



Foreign Matter Analysis

Foreign Particulate Matter (FPM) contamination is an issue even in highly regulated and controlled environments such as the pharmaceutical and biopharmaceutical industries.

Presence of FPM can affect product quality, safety and efficacy, leading to loss of batches, product recalls and regulatory action.



CENTRE OF
EXCELLENCE

IMPURITY AND
CONTAMINATION

Our Impurity and Contamination Centre of Excellence are experts in the identification and quantification of trace impurities and foreign matter in a wide range of materials used throughout the global pharmaceutical and healthcare sectors.

FPM can come from a variety of sources, its occurrence is unpredictable and controlling it can be difficult. Identification of FPM is the first step in determining its origin, which is essential for effective root cause investigations.

We have a dedicated team of scientists experienced in the forensic analysis of FPM.

With our in-depth knowledge and expertise in foreign particulate types and their origins, we can help with the characterisation of your contamination, identify any systemic issues and trends, and get you one step closer to achieving the ultimate goal of cleaner processes.

Our technical capabilities and expertise include

- » **Isolation of FPM** (as small as 25 µm) from a variety of matrices (API, raw materials, tablets, solutions, suspensions, creams) using appropriate techniques e.g. filtration, micro-extraction, pipetting and centrifugation
- » **Microscopy** for information on particle appearance, size, morphology, crystallinity, homogeneity and physical behaviour
- » **Fourier Transform Infra-Red (FT-IR) Spectroscopy and Microscopy** for determination of chemical composition. FT-IR mapping can identify components of a heterogeneous mixture without having to isolate each component. Our extensive spectral libraries (with over 260,000 spectra) allows for identification of the component
- » **Scanning Electron Microscopy/Energy Dispersive X-ray (SEM/EDX)** analysis for elemental composition e.g. determination of the alloy type or grade of stainless steel for metallic contamination
- » **Powder X-ray Diffraction (PXRD)** for identification of crystalline particulates (e.g. minerals, organic powders). PXRD can also be used to determine crystallinity and differentiate between polymorphs
- » **Mass spectrometry (GC-MS, LC-MS)** for structural elucidation
- » Inorganic trace analysis using **ICP-OES** and **ICP-MS**.



Let's discuss your project:
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