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Current Perspectives - Real-time attribute measurement in high shear wet granulation: An evolving paradigm

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Pharmaceutical processes for oral solid dosage forms have long occupied the realm of direct compression, dry granulation, and wet granulation (WG). WG can be either a low or a high shear process, including fluid bed granulation. Traditionally, WG is a batch process that is controlled based on process parameters. The effect of changes in the equipment, scale, or formulation is typically assessed on the attributes of dried granules or compressed tablets.

This approach increases the required experimentation, provides indirect controls, and the results on the measured attributes may be confounded with the role of unit operations such as drying, milling, and compaction. Such a drug product development work stream presents challenges for building quality by design into the processes and delineating interactions of process parameters used for different unit operations on product attributes.

Significant efforts have been invested in the recent years in developing the process analytical technology (PAT) tools for real-time measurement of relevant granule attributes in the granulator itself during processing. These measurements have included the indirect measures such as impeller power, torque, or the wet mass density. Direct measurements of attributes have utilized techniques such as focused beam reflectance measurement to measure granule chord length distribution during granulation, which can be correlated to the particle size distribution (PSD) of granules.

The most important question to these efforts, however, remains- What should we measure, and why? The end goal should always be kept in mind!

Traditionally, granule PSD has been the key parameter that is assessed through and across the unit operations. PSD has significant implications on the manufacturability parameters of the dosage form such as flow, density, and fines content. The chosen attributes for PAT development, of course, depend on the attributes specific to a drug product and processes. The critical quality attribute for several drug products is drug release- which usually correlates better with granule porosity or density rather than size.

These recent developments indicate an urgent need for the WG PATs to evolve with this paradigm shift or addition of focus to include granule densification.

Biography

Ajit Narang works for the Drug Product Science & Technology Department of Bristol-Myers Squibb, Co. (BMS) in New Brunswick, NJ in the development of oral solid dosage forms. He also serves as Adjunct Faculty at the Universities of Tennessee and Phoenix; Industrial Advisory Board member of Western Michigan University; and Editor of Journal of Applied Biopharmaceutics and Pharmacokinetics and BioMed Research International. He earned his Ph.D. from the University of Tennessee in Memphis and holds over 12 years of pharmaceutical industry experience in the development of oral dosage forms and drug delivery platforms working for BMS, Ranabxy, and Wockhardt in different capacities. He has published over 40 peer reviewed articles; 2 books; 5 patent applications; 40 poster presentations and 8 podium presentations at various scientific meetings; and has contributed to the development of several marketed drug products. His current research interests include innovations in dosage form development and drug delivery technologies that enable pharmaceutical development of challenging molecules to resolve stability, manufacturability, and bioavailability issues.

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