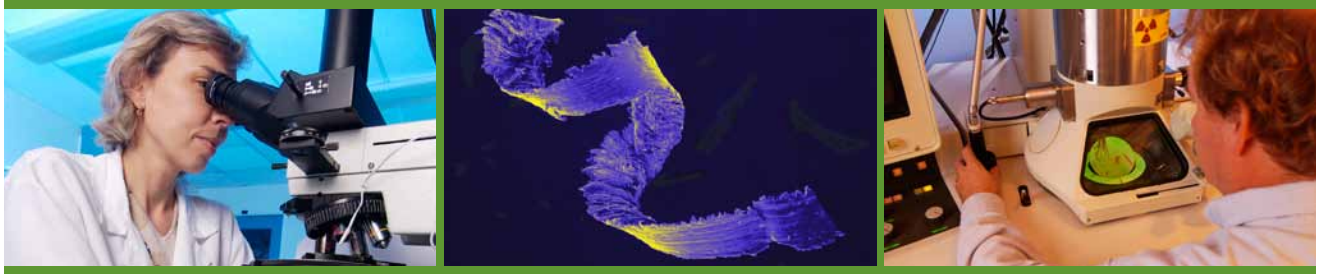


Microscopy and Microanalysis in Support of the Health Sciences



RTI International provides technical support in the areas of microanalysis and microscopy to pharmaceutical and other commercial clients, as well as state and federal agencies. With a staff of experienced scientists and state-of-the-art laboratories and equipment, RTI conducts rigorous testing and analysis—enabling our clients to have complete confidence in the quality of our results.

At RTI, researchers in our Microanalytical Sciences Department specialize in the characterization of pharmaceutical products by microanalytical techniques. Utilizing optical microscopy, transmission electron microscopy, scanning electron microscopy, and X-ray diffraction, we are able to

- Characterize the size, shape, and surface features of structures and particles
- Determine particle chemistry and composition
- Observe morphological characteristics of samples, including agglomeration
- Determine the source of foreign material present
- Assess the purity of crystalline compounds.

We specialize in helping clients solve problems associated with contamination, process control, and product research/development.

Solving Contamination and Formulation Problems for Pharmaceutical Clients

In the pharmaceutical environment, inconsistent formulation and presence of contamination can cause significant problems, potentially resulting in defective products, customer complaints, quality control noncompliance, and production cost overruns and

Case Study in Problem-Solving

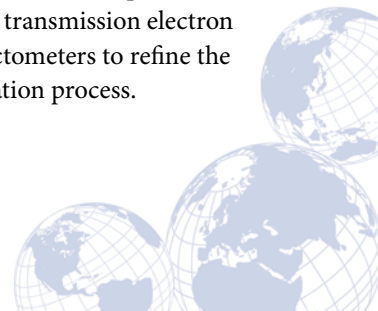
Client problem: Visible contamination in a parenteral drug sealed in a glass vial.

RTI analyses: Analysis by scanning electron microscopy revealed particles indicative of metal wear. X-ray spectroscopy analysis showed that the particles had an elemental content of iron, chromium, nickel, and molybdenum—which is typical of stainless steel 316.

Resolution: With this information, the company was able to locate a potential source of the metal filings within their vial washing system. Samples from that material were matched and the company was able to return quickly to contamination-free production.

slowdowns. To remedy such problems—and more importantly, to avoid recurrence—one must fully characterize the pharmaceutical product and potential contaminants.

This type of careful analysis requires qualified professionals and sophisticated instruments: optical microscopes, scanning electron microscopes, and transmission electron microscopes, as well as X-ray diffractometers to refine the compound identification and evaluation process.



At RTI, we have the skilled professionals and necessary instrumentation to conduct product characterization, particle identification, and source location tasks. We are leaders in the fields of microscopy and analytical chemistry and have helped numerous clients with particulate contamination problems—including determining the source of particulate contaminants in drug products and the nature of contaminants encrusted on processing equipment, glassware, and packaging materials. We have also helped clients solve unique formulation problems using techniques such as X-ray diffraction to investigate polymorphism.

Case Study in Problem-Solving

Client problem: Needed to verify production specifications for experimental microbead drug carrier.

RTI analyses: RTI characterized the beads' size, uniformity in diameter, surface smoothness, and tendency to agglomerate or remain independent of other beads.

Resolution: With this information, the company was able to adjust formulation procedures to match necessary specifications for microbead drug delivery.

Case Study in Problem-Solving

Client problem: RTI was asked to conduct a toxicological investigation of an inorganic test chemical to determine its purity and detect any significant structural changes to the material over time.

RTI analyses: RTI characterized the composition and internal atomic structure of this proprietary compound utilizing X-ray diffraction and other analytical methods.

Resolution: RTI established the identity of the test material and major impurities, and determined its stability at ambient and freezer temperatures, ensuring the material was stable and did not degrade in frozen storage over time.

Working Closely with Our Clients

RTI's experts work closely with our clients to understand the problems and constraints they face. To maximize the effectiveness and efficiency of the analysis and to better meet client needs, we often analyze samples with the client sitting side by side with the microscopist. RTI maintains strict client confidentiality at all times and routinely works with commercial clients under nondisclosure agreements.

More Information

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RTI International is one of the world's leading research institutes, dedicated to improving the human condition by turning knowledge into practice. Our staff of more than 2,800 provides research and technical expertise to governments and businesses in more than 40 countries in the areas of health and pharmaceuticals, education and training, surveys and statistics, advanced technology, international development, economic and social policy, energy and the environment, and laboratory and chemistry services. For more information, visit www.rti.org.

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