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Mechanical properties of powders for compaction and tableting: an overview

Gregory Amidon, geamidon@med.umich.edu

ABSTRACT

With the ever-increasing need for development speed, the ability to complete a thorough characterization of formulations with small quantities of material is critical but is possible. Thorough characterization of formulation components (both the API and excipients) is a valuable precursor to initiating tablet formulation development activities. Physicochemical and mechanical property data provides key information and insight needed to select ingredients and unit processes. It also provides a valuable benchmark that allows the formulator to monitor changes and set meaningful specifications in raw materials throughout the development process (i.e., QbD). The appropriate use of small scale equipment and, most importantly, the careful and thorough physicochemical and mechanical property characterization at every step of the manufacturing process facilitates the development of robust and well-characterized formulations that can be more easily scaled. Compaction is the critical unit process that is the focus of this discussion. Meaningful tablet compaction using small quantities of formulation is possible with tablet compaction simulators, emulators, and even with a simple hydraulic press. The critical information to be obtained is tablet: compactibility, compressibility, tableability, and manufacturability as a function of tablet solid fraction. Compactibility has been shown to be essentially independent of compaction speed whereas tableability, compressibility, and manufacturability may be significantly influenced by compaction speed (dwell time) and this is valuable information. This presentation will discuss the generation, interpretation, and application of this vital compaction data to direct compression and dry granulation formulations using tablet press simulation/emulation.