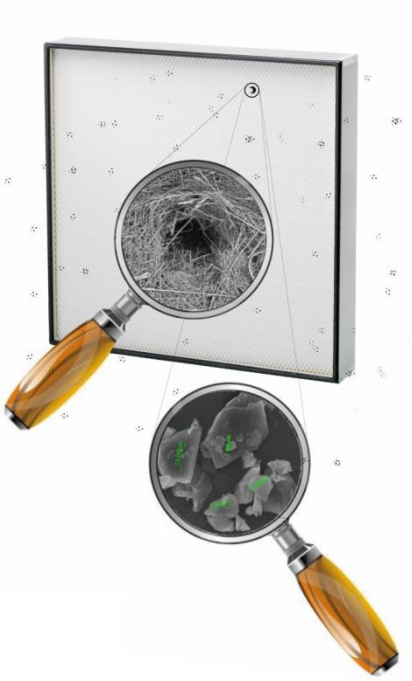
How to quantify the effect of a leakage in a HEPA filter



Production of medicine in a pharmaceutical company takes place in clean surroundings. This means that you have to know the maximum concentration of particles in the clean areas where the production takes place.

The production areas have an advanced ventilation system which includes HEPA or ULPA filters. These filters ensure that the maximum particle concentration is well-known. Due to this property, the ventilation filters are extremely important components in clean rooms.

From time to time a leakage may arise in these filters. When this happens there will be a potential risk of penetration of unwanted particles through the filter and potential cross contamination which is unacceptable for Novo Nordisk.

In this project permanent equipment has been built at the Danish Technological Institute to measure the concentration and size of particles when penetrating intact and perforated HEPA filters. The flexible test facility has been developed and built in close collaboration with Novo Nordisk and FORCE Technology. Furthermore, the filter supplier Camfil has delivered the special built, down-scaled HEPA filters and has supervised the project.

Several parameters can be varied in the equipment for example the type of ventilation filter, the size of the leakage in the filter, the type and size of penetrated particles, the air velocity and the pressure difference over the filter.

A large number of measurements have been performed in the project to investigate the particle penetration as function of the parameters listed above. A special focus has been attended to the potential penetration of Human Insulin nanoparticles. This is in order to achieve a better fundamental understanding of effects of potential cross contamination at Novo Nordisk.

The developed facility and results of the measurements has provided key knowledge on the different metrological parameters effect on particle penetration under real-life conditions using pleated HEPA filters. This has not previously been done at Novo Nordisk in such details.

Novo Nordisk has furthermore used the results and knowledge gained from the project when starting up new production facilities abroad where documentation of the potential effect of cross contamination has been in focus.