

CHARACTERIZATION AND IDENTIFICATION OF PARTICULATE CONTAMINANTS

Intertek (Schweiz) AG provides a comprehensive range of analytical services which are compliant to Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) and complemented by testing according to ISO/IEC 17025. This includes chemical trace analysis, complex analyses, substance identification, method development, and a wide range of other applications combined with consulting expertise and engineering support.

An important element of the service portfolio is our integrated approach for characterization and identification of particulate contaminants.

Our GMP/GLP-compliant laboratory site, which spans 2,100 m² floor space, is staffed with a multidisciplinary team of engineers, scientists and technical experts with more than 30 years' experience in serving different industries.

Sampling and Sample Preparation

Whether your contamination is embedded in a solid or liquid matrix, present in homogeneous or heterogeneous samples of organic or inorganic origin or appears as fibres or crystallites - we advise you on sampling and provide preparation methods for your samples.

Chemical Identification

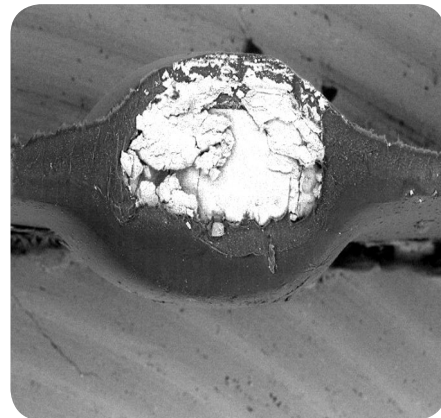
A broad array of instrumentation is applied including high spatial resolution spectroscopic techniques capable of analysing even minute details. This in combination with our experience in pharmaceutical, medical device, polymer and coating industries enables us to effectively characterize and identify unknown contaminants.

Visual Characterization

An essential function of each investigation is to accurately document the visual appearance of foreign particulate matter. For this task we have the advantage of a multidisciplinary team of experts with many years experience and a laboratory that is equipped with a wide range of techniques from light microscopy to scanning electron microscopy.

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 when we provide support in defining corrective and preventive actions.



An inorganic particle embedded in a polymer film

ANALYTICAL AND TESTING SERVICES FOR

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



We support in Sampling and Sample Preparation

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

We advise on proper sample collection, sample shipment or provide the proper packaging material.

We perform site visits, sample collection and transport.

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

Contaminants in Pharmaceutical Products

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

Standardized Services

Fast, standardized services for characterization and identification of particulate contaminants and impurities:

- Light microscopy and SEM/EDX
- Light- and ATR-FTIR microscopy
- Light- and Raman microscopy
- Compendial services
- Glass containers according to: PH. EUR. 3.2.1 / USP L660>
- Glass deamination testing: USP <1660>

Related Services offered

- Failure analysis
- Particle characterization (size and shape)
- Deformulation
- Material characterization
- Migration studies
- Extractable and leachable (E&L) studies
- Quality control

Examples of particulate Contaminants

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

Examples of liquid Contaminants


- Lubricants
- Detergents

Dedicated equipment to identify and characterize contaminants

- Laminar flow cabinet
- SEM and TEM
- ATR-FTIR
- FTIR imaging
- Confocal Raman microscopy
- Raman imaging
- Light microscopy
- Supporting or complementing techniques like TDS-GC/MS, GC/MS, LC/MS, NMR and optical spectroscopy

CONTACT

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