HOOKE
INSTRUMENTS

PartiGen™

Particle Analysis System

www. hooke-instruments. com

Comprehensive Characterization of Particle Size, Morphology and Chemical Composition

The Hooke Instruments PartiGen™ Particle Analyzer uses laser confocal Raman spectroscopy to characterize the count, size, morphology, and Raman fingerprint spectra of particles ≥0.5 μm. Raman spectroscopy offers highly specific molecular vibrational information.

By leveraging Hooke Instruments' proprietary BioSure™ biopharmaceutical particle database, PartiGen™ enables precise chemical identification of particles, tailored for the biopharmaceutical industry. With its superior optical throughput and advanced confocal performance, PartiGen™ significantly enhances detection capability for subvisible particles.

Its microscopic imaging unit fully complies with Chinese Pharmacopeia 2025 edition, including Method 0421 (Microscopic Counting) and Method 0903 (Insoluble Particle Test).

Workflow

Microscopic Imaging

Observe particle morphology in the field of view.

Particle Size Analysis

Automatically identify size parameters such as long/short axis and area.

Target Particle Localization

Locate the particle's coordinates.

Spectrum Acquisition

Collect Raman spectral data from particles.

Database Matching

Match spectra using the **BioSure™** database for rapid source identification.

Report Generation

One-click generation of customized reports including classification statistics, particle size analysis, etc.

Technical Advantages

Adjustable Laser Power (down to 0.1 mW)

Prevents damage to laser-sensitive particles while optimizing signal quality.
Xtrem Sig-P Particle Detection Chip
Designed for enhanced signal collection and resolution.

Direct Measurement without Filtration

Liquid sample can be loaded directly onto the chip without filtration, particle identification can be performed in liquid.

Hooke BioSure™ Pharmaceutical Database

Covers proteins, polysorbate degradation products, lipids, and process materials; also supports custom database creation.

Automated Software Reports

Includes spectral matching results, statistical charts, and more.

21 CFR Part 11 Compliance

Supports IQ/OQ/PQ validation, electronic signatures, and two-level password protection.

True Confocal Raman Technology

Enables chemical identification of mixed particles.

In-situ Detection of Large Particles

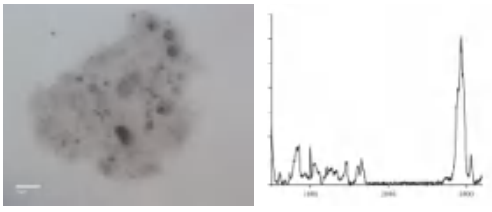
Allows direct analysis through container walls for visible particles.

Application Highlights

Biologics

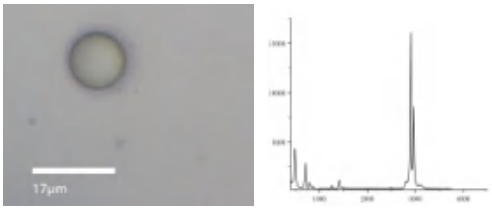
- **Protein Aggregates**

  60–80% of particles in therapeutic protein formulations are protein aggregates, which are semi-transparent and hard to detect. PartiGen™ effectively identifies and characterizes them.



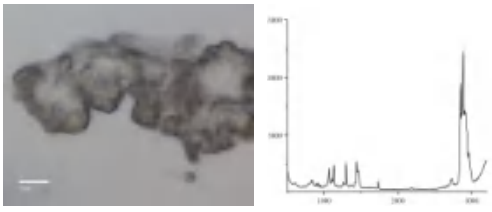
- **Silicone Oil Droplets**

  Commonly introduced from rubber stoppers or prefilled syringe coatings.



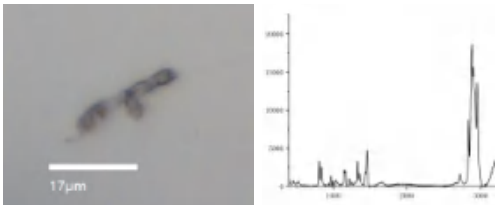
- **Polysorbate (PS) Degradation Products**

  These surfactants can degrade into fatty acids or esters, forming irregularly shaped particles.



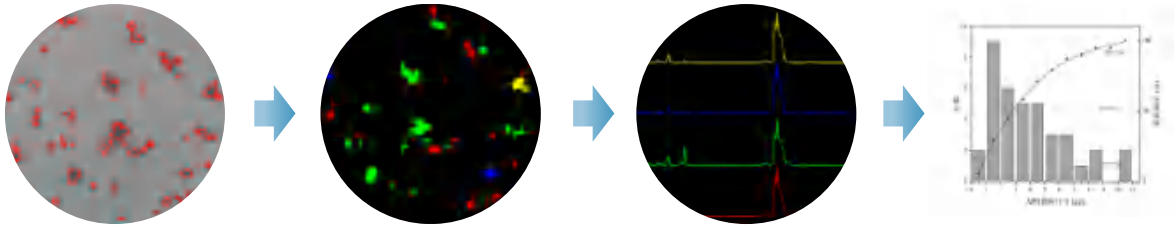
- **Polypropylene Contaminants**

  Found in manufacturing consumables, packaging, or tubing.



Small Molecule Drugs

- Supports particle size control, crystal form analysis, and uniformity assessments of APIs and excipients.
- Useful for studying how particle size or polymorph affects dissolution or disintegration behavior.



Application Scenarios

Technical Specifications

Technology	Confocal Raman Spectroscopy
Particle Size Range	≥500nm
Sample Types	Particle detection chip, filters, quartz slides
Raman Laser	532 nm excitation, 0.1 mW power adjustment precision
Objectives	10×，20×，50×，100×
Software	HOOKE IntP Analysis Software, HOOKE BioSure™ Database
Power Supply	220V，10A

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