

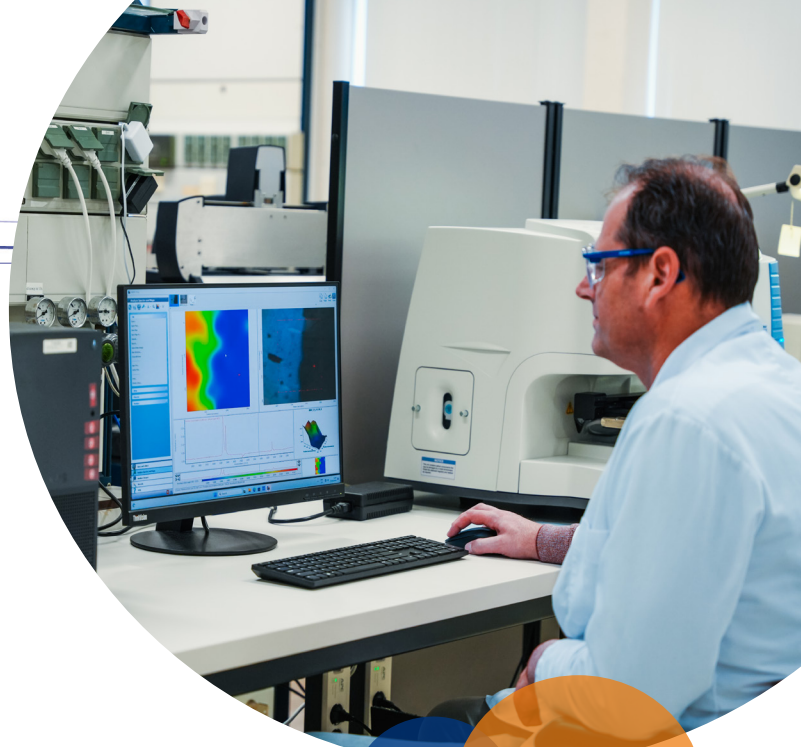
# Foreign Matter Identification

When unexpected particles, fibres, powders, or other foreign materials are detected in manufacturing processes, every delay can impact production continuity and batch disposition.

Eurofins BioPharma Product Testing delivers rapid, expert analytical support, empowering Quality Assurance (QA) and manufacturing investigation teams to act with confidence. This helps minimise downtime, avoid unnecessary batch rejection, and enable clear, effective communication with regulators.

## Why choose Eurofins for Critical Investigations?

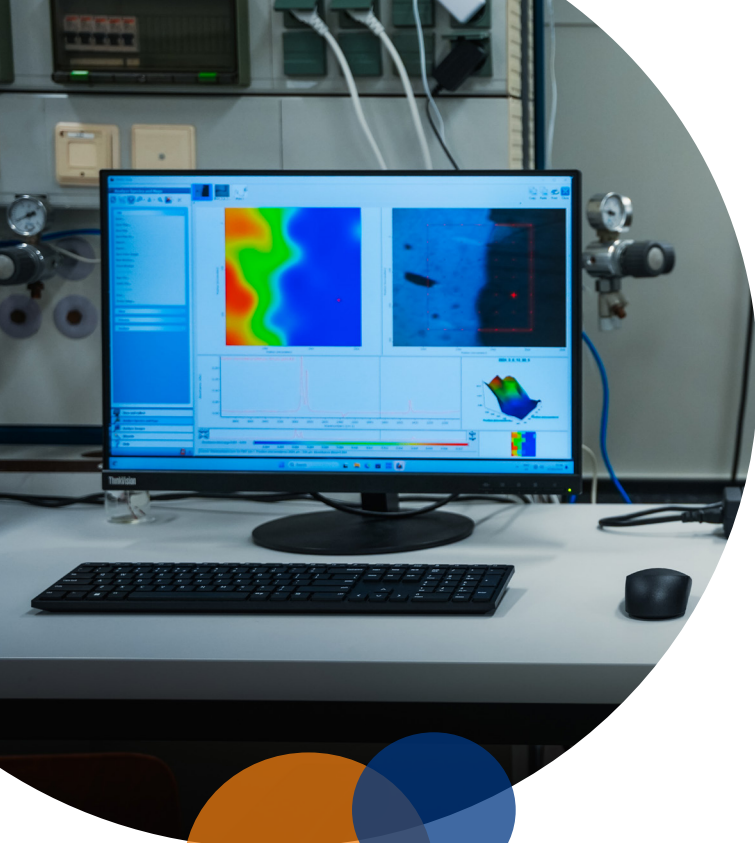
- **Rapid Support When Issues Arise:** Our experts respond within hours to assess the situation, review available information, and define an appropriate analytical strategy.
- **Reduce Batch Rejection & Unplanned Downtime:** Fast identification enables quicker decision-making, clearer risk assessment, and minimal disruption to production.
- **Strengthen QA Response to Regulators:** High-quality, defensible analytical data enables QA teams to demonstrate thorough investigations and confidently justify decisions.



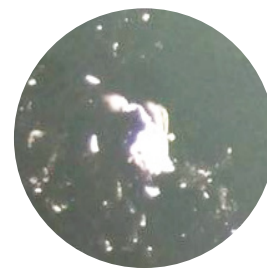
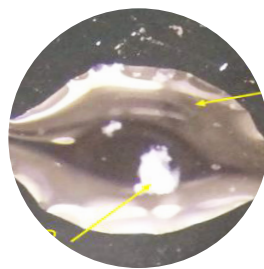
- **Broad Analytical Toolkit:** FT-IR microscopy, Raman, microscopy, SEM-EDX, micro-XRF, NMR, LC-MS, ICP-OES/MS, and XRPD together provide a high degree of confidence in accurately determining particle or material composition.
- **Fast Turnaround Time (typically 2–5 working days):** Urgent cases are handled on a rush basis, with preliminary results shared as soon as they become available.

## How do we protect your Production Continuity?

- Rapid investigations that maintain production schedules by providing clarity during critical events
- Reduced risk of unnecessary batch rejection through timely, conclusive analytical data
- Reliable identification data that support robust risk assessment and effective regulatory communication



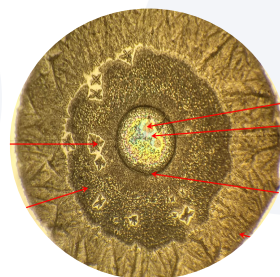
## Examples



### **Fiber observed in cell culture bioprocessing bag**

The fiber was isolated from the cell culture medium. FT-IR analysis showed that the fiber spectrum is consistent with cellulose, while the spectrum of the cell culture medium is consistent with a protein.

- Clear, structured reporting to enable confident QA decision-making and justify actions during inspections
- Improved internal investigation efficiency, driven by early insights and regular progress communication



### **Particle observed in injectable vial**

The droplet containing the particle was collected and dried. FT-IR spectra were collected and compared at multiple locations using FT-IR microscopy. This approach enabled identification of the particle composition and its correlation with the product. Results were reported to the customer within three days.

Set up PO in advance for potential future use

Unexpected particulate or foreign matter observed

Contact Eurofins to agree on proposed action plan and indicative budget

Samples sent express to Eurofins and tested with priority

Receive interim results; action plan and budget adjusted if required

Detailed report with final results provided

## Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing  
Cell Banking Services • Virology Services • Facility & Process Validation  
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology  
Stability Testing & Storage • Primary & Secondary Package Testing

## Contact Us

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