INDUSTRIAL SOLUTIONS
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AEROSPACE / INDUSTRIAL
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High Efficiency Particle Air (HEPA)

and its Importance in Sterile Pharmaceutical Preparations

Life Sciences / Pharmaceutical / Industrial

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High Efficiency Particle Air (HEPA)

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ALL ABOUT HEPA FILTERS SUCH AS PORE SIZE, LEAKAGE TEST, DOP TEST AND IMPORTANCE IN THE MANUFACTURE AND ANALYSIS OF STERILE PHARMACEUTICALS.

HEPA filter integrity must be maintained to ensure aseptic conditions. Leak tests must be performed at the facility to detect integrity gaps around sealing joints, through frames or through various points in the media. Subsequently, leak tests should be performed at appropriate time intervals for HEPA filters in the aseptic processing facility. For example, such tests should be performed twice a year for the aseptic processing room. Further tests may be appropriate when air quality is found to be unacceptable, facility renovations may be the cause of disturbances in roof or wall structures, or as part of a research on a media filler or a Failure of sterility of the pharmaceutical product. Filters to be tested for leakage include those installed in tunnels and dry heat depyrogenation furnaces commonly used to depogenize glass vials. If warranted, alternative methods may be used to test HEPA filters in the hot zones of these tunnels and furnaces. The same general principles can be applied to ULPA filters.

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Any aerosol used to challenge a HEPA filter must meet the specifications of critical physico-chemical attributes such as viscosity. Dioctylphthalate (DOP) and poly-alpha-olefin (PAO) are examples of appropriate leak test aerosols.

Some aerosols are problematic because they represent the risk of microbial contamination of the environment being tested. Accordingly, the evaluation of any alternative aerosol involves ensuring that it does not promote microbial growth.

There is a big difference between leakage filtration tests and efficiency tests. An efficiency test is a general test used to determine the classification of the filter. An intact HEPA filter should be capable of retaining at least 99.97 percent of particles larger than 0.3 µm diameter.

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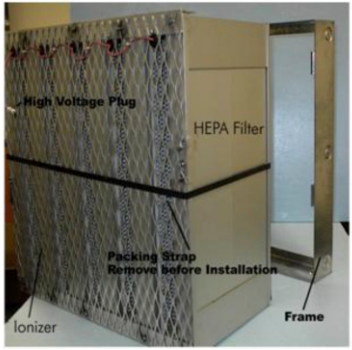
On the other hand, the purpose of regularly scheduled leak testing is to detect leaks from the filter media, the filter frame or the seal. The challenge involves the use of a polydisperse aerosol usually composed of particles having an average diameter of light scattering droplets in the submicron size range 9, including a sufficient number of particles at about 0.3 µm. Performing a leak test without introducing a sufficient "upstream" challenge of particles of known "upstream" size of the filter is ineffective in detecting leakage. It is important to introduce an aerosol upstream of the filter in a concentration that is appropriate for the accuracy of the aerosol photometer.



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The leak test must be performed in place, and the filter face should be scanned on the "downstream" side with an appropriate photometric probe at a sample rate of at least one cubic foot per minute. The downstream leakage measured by the probe should then be calculated as a percentage of the "upstream" challenge. Adequate scanning shall be carried out on the entire surface of the filter and on the frame at a position approximately one to two inches from the filter face. This extensive exploration of HEPA filters must be fully documented.

A single probe reading equivalent to 0.01 percent of the "upstream" challenge would be considered as indicative of a significant leak and requires replacement of the HEPA filter or, where appropriate, repair in a limited area. A further confirmatory test should be performed in the area of any repair.

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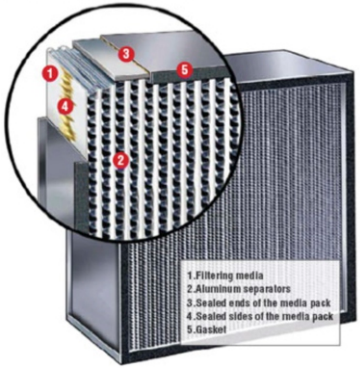
The HEPA filter filtration test alone is insufficient to monitor the performance of the filter. It is important to periodically monitor the attributes of the filter, such as the uniformity of velocity through the filter (and in relation to the adjacent filters). Variations in velocity can cause turbulence that increases the possibility of contamination. Unidirectional air velocities should be measured 6 inches from the face of the filter and at a defined distance proximal to the working surface for HEPA filters in the critical area.

A closer look at a HEPA filter



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Speed monitoring at suitable intervals can provide useful data on the critical area in which aseptic processing is performed. The measurements should be correlated with the velocity range established at the time of the analysis of in situ air patterns. HEPA filters should be replaced when non-uniformity of air velocity is detected across a filter area or airflow patterns can be adversely affected.

The efficiency test uses a monodisperse aerosol of particles of 0.3 micron in size and evaluates the filter media. The readings downstream represent an average over the entire surface of the filter. Efficiency tests are not designed to test for filter leaks.

Although the mean is usually less than one micron, it is greater than 0.3.

Although contractors often provide these services, drug manufacturers are responsible for ensuring that equipment specifications, test methods and acceptance criteria are defined and that these essential certification activities are carried out satisfactorily.

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