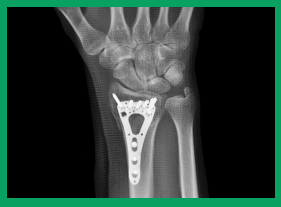
RJ Lee Group

2025 Laboratory Testing Guide

Pharmaceutical Services and Medical Devices

Pharmaceutical Services - Laboratory Testing Guide 2025

RJ Lee Group's Pharmaceutical Services Department is a cGMP compliant, ISO 17025 certified, FDA-registered analytical testing laboratory committed to applying an industrial forensics approach to Foreign Particulate Matter (FPM) investigations. Our experts use advanced materials research and quality control principles to investigate, define, isolate, and resolve problems faced within the Pharmaceutical and Biotechnology sector. Whether it's related to foreign particulate matter identification in raw materials, CAPA/OOS investigations for quality control groups, or evaluating the content uniformity in finished products, we work closely with our clients to understand the issues surrounding each unique situation.

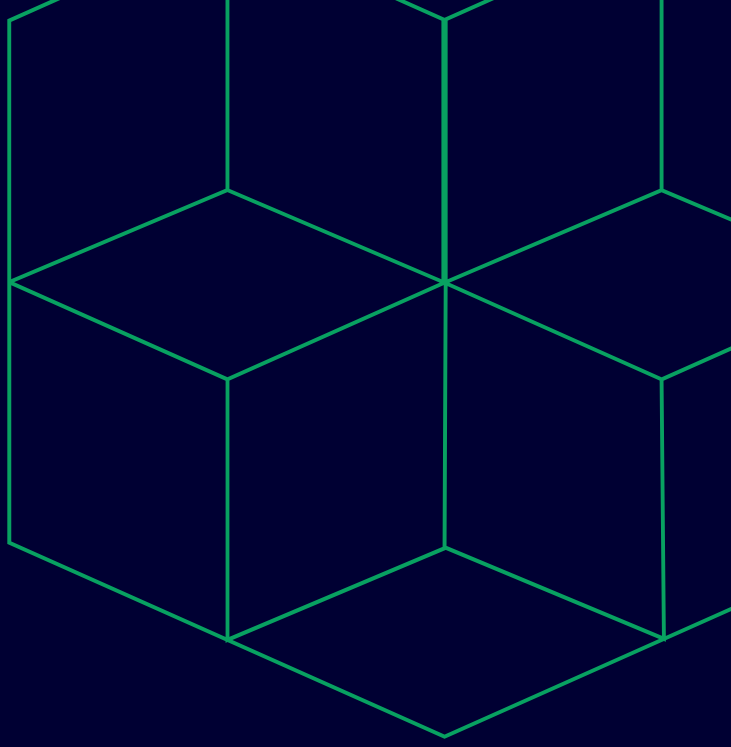
Test	Technique
Expedited Foreign Particulate Matter (FPM) - Full Particulate Characterization	FTIR, SEM/EDS, Raman, Optical Microscopy, PLM
Foreign Particulate Matter (FPM) - Full Particulate Characterization	FTIR, SEM/EDS, Raman, Optical Microscopy, PLM
Foreign Particulate Matter -FTIR	FTIR Analysis
Foreign Particulate Matter - SEM/EDS	SEM/EDS Analysis
Foreign Particulate Matter – PLM	PLM Analysis
Foreign Particulate Matter – Optical	Optical Imaging and Sizing
Automated Particulate Characterization – CCSEM	CCSEM Analysis
Foreign Particulate Matter – XRD	XRD Analysis
Morphology and Content Uniformity Testing	HR-SEM/EDS, SE-SEM, EDS Mapping

Medical Device Testing Services - Laboratory Testing Guide 2025

Our expert work independently or with our clients' internal talent to provide critical assistance during the all manufacturing phases for medical devices, including work with proprietary materials and processes. We assist companies in delivering their product to market by helping product engineers understand the microstructure of their chosen materials, and by responding to challenges within the marketplace. Our services include:

- Raw materials specification, selection, consistency and validation
- Quality control testing
- Device cleanliness assessments and impurity identification
- Wear debris studies
- Environmentall health and safety issues
- Technical support for FDA submittals and regulatory compliance

Test	Technique
Wear debris particulate	CCSEM/ICP Analysis
Nano-particulate investigation	CCSEM/ICP Analysis
Device defect/cleaniness identification	Optical/ICP Analysis
Fixture contamination identification	Optical/SEM/EDS/ICP
High resolution SEM imaging	FE-SEM/SEM
Particle sizing	Laser Diffraction/CCSEM
Automated Particulate Characterization – CCSEM	CCSEM Analysis
Foreign Particulate Matter – XRD	XRD Analysis
Morphology and Content Uniformity Testing	HR-SEM/EDS, SE-SEM, EDS Mapping
Technical consulting for FDA submittals and litigation support	



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