

**HORIBA**

**Accelerating  
Pharmaceutical  
Advancements**  
Through Partnership

# HORIBA's Solutions for Pharmaceutical Analysis and Manufacturing

HORIBA is leading the charge to support Pharma in advancing next-generation biotherapeutics and pharmaceuticals, leveraging patented technologies to provide solutions that aid the development and manufacture of novel biomolecules and innovative delivery mechanisms to address a wide range of diseases.

## Most Comprehensive Fluorescence Solutions

From Modules to Modular to TCSPC Lifetime...to FLIM



Steady State Fluorescence in cuvettes, TCSPC Lifetime Fluorescence, Fluorescence Lifetime Imaging

From Fluorescence to A-TEEM to A-TEEM for Pharma...to Process A-TEEM



Development, Quantitative & Qualitative, CQA's, Pharma, Reaction Monitoring, At-line, In-line, On-line

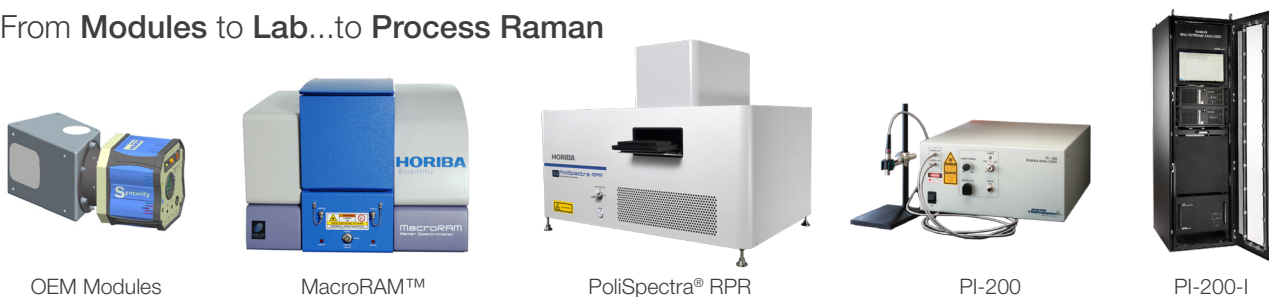
## Most Comprehensive Raman Solutions

From Macro to Micro...to Nano Raman



Raman Microscopes for Imaging & Chemical Analysis (down to  $\mu\text{m}$ ), Nanostructure sub  $\mu\text{m}$  imaging (AFM)

From Modules to Lab...to Process Raman



Quantitative & Qualitative Analysis, CQA's, Reaction Monitoring, Off-line, At-line, In-line, On-line

# Most Comprehensive Particle Characterization Solutions

From **Particle Size** to **Zeta Potential** to **Shape Identification**...to **Particle Concentration**



Laser Diffraction, Image Analysis, Dynamic Light Scattering, Zeta Potential, BET, Nanoparticle Tracking

From **Actives** to **Excipients** to **Biotherapeutics**...to **Continuous PAT Analysis**



Life Science, Pharmaceutical, Semiconductor, Battery, Material, Food & Beverages

**Spectroscopic Analysis**

Technology to analyze materials by using ultraviolet, visible, and near-infrared light

**Particle Measurement**

Technology to characterize particles including size, shape, concentration, zeta potential, and identification

**Infrared Measurement**

Technology to analyze components in gas in real time

**Fluid Control**

Technology to instantly measure and control the flow of fluids

**Liquid Analysis**

Technology to measure components or characteristics in liquid, such as pH, sodium, acids, and alkalis

HORIBA utilizes solutions created from our core technologies to ascertain the changing needs of the market. The technologies have been cultivated from around the world to measure and analyze liquids, gases, and solids.

# Solutions for the BioPharma/Pharma Value Chain

## PoliSpectra® RPR Rapid Raman Plate Reader



Fully automated, high-throughput, non-destructive screening provides rapid testing of 96 liquid well plates per minute with live reaction monitoring.

### Common Applications

- Research & Discovery
- Preclinical Trials
- Formulation & Quality Control



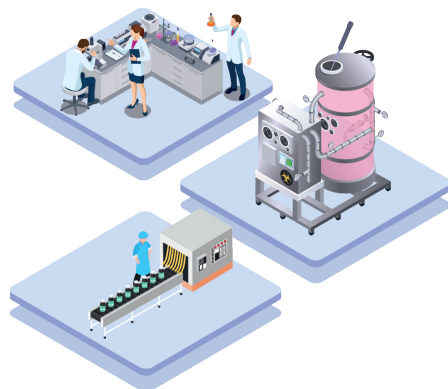
## MacroRAM™ Raman Spectrometer



Fast and reliable bulk analysis Raman spectrometer analyzes high concentration materials in cell media and API identity tasks.

