

# “GiANT”

**WORLD’S FIRST “3 in 1”**

**SPECTROSCOPY PLATFORM  
WITH INTEGRATED:**

- **UV-VIS**
- **NIR**
- **RAMAN**

***Inline process monitoring  
directly in extrusion & other  
continuous processes***

The GiANT system is designed to meet the needs of the evolving Pharma industry, as it adopts advanced manufacturing and continuous processing methodologies.

Batch-based manufacturing is often characterized by its inflexible protocols, repetitive offline quality analysis, long cleaning & turn-around times, and generally high operating costs. Continuous Manufacturing (CM) is a new, disruptive approach to primary and secondary pharmaceutical production.

Extruder-based Hot Melt Extrusion (HME) and Wet Granulation (WT) are examples of advanced CM methods that more easily allow for automation, improve efficiency by reducing waste, and can enhance bioavailability for poorly soluble molecules.

To support the Pharma manufacturers adopting CM methodologies, ColVisTec has developed new, integrated UV-VIS, NIR and RAMAN spectrometer platforms that are designed to provide reliable process control data with full cGMP compliance.

ColVisTec provides spectroscopy-based process control solutions for a wide range of extrusion applications, including pharmaceutical, chemical, polymers & plastics.



The GiANT integrated PAT (Process Analytical Technology) system comprises:

- cGMP compliant materials (current Good Manufacturing Practice), hardware & software
- Single user terminal interface for all 3 spectrometers
- With centralized data processing & communications
- Fully insulated modules
- Resistant to temperature variances and vibrations
- Small footprint
- Designed for easy disassembly & cleaning
- Proprietary optical probes & fibers
- Designed for compatibility with various industrial extruder types

### Specifications UV-VIS

Reflectance and transmission modes  
 Wavelength range 220 - 820 nm  
 Resolution is 1 nm (whole range)  
 Measurement time 10 ms (adjustable)  
 4 Channels (2 measurement + 2 reference)  
 Two probes in parallel operation  
 Light source is Xenon flash lamp  
 Color scales: L\*, a\*, b\*, C\*, h, dE\*, YI, WI, CIE-2000 etc.

### Specifications NIR

Reflectance and transmission modes  
 Wavelength range 1000 - 2300 nm (4300 - 10000  $\text{cm}^{-1}$ )  
 Resolution is 2.6 nm  
 InGaAs Linear Array detector with 512 pixels  
 Integration time 10  $\mu\text{s}$  - 5 ms (adjustable)  
 Light source is broadband 360 - 2600 nm lamp

### Specifications RAMAN

Reflectance mode  
 Range of detection 0 - 3350  $\text{cm}^{-1}$  Raman shift  
 Resolution is 1.8  $\text{cm}^{-1}$   
 High quantum efficiency CCD array detector  
 Integration time 100 ms - 10 s (adjustable)  
 Light source is Laser at 785nm  
 365mW maximum intensity at probe focus point

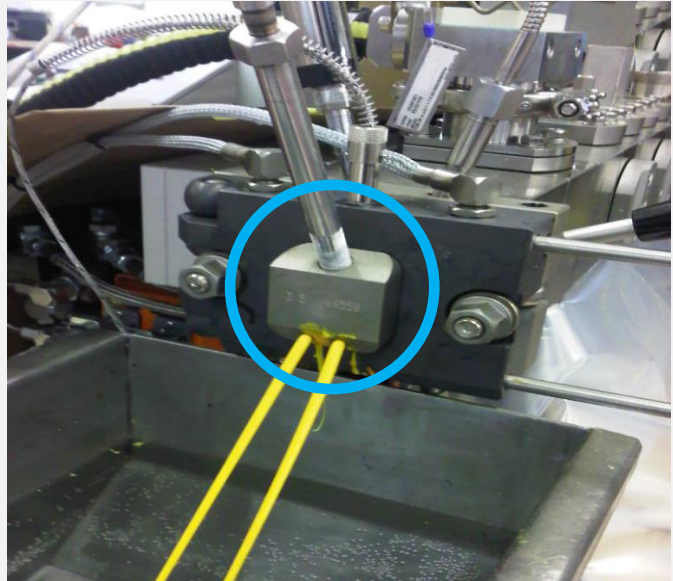


Figure 2: Combined UV-VIS + NIR probe operating in reflectance mode in an extruder application.



Figure 1: Combined UV-VIS + NIR probe for reflectance and/or transmission application.  
 Hastelloy probe tip with sapphire window.  
 Probe design with  $\frac{1}{2}$ "-20UNF (typ. Dynisco®)  
 made for 200 bar and 350 °C

#### User benefits:

- **Real-time information about process stability & quality**
- **Impact of speed changes on the quality of the extrusion**
- **Determination of optimal extruder screw configuration**
- **Innovative residence time measurement and analysis**
- **Controlled product changes: start phase, drift etc.**
- **Detection of pulsing pumps, mixing etc.**
- **Avoid off-specification batches & waste production**
- **Detection of feeder elevations**
- **Detection of formulation components e.g. API**
- **Optimized formulation & processes design**
- **Optimized control of R&D processes**
- **Fast measurement, immediate results**
- **Reduced costs - higher ROI**

**Please contact us for further information and a conversation around your needs.**

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