

PHARMACEUTICAL POWDER CHARACTERISATION SERVICES

Analytical support for production and formulation development

It is critical to characterise powders in advance of developing pharmaceutical manufacturing processes as particle size, shape and morphology can impact powder flowability, blending and tableting processes. Powder characteristics are also intrinsically linked to dissolution, bioavailability and stability.

Pharmaceutical manufacturing processes and final products often involve powders. Particle size, shape and morphology will influence physical properties such as the flowability of a bulk powder, which in turn will impact processes such as blending, capsule / blister filling and tableting. Parameters such as dissolution are also affected, which are in turn intrinsically linked to bioavailability and stability. It is critical to well characterise powders (both raw materials and final product) in advance of developing manufacturing processes.

Powder challenges

During product development, R&D scientists aim to achieve improved properties such as enhanced drug delivery or bioavailability through refinement and adjustment of formulations of powders. These adjustments (in composition or process) can impact particle size and morphology, and ultimately impact flow properties. This can potentially lead to problems in the production process, particularly when it is scaled up to high volume. The classic challenges here include failure to discharge reliably from hoppers or silos and poor or unpredictable flow in feeders and dosing machines. This can cause unwanted interruptions in the production process (or a complete redesign), leading to unwanted shutdowns and stoppages. In addition, if the pharmaceutical product is delivered via a device (e.g. inhaled or nasal), device development challenges related to the powder properties



POWDER & PARTICLE CHARACTERISATION

Powder Rheology, including assessments of;

- Consolidation
- Aeration
- Flow (Shear) rate
- Wall friction
- Compressibility
- Permeability
- Stability and variable flow rate
- Moisture Content
- Surface Area Determination by BET
- Particle Size
- Particle Shape and Morphology

may be experienced, such as inaccurate dosing, unsuitable particle size distribution or problems relating to static charge.

Quality Control Departments are also constantly dealing with raw materials in powder form, which can come from multiple suppliers. The variability in particle properties (size distribution, shape, moisture content) requires a battery of release tests, often not assessing how the powder will perform when loaded into plant equipment.

Understanding powder morphology, shape and flow

Characterisation of powder behaviour, particularly flowability and shear properties can drive understanding about processes

and products where powders are involved, helping to overcome challenges faced during product development and production. Our powder characterisation experts employ a range of techniques to study powder flow to generate valuable insight that can help you to overcome the potential issues faced during pharmaceutical development and manufacturing. Combining rheological assessments with typical physical properties analysis contributes to a fuller understanding of powders.

Driving insight

The insight we bring, based on powder characterisation measurements, can aid problem solving related to powder blending or caking of powders in hoppers, device / drug product compatibility, selection of materials suitable for powder processing equipment, quantifying humidity effects, supporting the development of granulation methods and benchmarking and comparison of powders in terms of flowability. Our teams are experienced in device and formulation compatibility assessment with the ability (and technology) to map and characterize device / formulation performance during early stage development in order to address problems related to device development. Intertek's network of GMP compliant laboratories provide compliant data to support regulatory requirements or product development activities of our global clients. By deploying our Total Quality Assurance expertise, we help you bring your product to market quickly, responsibly, and economically to keep your business smoothly moving ahead.

FOR MORE INFORMATION



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