



INLINE/INSTANT MEASUREMENT FOR PHARMA EXTRUSION - IMPAX

A NEW MULTI-SPECTRUM INTEGRATED PAT TOOL FOR SIMULTANEOUS NIR, RAMAN & UV-VIS SPECTROSCOPY

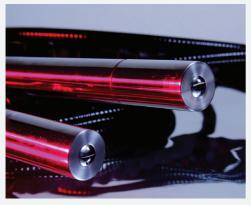
COLVISTEC AG has developed an innovative approach to in-line spectroscopic analysis for pharmaceutical manufacturing.

The IMPAX system represents a step-change in PAT functionality.

Our innovative platform comprises three spectroscopic techniques (NIR, Raman and UV-Vis) to provide comprehensive process analytics for hot-melt extrusion, wet granulation and amorphous solid dispersion manufacture.







NIR 800-2000 nm

- Measure moisture content & drying processes
- Characterize raw materials & feedstocks
- Study blend uniformity
- Finished product ID & specification

UV-VIS

- Accurate quantification of API
- Study API dissolution kinetics
- Assess impurity profile in chemical feedstocks
- Measure thermal stability & API / polymer degradation kinetics
- Monitor process deviations, intervene & rescue

RAMAN 780 OR 830 nm

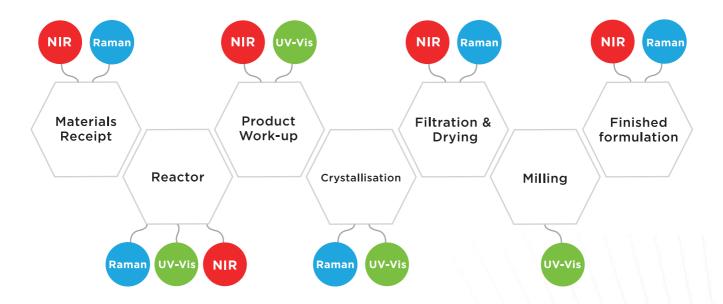
- Measure compound crystallization state
- Track specific impurities
- Finished product ID & specification

Bespoke optical probes are constructed from approved, inert materials (stainless steel / Hastelloy® body with sapphire lens), stable up to 350°C and 200 bar.



IMPAX REPRESENTS THE FIRST PRODUCTION MONITORING PLATFORM TO COMBINE THREE SPECTROSCOPY TYPES (UV-VIS, NIR, AND RAMAN) INTO ONE SYSTEM.

FROM RAW MATERIALS TO FINISHED PRODUCT, THE IMPAX SYSTEM SUPPORTS EVERY STAGE OF THE PHARMACEUTICAL MANUFACTURING PROCESS.



THE IMPAX SYSTEM COMPRISES:

- cGMP compliant materials, hardware & software
- Proprietary, optimised probes & optical fibres designed for compatibility with various industrial extruder types
- Single user terminal & interface for all three spectrometers, with centralised data processing & communications
- Insulated against temperature variances and vibrations
- Small footprint, designed for easy disassembly & cleaning

