

Characterization and Identification of Particulate Contaminants



Valued Quality. Delivered.



Sampling and Sample Preparation: Whether your contamination is embedded in a solid or liquid matrix, is present in a homogeneous or heterogeneous environment, is of organic or inorganic nature or appears as fibres or crystallites – we advise you on sampling and provide preparation methods for your samples.

Visual Characterization: An essential function of each investigation report is to carefully document the visual appearance of foreign particulate matter. For this task we have the advantage of a large multidisciplinary team with many years experience and laboratory that are equipped with a wide range of techniques from

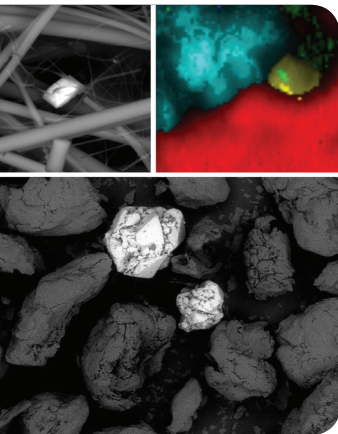


light microscopy to scanning electron microscopy.

Chemical Identification: A broad array of instrumentation is applied including high spatial resolution spectroscopic techniques, which are capable to analyze even minute details. This in combination with our broad experience in pharmaceutical, medical device, polymer and coating industries gives us the necessary know how to effectively identify unknown contaminants.

Cause Analysis: We have the capability to fully review analytical results and to assess facts and findings from other sources like production, engineering and supply chain. This is taken into account to provide support in defining corrective and preventive measures.

- Sampling and Sample Preparation
- Visual Characterization
- Chemical Identification
- Cause Analysis



Sampling and Sample Preparation

Sampling of particles is rarely straightforward and cross contamination has to be avoided.

- We give advice on proper sample collection
- We suggest appropriate sample packing or can provide the proper packaging material
- Alternatively our experts can visit on site and take care of sample collection and transport

In many cases particulate impurities or contaminations must be prepared to make them accessible for an analytical examination – they might either be hidden below a surface or be dispersed in liquids.

- We can instruct you in simple sample preparation techniques
- Complex sample preparation problems can be performed in our laboratories making use of dedicated tools and the experience of our experts

Contaminants in Pharmaceutical Products

Typical forms of contaminants

- Particulate matter in liquid preparations
- Discoloured or odd shaped particles in powders
- Discoloured spots on tablet surfaces
- Contaminants in tablet coatings
- Residuals, particles and fibres in filters

Examples of particulate contaminants

- Metal abrasion and corrosion
- Teflon particles from filters, joints or gaskets
- Glass fragments caused by delamination or breakage
- Biological matter of microbiological origin
- Charred material
- Cellulose and synthetic fibres
- Silicone, rubber or other polymeric particles

Examples of liquid contaminants

- Lubricants
- Detergents

Our experts are your professional partners for all questions regarding identification of contaminants and foreign particles

Dedicated Equipment to Identify and Characterize Contaminants

- SEM/EDX
- ATR-FTIR
- FTIR Imaging
- Confocal Raman Microscopy
- Raman Imaging
- Light Microscopy
- TOF-SIMS
- XPS
- Supporting or complementing techniques like TDS-GC/MS, GC/MS, LC/MS, NMR, MALDI-MS and optical spectroscopy

Standardized Services

We offer fast standardized services for identification and characterization of particulate contaminants and impurities:

- Light Microscopy and SEM /EDX
- Light- and ATR-FTIR Microscopy
- Light- and RAMAN Microscopy

Related Services Offered

- Failure analysis
- Particle characterization (size and shape)
- Deformulation
- Material characterization
- Migration studies (e.g. MOSH/MOAH)
- Extractable and leachable studies
- Quality control

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