Pharmaceutical Physical Characterisation

Morphology, particle size and more

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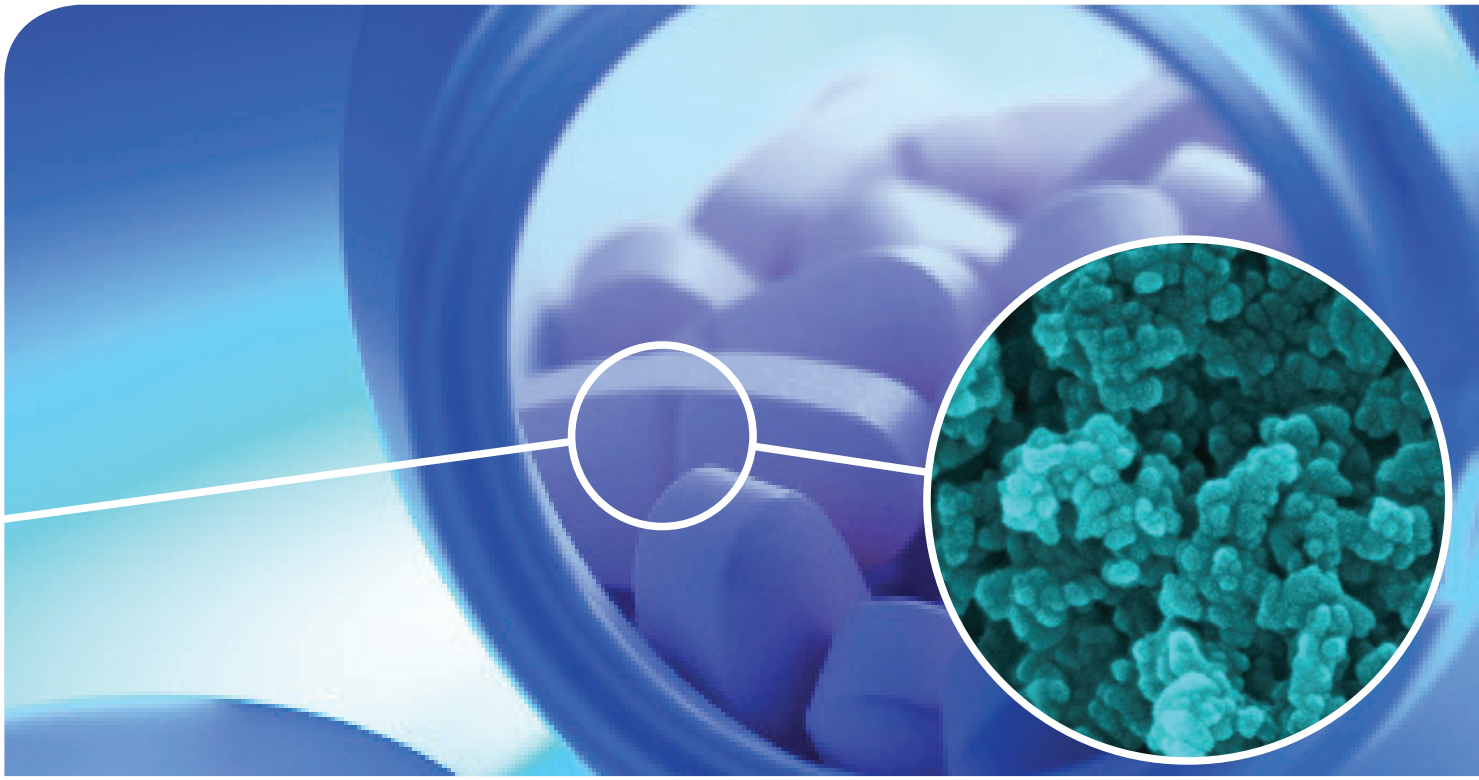

Understanding the physical properties of pharmaceutical solid materials is key to successful drug product and process development.

These physical properties can have an impact on the material's bulk properties, product performance, processability, stability and product appearance.

The melting point, chemical reactivity, apparent solubility, dissolution rate, optical and mechanical properties, vapour pressure, and density can all be affected.

