

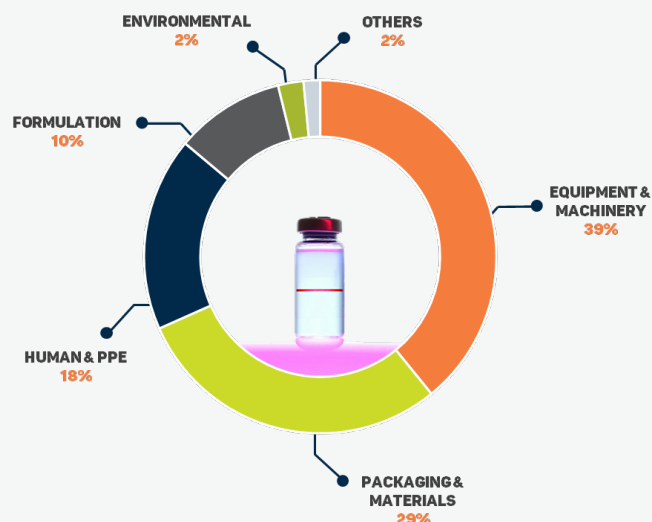
Foreign Matter Analysis

Protecting your pharmaceutical or biopharmaceutical business from foreign matter contamination is vital. Foreign particulate matter (FPM) contamination can have a devastating impact on product quality, safety, and efficacy, which can lead to costly recalls, delays in development or production, regulatory penalties, and damage to your reputation.

Foreign particulate matter can be introduced into your products during manufacturing, packaging, or shipping, and can come from various sources and factors, including:

- » Impurities found in raw materials
- » Equipment wear and tear
- » Corrosion or product-packaging incompatibility
- » Environmental contamination
- » Cross-contamination
- » Human error
- » Tampering

Identification of FPM is the first step in determining its source and potential impact, which is essential for effective root cause investigations and subsequent decision-making.



Why Outsource Foreign Matter Analysis?

Due to the unpredicted nature of contamination events, combined with the expertise required and the need for a rapid response, it is essential for a company to have access to a specialist team.

Having a team in-house is often not commercially viable.

It is, therefore, necessary to identify a credible outsource partner to work alongside.

This partner must be able to:

- » **Respond rapidly to unpredictable events.**
Contamination events are unpredictable. Our dedicated team with specialized equipment can react quickly when you need them
- » **Use advanced analytical tools for trace-level foreign matter analysis.**
Specialized equipment is crucial for trace contamination, demanding meticulous microscopic techniques.
- » **Interpret data from vast experience and expertise.**
Instrument data collection is one aspect; our extensive databases, know-how, and prior work give context to the results.

What is Foreign Particulate Matter (FPM)?

Foreign matter is any material or residue that is not meant to be in the product.

The United States Pharmacopoeia Ch. 788 defines Particulate Matter (in injections) as "mobile undissolved particles, other than gas bubbles, unintentionally present in the solutions."



How we can help

We specialize in foreign matter investigations across several industries, including pharmaceutical/biopharmaceutical, veterinary medicine, consumer healthcare, medical devices, catalysts, agrochemicals, and cosmetics.

Located in the cGMP compliant labs, we provide an extensive range of testing and consulting services tailored to address your unique challenges at every phase of your product's lifecycle.

Our team of experts, with decades of experience, excels in identifying foreign matter in your products, regardless of their development stage.

Typical contaminants identified in studies include:

- » Fibres
- » Metallic particles
- » Glass shards and delamination
- » Microplastics and polymers
- » Lubricant droplets
- » Corrosion products
- » Smears and stains
- » Residues and precipitates
- » Agglomeration

FDA (US)

Audited

MHRA (UK)

Audited

Home Office

Controlled substance license

Your product's integrity and safety are our top priorities

- » Protect your patients from the risks of contaminated products
- » Ensure regulatory compliance
- » Maintain product quality
- » Achieve batch consistency
- » Improve cost efficiency
- » Protect your supply chain
- » Support your research and development efforts

Our instruments and capabilities in particulate matter characterization include:

- » **Isolation of FPM** from a variety of matrices (API, raw materials, tablets, solutions, suspensions, creams) using appropriate techniques e.g. filtration, micro-extraction, pipetting and centrifugation in specialised sample preparation facilities
- » **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) allow 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**.

Learn more about
our services



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