



Identification of Foreign Particles

A number of **inspectional observations from various Regulatory Authorities** related to visible and subvisible particles in pharmaceuticals has risen considerable concern. **Manufacturers** of pharmaceutical and medical device products have to **demonstrate that they have implemented all possible appropriate investigations** to determine the identity and origin of any contamination that may occur.

The presence of **foreign particles in sterile pharmaceutical products and/or medical device can affect their safety and efficacy**. Foreign particles may originate from both organic and inorganic sources, as corroded or damaged equipment parts, cross contamination during the process, microplastics or from biological sources.

The **implementation of quality controls for particles** can be a good strategy in order to minimize the contamination probability.

Mérieux NutriSciences has developed various strategies and complementary approaches for the identification of foreign visible and subvisible particles, thanks to sophisticated instrumentations combined with a pool of experts in different fields.

OUR TEAM

- Dedicated team for foreign particles/bodies identification
- Dedicated lab for microplastics/nanomaterial identification and characterization (ECSIN LAB, European Center for the Sustainable Impact of Nanotechnology, part of Mérieux NutriSciences)

ANALYTICAL TECHNIQUES

- Traditional optical equipment (Stereomicroscope 7-45x, Optical microscope 100-1.000x, Laser Confocal microscope)
- Microscope-ATR-FTIR (down to 100µm particles dimension)
- µFTIR / chemical imaging (down to 5µm particles dimension)
- SEM-EDS (non destructive, visible and subvisible particles)
- TEM-EDS (200 KV, down to 10nm particles dimension, e.g. nano-dispersions)

Mérieux NutriSciences capabilities for the identification of foreign particles

Morphological characterization

Microscopic examination for visible and sub-visible particles.

The technique allows a first evaluation of sample and the information acquisition in order to decide eventual further microbiologic analyses. In some cases, it allows the identification of the foreign particles.

Elemental characterization

SEM/EDS.

The association between SEM (Scanning Electron Microscope) and EDS (Energy Dispersive Spectrometry) allows to carry out microanalyses on small organic and inorganic particles with non-destructive analysis.

TEM/EDS.

TEM (Transmission Electron Microscope - maximum potential magnification of 1 nanometre) and EDS (Energy Dispersive Spectrometry) allows to extend the investigation to nanoparticles and relative aggregates/agglomerates.

Spectral identification

FT-IR microscopy allows to carry out spot FT-IR analysis on small particles above 0,1 mm and is suitable for both organic and inorganic materials.

μ-FT-IR/Chemical Imaging technology is the golden standard to detect and identify microparticles and microplastics of dimension between 10 μm and 1 mm.

Additional tools available

LC-HRMS is an additional tool available within Mérieux NutriSciences that could assist in the identification of organic solvent soluble particles in some cases.

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