GLP, GCP or cGMP compliant physical characterization services assist with formulation or process development, regulatory submission data, QC testing, GMP lot release and manufacturing troubleshooting.

Physical Characterisation Techniques

Available as part of R&D or GLP / cGMP projects, techniques available within Intertek include microscopy (SEM, EDX, TEM and LM), X-Ray Powder Diffraction (XRPD), thermal analysis (DSC and TGA) and particle size technology.

Including:

- Particulate size, distribution and shape
- Particle properties e.g. zeta potential
- Surface area & porosity
- Powder flow characteristics
- Polymorph analysis
- Microstructure analysis e.g. encapsulation
- Thermal properties
- Physico-chemical properties

Did you know?

The global network of Intertek Pharmaceutical Services provide advanced R&D, GLP, GCP and cGMP analytical support services to customers engaged in the development and manufacture of pharmaceuticals, biopharmaceuticals and specialist products for the healthcare industries.

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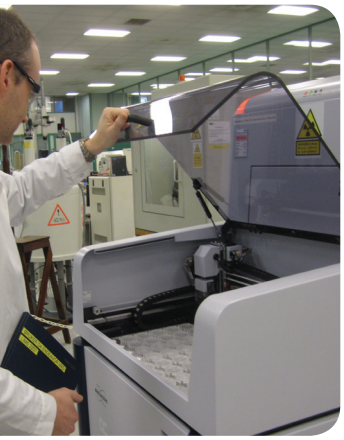

Molecular Level

- FTIR or RAMAN Microscopy
- Light Microscopy
- NMR Spectroscopy
- FTIR or RAMAN Spec.
- UV-vis or Fluores Spec.
- Interferometry
- MALLS & SEC-MALLS

Particulate level

- Particle Size
- Light & Electron Microscopy (SEM, TEM)
- Particle Morphology
- Particle size analysis
- SEM-EDAX for Elemental
- Particle Size in Suspension
- Aggregation Studies
- Zeta Potential

Bulk level

- Powder X-ray Diffraction (XRPD)
- Thermal analysis (DSC, TGA)
- Surface area (BET N_2), porosity, porosimetry
- Powder flow characteristics (bulk density, pourability, dustability)
- Physico-chemical properties (viscosity, LogP, vapour pressure and more)

X-Ray Powder Diffraction

X-ray powder diffraction (XRPD) is a core technique for the identification and characterization of solid form pharmaceutical material in terms of the structural order or disorder of solid APIs or other substances. XRPD is able to detect and quantify polymorphic contamination, detect crystallographic changes, and quantify active ingredients in the final dosage form and used to monitor and control the quality of API's, raw materials, excipients and finished products. This is important because any change in the morphology of fillers, or in the crystalline state of active ingredients in the final product, resulting from the manufacturing process, can influence a drug's bioavailability.

Applications include:

- Identification of existing forms of the active pharmaceutical ingredient (API)
- Identification of the type of order present in the API (crystalline and/or amorphous)
- Studies of physical and chemical stability
- Identification of the solid form of the API in the drug product
- Identification of excipients present in a drug product
- Detection of impurities in a drug product
- Quantitative analysis of mixtures of crystal forms

Light and Electron Microscopy

Electron microscopy (TEM, SEM, SEM-EDAX) services are available for particulate or bulk materials (particle size, morphology and count studies). Cryo-electron microscopy is available for gels/liquid emulsions. Light microscopy (IR, fluorescence, polarised light, DIC mode), Confocal Raman microscopy and interferometry all also available.

Investigational Experience

Our experts have considerable cross sectional and investigational experience with projects involving solid pharmaceutical products, APIs, drug delivery systems, medical equipment and diagnostic devices to address contamination, development or manufacturing support issues.

Nanoparticle Expertise

Nanoparticles have been developed for a range of applications in healthcare products from therapeutics, medical devices, drug delivery, diagnostics, disease and infection prevention. Intertek provides a comprehensive R&D or cGMP analytical capability for nanotechnology systems via it's suite of relevant analytical technology.

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