CENTRE FOR ADVANCED PHOTONICS & PROCESS ANALYSIS



Photonics for Pharmaceuticals

Application Case Study

The importance of the pharmaceuticals sector to Ireland is well established, with **9 of the top 10 global companies** based in Ireland. The largest cluster of pharmaceutical operations is in Cork, employing over 8,000 people in the region alone. Photonics makes significant contributions to the development and deployment of Process Analytical Technologies (PAT), a major priority within the industry currently, and has applications inline, at-line and offline.

- Drug identification, raw material classification
- Blend uniformity, API distribution
- · Chemometrics, multi-variate analysis

- Process Analytical Technologies (PAT)
- Inline/online sensors (gases, pH, ...)
- Monitoring phase changes



- Cleaning verification
- Particle size analysis for powders
- Root cause analysis of contaminants

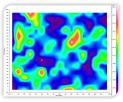
- Laser-inscribed tablet labelling
- · Anti-counterfeit measures

Case Study: Blend Uniformity via Raman Spectroscopy

Concentration: Sample blends with between 10% and 90% API were prepared; standard HPLC (calibration set) was compared with Raman spectroscopy measurements (validation set); R^2 values were 0.9974 for the calibration set, 0.9602 for the validation set.

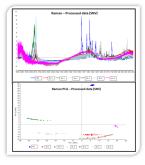
Distribution: The distribution of API over a 2.08 mm² area was measured with Raman mapping, using the main Raman peak at 1620 cm⁻¹. Results indicate a slight separating of the API from other excipients. For a sample with nominal 25% API concentration, the average measured via Raman was 25.4% (st. dev. 8.8%), with a min. of 6.9% and max. of 45.6%.

Identification: Spectra from 7 ingredients (1 API & 6 Excipients) were collected. Data pre-processing with SNV (Standard Normal Variant) and analysis with PCA (Principle Component Analysis) indicated clear clustering of results, allowing rapid raw material classification.



Above: Raman map of API distribution.

Right: PCA analysis of spectra for raw material classification.



Pharmaceutical Manufacturing Technology Centre (PMTC)

CIT/CAPPA are members of the industry-led, EI/IDA-funded Pharmaceutical Manufacturing Technology Centre:

www.pmtc.ie



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