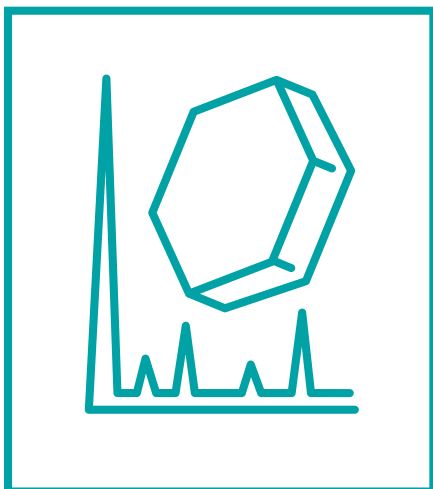


# WE'VE GOT UNKNOWN PARTICULATE IDENTIFICATION AND CONTAMINANT ANALYSIS DOWN TO AN EXACT SCIENCE



## Analytical and Solid State Services

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

## REDUCE RISK, IMPROVE QUALITY

Every pharmaceutical, nutritional and food product has the inherent risk to contain unknown particulates. AMRI has the expertise to rapidly characterize these contaminants, providing clients with the information they need to resolve the issue.

From our experience, particulate matter can appear from four major sources of contamination — raw materials such as packaging, the working environment, processing steps and instability of the container or product — and can occur in injectables, liquids, semi-solid or solid dosage forms or food.

Unknown particles must be identified, and their source(s) investigated and confirmed. For pharmaceuticals, corrective and preventive actions must be established according to ICH Q10: Pharmaceutical Quality System, with a thorough evaluation of the potential risk as defined in ICH Q9: Quality Risk Management.

Gaining an understanding of where the unknown particulates first appear and the extent to which they appear can help determine which analytical techniques are most appropriate. Most often, AMRI uses light microscopy as the first step to start the identification as this technique can sometimes be used to positively identify materials such as fibers and human hair, for example.

AMRI may also deploy IR microspectroscopy to provide absolute identification of many materials including polymers, organic compounds such as drugs, vitamins or excipients/food additives, and sometimes inorganic metals, to name only a few.



Complex Science. Expert Solutions.

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Subsequent testing is based on these initial techniques and is used to either confirm the material's identity or provide additional data to make an identification. To enable root cause analysis, we compare results with a clean sample, as well as a sample of the suspected source of contamination — a piece of filter or screen, ink that might have rubbed off a packaging material or lubricating grease used on a packaging line, for example.

By using qualified instrumentation maintained under current Good Manufacturing Processes (cGMP) and data handling systems, we give our clients confidence in the results and subsequent conclusions made by our team of highly skilled microscopists and microspectroscopists.

### Unknown Particulate Testing Services

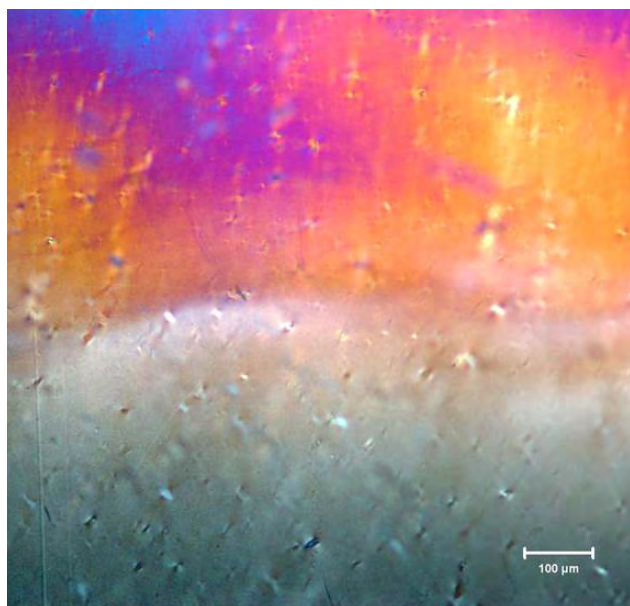
AMRI uses the following microscopy and microanalytical techniques and equipment to characterize unknown particulates:

- FEI Quanta 200 ESEM
- Energy dispersive X-ray
- Leica DMLP compound polarized light microscope
- Leica stereomicroscope, MZ6, MZ12.5 and M80
- Leica polarized light stereomicroscope, DMLP
- Linkam hot/cold stage (-196 to +350 °C)
- Linkam lyophilization stage (freeze drying, -196 to +100 °C)
- Nikon Optiphot-pol compound polarized light microscope
- Wagner & Munz Kofler hot stage and hot bar
- Continuum Fourier transform infrared (FT-IR) microscope with fluorescence illumination capabilities
- Raman microspectrometer
- Zeiss Imager.A2m, compound polarized light microscope with darkfield/brightfield reflection and transmission modes

### Contaminant Analysis Services, USP <788> and <789>

AMRI provides expert services to support contaminant analysis specifically for injectable products. We are able to count and size particles between 0.5 to 400 micrometers, using Particle Sizing Systems' AccuSizer 780 SIS, which is a single particle optical sensing system, also known as light obscuration. Operating in a HEPA-filtered laminar flow hood to create a Class 100/ISO 5 work environment, our experts use a syringe pump to pull accurate and precise aliquots of liquid samples through a light obscuration sensor.

With this technique, our skilled microscopists characterize extraneous, undissolved sub-visible particles unintentionally present in the solutions using light obscuration and microscopic particle counting (Methods 1 and 2) in accordance with USP <788> (Particulate Matter in Injections) and USP <789> (Particulate Matter in Ophthalmic Solutions). For both USP <788> and <789>, Method 2 is also available for microscopic counting of particles collected on a membrane filter or for liquid samples that exceed the particle count parameters as stated in Method 1.



**AMRI is a global contract research and manufacturing organization that has been working with the life sciences industry to improve patient outcomes and quality of life for more than 25 years.**

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