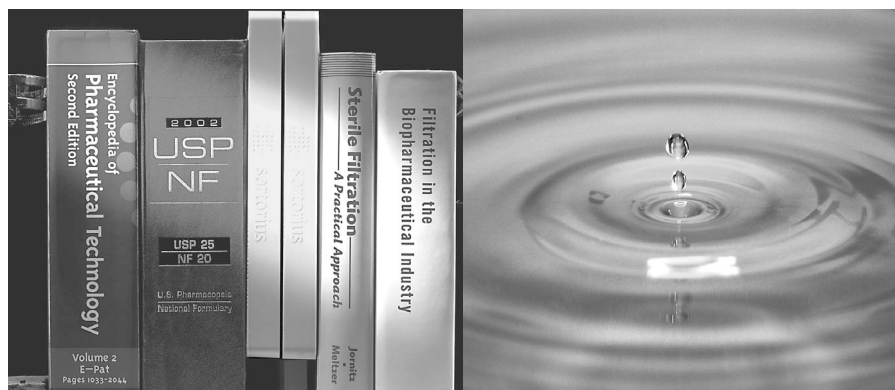


Particulate Testing



Test Specifications:

The particle release from filters and other components in contact with the formulation should be minimized.

Particulate testing is performed after the test device has been in contact with the actual pharmaceutical formulation under customer-specified process conditions.

Description

The presence of particles in injectable solutions is potentially harmful and can result from a variety of sources including the container. In a worse case scenario a particle can cause the blockage of a blood vessel resulting in embolism formation. Consequently it is essential that the presence of particles is monitored.

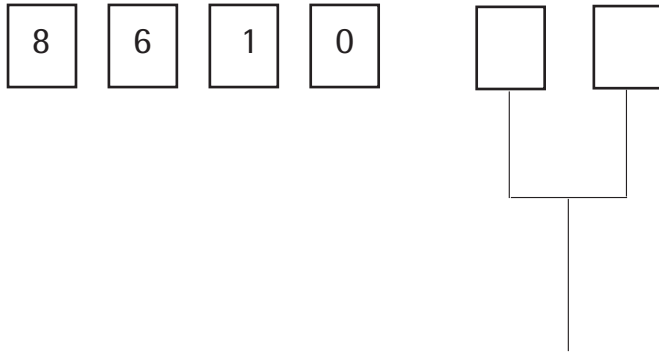
Current USP guidelines stipulate that Large Volume Parenterals (LVPs) should essentially be free of particulates that can be observed by visual inspection.

The recommended maximum numbers of particles for large injection solutions are:

25 particles/mL = 10 μ m
3 particles/mL = 25 μ m

Sartorius uses an automated system involving a laser sensor for the precise determination of particle counts in customer formulations.

Ordering Guide



Test Description

31= Particulate testing; three filters/ test components taken from three different lots, tested with pharmaceutical formulation under process conditions.

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