as an indication of pore size and a barrier to particulates. The bubble point is dependent on the liquid used to wet the membrane; for a given pore size the bubble point will be higher in a liquid with a higher surface tension (such as water) than in a liquid with a lower surface tension (such as isopropyl alcohol). The bubble point rating is determined when the largest pore yields a bubble; the larger the pore, the less pressure required to form the bubble. Expressed in units of pounds/square inch (psi) or bar for membranes.



Water Breakthrough

Measure of the amount of pressure required to transmit water through the largest pore of a dry hydrophobic media. Serves as an indication of pore size for a hydrophobic membrane. The larger the pore size, the less pressure required to intrude the water. Expressed in the membrane industry in units of pounds/square inch (psi) or bar.

Water Flow

Measure of the amount of water that flows through a membrane. Related to the degree of contamination, differential pressure, total porosity, and filter area. Expressed in the membrane industry in units of milliliters/minute/square centimeter at a defined pressure.

Air Flow

Measure of the amount of air that flows through a membrane. Related to the degree of contamination, differential pressure, total porosity, and filter area. Commonly expressed in the membrane industry in liters/minute/square centimeter at a given pressure.

Filter Efficiency

Measure of the quantity of particulate retained as a function of the total number and size of the challenging particles and differential pressure. Usually expressed as a percentage of retention of predetermined particle size at a given challenge concentration. In the case of bacterial removal efficiency, this may be expressed as a log reduction value.

Biological Safety Test

Tests conducted on filter construction materials that come in contact with test solutions that simulate most body fluids. Extracts of filter construction materials are tested to establish whether there are potential "leachables" present. Testing is performed to determine whether leachables are capable of inducing measurable degrees of systemic toxicity, localized skin irritation, sensitization reaction, or other biological responses.

Pirogenicity

Property of a substance that, when injected into the body, causes a rise in body temperature. Filtration materials that come in contact with injectable fluids must meet pyrogenicity standards and are therefore classified as non-pyrogenic.