

Table 18-1 General Types of Filters Used in the Sterile Product Industry

Filter type	Size range (μm)	Examples of what is removed by this filter type
Particle	10–200	Pollens Particles
Microfilter	0.1–10	Some bacteria All bacteria Yeasts Colloids
Ultrafilter	0.001–0.1	Most viruses Large organic compounds (>10,000 Da)
Nanofilter (reverse osmosis)	Less than 0.001	Small organic compounds Ions

Absolute ratings, much more commonly used in the sterile filtration industry, define the diameter of the largest particle that will pass through the filter. Therefore, using the 0.22 μm filter means that no particle larger than 0.22 μm will pass through that filter, unless, of course, the filter is damaged.

After a product has been compounded, it must be filtered if it is a solution. The primary objective of filtration is to clarify a solution. A further step, removing particulate matter down to 0.2 μm in size, would eliminate microorganisms and would accomplish cold sterilization. A solution with a high degree of clarity conveys the impression of high quality and purity, desirable characteristics for a parenteral solution.

MECHANISMS OF AND FACTORS AFFECTING FILTER REMOVAL OF PARTICLES AND MICROORGANISMS

Filters are thought to function by one or, usually, a combination of the following: (i) sieving or screening, (ii) entrapment or impaction, and (iii) electrostatic attraction (Fig. 18-1). When a filter retains particles by sieving, they are retained on the surface of the filter. Entrapment occurs when a particle smaller than the dimensions of the passageway (pore) becomes lodged in a turn or impacted on the surface of the passageway. Electrostatic attraction causes particles opposite in charge to that of the surface of the filter pore to be held or adsorbed to the surface. It should be noted that increasing, prolonging, or varying the force behind the solution may tend to sweep particles initially held by entrapment or electrostatic charge through the pores and into the filtrate.

➤ 65–75% porous → high flow

➤ Particles retained by Sieving

Entrapment (“Tortuous pathway”)

Adsorption (Large internal surface area)

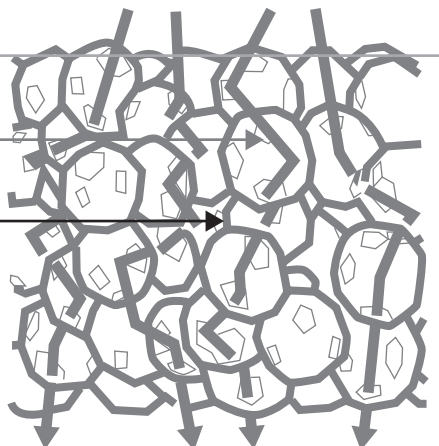


Figure 18-1 Membrane filter characteristics. Source: Courtesy of Millipore Corporation.