

**Table 18-2** Microfilter and Ultrafilter Polymers

Membrane polymer	Advantages	Disadvantages
Cellulose acetate	Very low adsorption High flow rates	Limited pH compatibility
Cellulose nitrate	Good flow rate	High adsorption Limited pH compatibility
Regenerated cellulose	Very low adsorption Very high flow rates	Limited pH compatibility
Modified regenerated cellulose	Very low adsorption Broad pH compatibility	Moderate flow rates
Polyamide (nylon)	Good solvent compatibility Good mechanical strength Broad pH compatibility	High protein adsorption Moderate flow rates
Polycarbonate	Good chemical compatibility	Moderate flow rates Difficult to produce
Polyethersulfone	High flow rates Broad pH compatibility	Moderate-to-low adsorption Limited solvent compatibility
Polysulfone	High flow rates Broad pH compatibility	Moderate-to-high adsorption Limited solvent compatibility
Polypropylene	Excellent chemical and mechanical resistance	Hydrophobic material High adsorption
Polyvinylidenedifluoride (PVF)	Low adsorption Good solvent compatibility	Moderate flow rate Hydrophobic base, made hydrophilic by chemical surface treatment
Polytetrafluoroethylene (PTFE)	Excellent chemical and mechanical resistance	High cost Hydrophobic material High adsorption High cost

Source: From Ref. 2.

## FILTER VALIDATION

Filter validation includes both destructive testing to qualify the filter initially and nondestructive testing that is performed prior to and after using the filter in batch production. Destructive testing includes three main tests—(i) bacterial retention using actual final formulation of drug product, (ii) filter extractables/leachables, and (iii) compatibility of filter with drug product.

### Bacterial Retention

In this testing phase, the filter is challenged with a known population of microorganisms using conditions that simulate the actual process. It is important that the microbial challenge involves the final product formulation. Formerly, it was acceptable to use a placebo form of the final product where critical attributes like pH, viscosity, osmolarity, ionic strength, and surface tension were simulated, but today the actual final product must be used as the solution



**Figure 18-2** Cartridge and disc filters. Source: Courtesy of Millipore Corporation.