### Common Applications

- Research & Discovery
- Pilot Processing
- Formulation & Quality Control



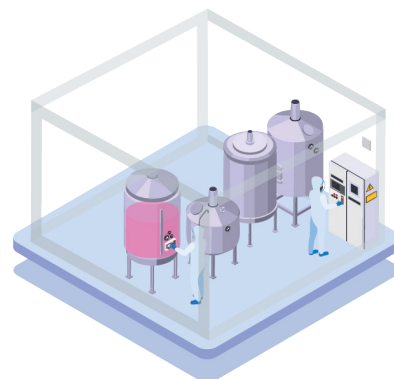
## PI-200-I Raman Multi-stream Analyzer



Process Raman spectroscopy enables in situ monitoring of critical nutrient, metabolite, and byproduct concentrations, including glucose, lactate, and ammonia.

### Common Applications

- Upstream Processing



## Yumizen™ C560 Clinical Chemistry Analyzer



Supports more than 75 general chemistry tests and can process up to 560 tests/hr. Offers a broad range of open-channel general chemistry reagents.

### Common Applications

- Clinical Trials



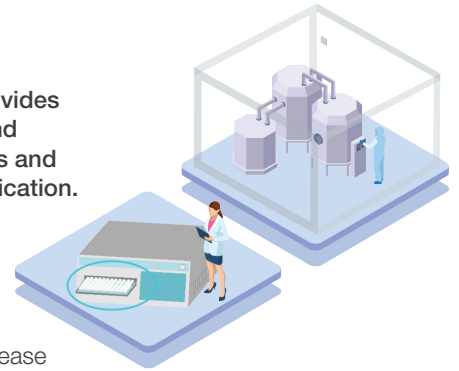
## Veloci™ BioPharma Analyzer



A-TEEM fluorescence spectrometer provides rapid, cost-effective characterization and quantification of upstream raw materials and downstream product quality and identification.

### Common Applications

- Cell Culture Media Preparation
- Downstream Processing and Product Release
- BioPharma Active Molecule and Formulation Development



## A-TEEM™ Compliance Package



EzSpec with EzSpec-P11/  
PLATINALINK



EzPAT



A-TEEM Direktor



Software and Instrument  
Validation

EzSpec-P11 and PLATINALINK  
for Part 11 compliance on benchtop  
instruments

EzPAT server for integration of A-TEEM  
into PAT orchestration software

A-TEEM Direktor for multivariate  
analysis modeling and prediction

IQ/OQ documentation and procedures  
for instrument and software validation

### Common Applications

- Regulatory Approval



## ViewSizer® 3000 Nanoparticle Tracking Analysis (NTA)



Monitors particle size and concentration,  
supporting applications such as lipid  
nanoparticles (LNP), extracellular vesicles,  
viruses, and protein aggregates.

### Common Applications

- Research & Discovery
- Formulation & Quality Control



## Partica™ LA-960V2 Laser Diffraction Particle Size Analyzer



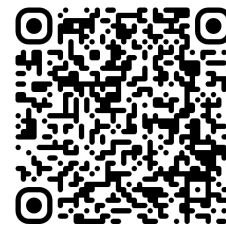
Unparalleled rapid particle size  
analysis from 10 nanometers up to 5  
millimeters.

### Common Applications

- Research & Discovery
- Formulation & Quality Control



# Application Case Studies



## Reliable Analysis for Biological Nanoparticles

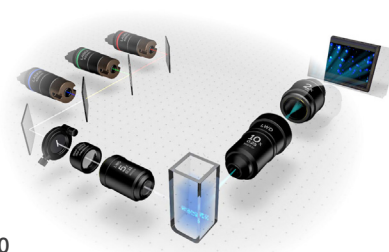
with Simultaneous Multispectral Detection (SMD) NTA

The ViewSizer® 3000 effectively monitors protein aggregation under different conditions, providing valuable insights for formulation development, manufacturing performance, and long-term product stability.

This information is crucial for ensuring the safety and efficacy of protein therapeutics in the biopharmaceutical industry.



ViewSizer® 3000



## Analysis of Adjuvants

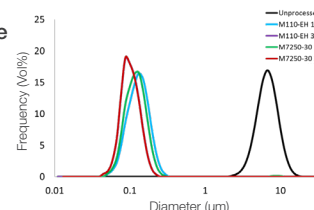
with Laser Diffraction

The HORIBA LA-960 laser diffraction analyzer effectively measures emulsions, from unprocessed particles above 1 micron to nanoemulsions below 100 nm after multiple passes through a microfluidizer. It has proven valuable in monitoring vaccine adjuvant sterile filtration processes, detecting agglomeration, and delivering highly repeatable results, making it an essential tool for both research and process control in drug delivery system development.

Automatic laser alignment and wide range of sample handlers ensure consistent and accurate results.



