

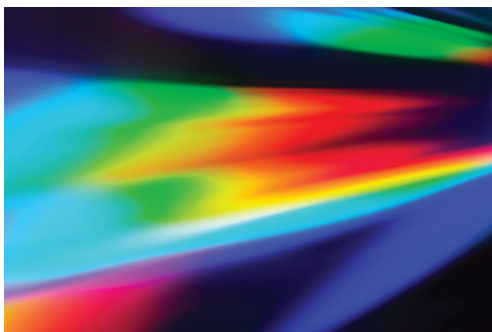
IMPAX - INLINE / INSTANT MEASUREMENT FOR PHARMA EXTRUSION

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

COLVISTEC AG has developed an innovative approach to inline spectroscopic analysis for pharmaceutical manufacturing.

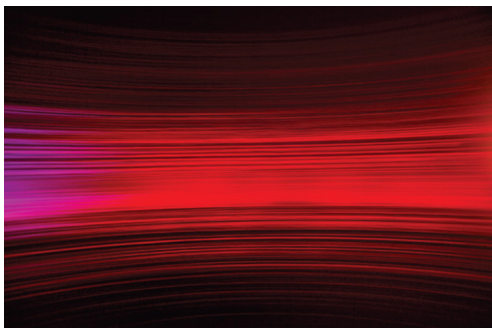
The IMPAX system represents a step-change in PAT functionality.

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



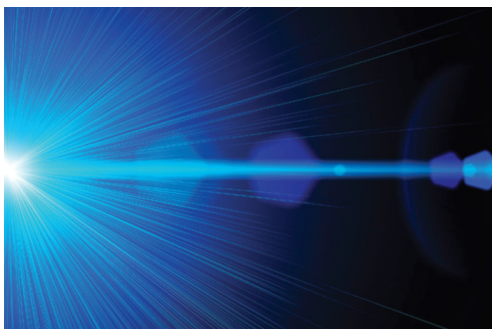
UV - VIS 220 - 820 nm

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



NIR 1000 - 2300 nm

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



RAMAN 785 nm

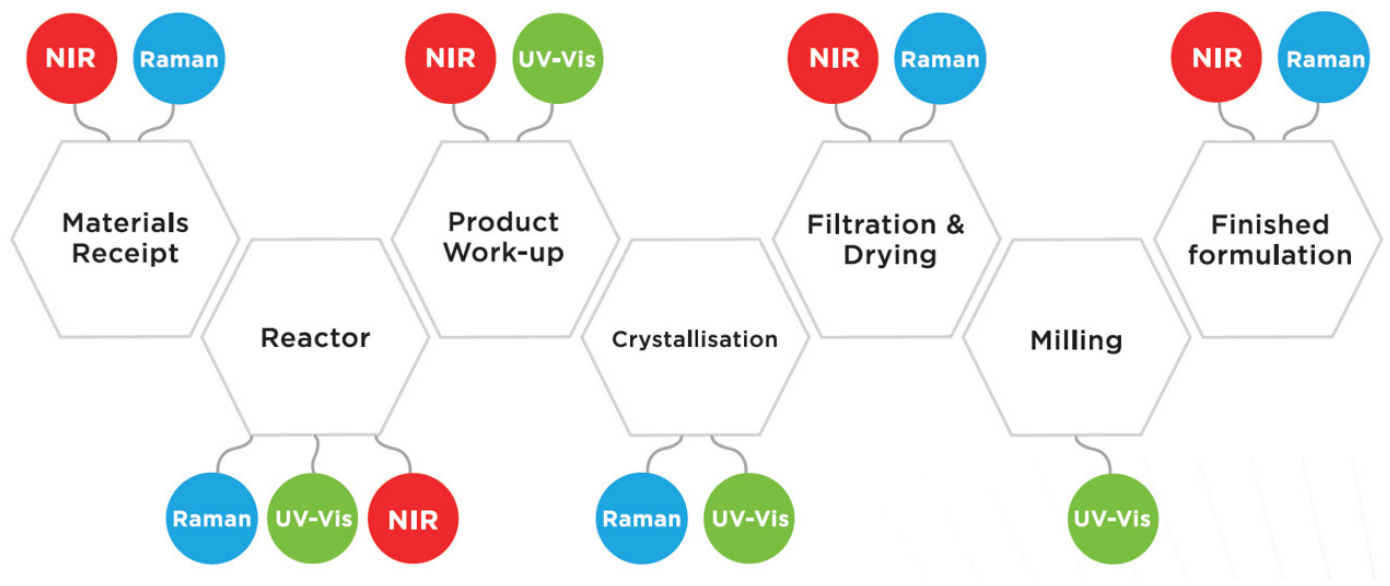
- Measure compound crystallization state
- Track specific impurities
- Finished product ID & specification



Bespoke optical probes are constructed from approved, inert materials (Stainless steel body, Hastelloy® tip with sapphire window) 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 PHARMA MANUFACTURING CHAIN



THE IMPAX SYSTEM COMPRISES:

- cGMP compliant materials, hardware and 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



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