Pharma BioTech Chemicals

CHAUVIN ARNOUX
INDATECH

Viserion 785

Faster process development and better production efficiency

Nutriments Metabolites Upstream Downstream process Single-use compatibility In-situ monitoring

Measure up

The Pharmaceutical industry has been reliant upon combinatorial chemistry for API discovery and production, but finding new drug candidates is more and more challenging. However, Biotechnology has demonstrated the ability to produce new drugs and blockbusters, and it is now a critical strategic domain. This process relies on living organisms and is far more complex to understand than conventional chemistry, and the ability to develop a robust and reproducible bio-process with high productivity is highly desirable.

The Viserion Raman Analyser @ 785nm will improve financial performance with faster process development times and enhanced process understanding using a QbD approach. It enables a significant reduction of laboratory analyses, fast in-situ analysis of critical process parameters and attributes, and yield optimization.

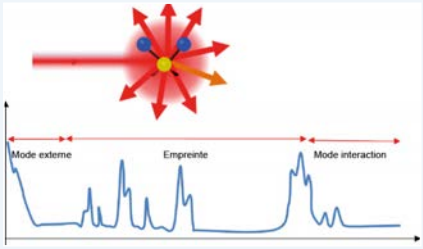
▪ Upstream Process(USP)

- **Quantitative analysis of nutriments and metabolites**
- Pilot to large production **scale-up**
- **Laser safety** interlock option
- **OPC-UA** for communication with PLC
- Industrial **stainless steel** enclosure
- Simultaneous **multichannel batch capabilities**

▪ Downstream Process (DSP)

- **Specific flow cell** for 1/8 connector
- **Prediction of purity**
- Abnormal spectra / event identification
- Product identification
- Start point/**end point detection**
- **Single-use** compatibility

▪ Viserion at a glance



- The Raman effect is based on inelastic scattering of photons
- The sample generates emissions under laser illumination
  - the wavelength shift provides chemical information
  - the intensity provides component concentration
- High chemical information and reduced impact of water
- In-situ monitoring with a wide range of probe customization options available

Typical Performance (e.g. CHO cell culture)	
Parameter	Error (Range) in g/l
Glucose	0,35 (0-10)
Lactate	0,30 (0-8)
Ammonium	0,30 (0-7)
Antibody concentration, VCD, glutamate, plasma compounds, etc.	

▪ Data security

- 21 CFR Part 11 compliance
- Full IQ/OQ/PQ support
- GMP compliance

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906 211 599 - Ed.3 - 05/2025 - LB - Non-contractual document