Partica™ LA-960V2



Suitable for a wide variety of sample types

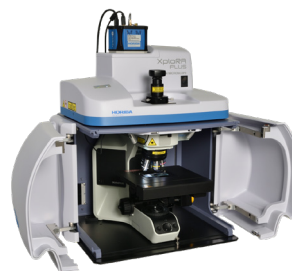


## Assessing Biotherapeutics Stability

with Raman Spectroscopy

Specific Raman vibrational bands, such as those associated with amide I, amide III, tryptophan (Trp), and tyrosine (Tyr), can be used to monitor protein folding, unfolding, and structural reorganization. The findings in one study highlight the potential of Raman spectroscopy for evaluating the stability and quality of biotherapeutics, offering valuable insights for the pharmaceutical industry in ensuring drug efficacy and safety.

Precise chemical and structural analysis with exceptional sensitivity



XploRA™ PLUS  
MicroRaman spectrometer and confocal Raman microscope



## Fluorescence in Vivo on Human Skin

Brief synopsis of case study and HORIBA product involved

In one study, the HORIBA Jobin Yvon Fluorolog® spectrofluorometer highlighted distinct fluorescence peaks at 295 nm, 340 nm, and 360 nm, corresponding to tryptophan in the epidermis and collagen cross-links in the dermis.

These fluorescence markers allow for the characterization and quantification of skin aging and photoaging, showing that UV exposure significantly alters the fluorescence spectra

Highly customizable system allows users to add or change components to suit specific research needs



Fluorolog-QM  
Advanced modular fluorescence spectroscopy





## Sensitive Detection of Protein Fingerprint Variations

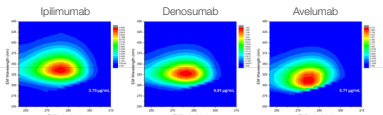
with Absorbance, Transmittance, and Fluorescence Excitation Emission Matrix (A-TEEM™)

Tryptophan steady-state fluorescence spectroscopy is a powerful tool for studying local structural changes, sub-unit interactions, substrate binding, and denaturation.

When combined with A-TEEM fluorescence molecular fingerprinting, it enables precise discrimination and quantification of key proteins like monoclonal antibodies (mAbs) and antibody-drug conjugates, supporting both R&D and quality control efforts.



Superior sensitivity compared to HPLC/MS and other techniques



Veloci™ BioPharma Analyzer



## Quantitative Analysis of API in Formulations

with Raman Spectroscopy in Pharmaceutical Applications

Raman spectroscopy is capable of qualitative and quantitative chemical analysis.

In one study, the MacroRAM™ demonstrates its utility for quantitative analysis in diverse solution matrices, including single solutes, azeotropic mixtures, and multi-component formulations to determine active pharmaceutical ingredient (API) content in products like Excedrin®, DayQuil®, and NyQuil®.



MacroRAM™

Perfect for bulk analysis of solids, liquid solutions, powders, and gels

External probes allow for fast and easy measurements



## Determining the Concentration of Nucleoside Triphosphates

High-speed, High-throughput Temperature-controlled Screening of Biomedical Materials in Multiwell Plates

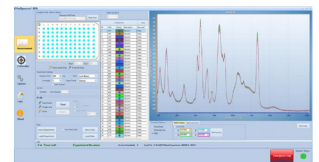
PoliSpectra® Rapid Raman Plate Reader (RPR) reads biomedical materials presented in multiwell plates to monitor their reactions, determine their concentrations, and much more.

In one case, RPR was used to determine the concentration of nucleoside triphosphates (NTPs) solutions in phosphate-buffered saline (PBS).



PoliSpectra® RPR

Fully automated process with dedicated control software



## Protein Quantification at Low Concentration

with Duetta™ 3-in-1 Fluorescence and Absorbance Spectrofluorometer

The Duetta™ spectrofluorometer is known for its high sensitivity and ability to correct for the inner-filter effect (IFE).

In one study, the Duetta was used to measure transferrin at a concentration range from 50 µg/mL to 0.75 µg/mL in 10 mM PBS. With the excitation wavelength set to 250 nm and the emission collected from 265 nm to 550 nm with 2s integration time on the CCD and 10 nm slits, the Duetta was able to detect transferrin at 0.75 µg/mL using fluorescence.



Duetta™  
3-in-1 Fluorescence  
and Absorbance  
Spectrofluorometer

Acquires a full spectrum from 250 nm to 1,100 nm in less than one second





**HORIBA**

**info.sci@horiba.com**

**USA:** +1 732 494 8660  
**UK:** +44 (0)1604 542 500  
**China:** +86 (0)21 6289 6060  
**Taiwan:** +886 3 5600606

**France:** +33 (0)1 69 74 72 00  
**Italy:** +39 06 51 59 22 1  
**India:** +91 80 41273637  
**Brazil:** +55 (0)11 2923 5400

**horiba.com/biopharma**

**Germany:** +49 (0) 6172 1396 0  
**Japan:** +81(75)313-8121  
**Singapore:** +65 (0)6 745 8300  
**Other:** +33 (0)1 69 74 72 00