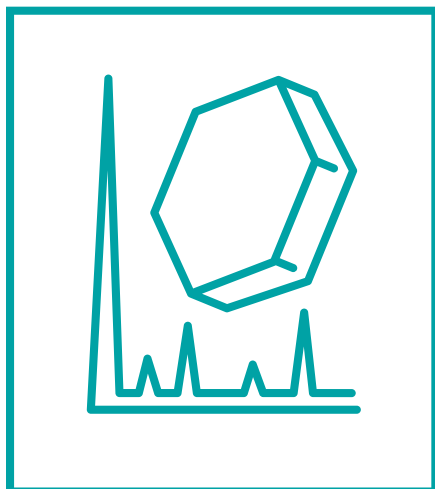




WE'VE GOT ANALYTICAL AND SOLID STATE SERVICES DOWN TO AN EXACT SCIENCE



Analytical and Solid State Services

Speed product development and improve the quality of your compound with solid state chemistry and analytical testing services.

MICROSCOPY AND MICROANALYSIS FACT SHEET

Microscopic materials or contaminants are present in nearly all manufacturing and product handling processes. Regardless of the degree or size, contaminants may come from a large variety of materials in our environment, and many of them may truly be foreign to the manufacturing processes, requiring them to be identified or characterized. In some instances, the contaminant must be identified and its inferential source attribution or environmental origin identified.

Contaminant materials analysis includes microstructure characterization of materials including trace chemical residues, complex matrices, liquids, solids, gases, metal and inorganic particulates, organic materials, unknown chemicals, polymers, thin films or coatings, pharmaceuticals, raw materials, plastics, glass or ceramics, fibers or hairs, food contaminants, greases and lubricants, silicones, and truly unknown fragments, particles and more. Unknown materials can occur in nearly any form: specks, dust, smears, residues or airborne particulates.

SSCI identifies and determines contamination composition and provides our clients crucial data pointing to potential contamination origin, often from complex sources. Rapid troubleshooting capabilities and expertise are available for the most demanding and time-sensitive situations.

A concerted effort to enhance forensic sciences began in 2009 as reported by the National Academy of Sciences in the National Research Council report, "Strengthening Forensic Science in the United States: A Path Forward."¹ A multiagency endeavor that included the U.S. Department of Justice and the National Institute of Standards and Technology introduced the National Commission on Forensic Science and the Organization of Scientific Area

Committees (OSAC) to assist efforts in strengthening forensic science in the United States. Ultimately, standards and guidelines from these OSAC groups will enable accrediting bodies to audit service providers and laboratories to these discipline-specific standards of practice.

The combination of optical, electron, Raman and infrared microscopy techniques is a powerful tool in contamination analysis, identification, characterization and source determination. In many cases, we use our expertise, qualified instrumentation, validated methods and techniques to confidently identify contaminants. When necessary, our experts work directly with clients to interpret our findings in light of contextual information. Investigative, inferential and comparative analyses provide more detailed information about identification, source and significance of material contaminants.

Compliance with Good Laboratory Practices (GLP) and current Good Manufacturing Practices (cGMP) allow our microscopists and microspectroscopists to provide validated analytical support to forensic investigations through problem-solving, consultancy and scientific reports that document results and clearly state conclusions. We also will provide depositions or expert testimony when requested.

Examples of Our Support:

- Scientific and technical analysis in support of litigation cases or civil lawsuits
- Counterfeit identification and intelligence (packaging materials, API, excipients, etc.)
- Product contamination
- Art conservation
- Insurance companies

Microscopy and Microanalytical Techniques

- Light microscopy: stereomicroscopy, polarized light microscopy, hot-stage and cold-stage microscopy, dark-field microscopy
- Raman microspectroscopy
- Fourier Transform Infrared (FT-IR) microspectroscopy
- Near-infrared mapping
- Scanning electron microscopy
- Energy dispersive X-ray spectroscopy (EDS, EDX or XEDS)
- Image analysis and particle sizing

Microscopical Characteristics That Assist in Particulate Identification

- Morphology
- Size
- Surface texture
- Reflectivity
- Transparency
- Color
- Refractive index/indices
- Birefringence (uniaxial or biaxial)
- Twinning
- Pleochroism/dichroism
- Extinction angle
- Sign of elongation
- Optical axial angle
- Interference figure

Particulate materials may be analyzed for their chemical composition and physical characteristics.

- Magnetism
- Melting point
- Polymorphs
- Eutectic point
- Boiling point
- Sublimation
- Solubility
- Absorption characteristics (FT-IR, Raman)
- Functional groups, ions, elemental composition
- Energy dispersive X-ray spectroscopy
- Micro-X-ray fluorescence (μ XRF)
- Stable isotope ratio analysis on API and excipients

References:

1. Strengthening Forensic Science in the United States: A Path Forward, (2009), National Academy of Sciences, National Research Council. The National Academies Press, Washington, DC. Available: <http://www.nap.edu/catalog/12589.html>