

More Questions and Answers

Tablet hardness, capsule shell strength

Q: How important is it to assess tablet hardness and capsule shell strength for a newly formulated drug product?

A: [Claire Freeman](#), [Ametek Brookfield](#), says:



Oral administration is a widely used route of drug delivery around the world, and tablets and capsules are a convenient way to administer formulations to patients.

Tablets are the most widely used dosage form, and tablet hardness is a critical attribute for successful active pharmaceutical ingredient (API) delivery. A poorly compacted tablet can accelerate disintegration due to weak bonding and cause premature API release, while an extremely hard tablet can slow a tablet's dissolution due to excessive bonding between the API(s) and excipients and decrease API bioavailability.

Gelatin capsules are a convenient way of prescribing powdered herbs and liquids that patients would otherwise not accept due to unpleasant tastes or textures, but some fillings can affect the hardness of the capsule shell, which can impact a formulation's bioavailability and safety. When formulating a drug product for encapsulation, it's key that the API be compatible with the gelatin capsule shell.

Factors affecting hardness

Tablets. The compaction of a tablet to a size that's easy to swallow is important, with the size and texture dependent on the composition and quantity of ingredients in the formulation. A poorly compacted tablet may not be hard enough to withstand the stresses of subsequent processing, packaging, storage, and transportation as well as handling by pharmacists and patients without crumbling or chipping.

During formulation, excipients—such as diluents, binders, glidants, lubricants, and disintegrating agents—can not only affect the stability, safety, dissolution rate, bioavailability, and efficacy of APIs but also can impact the tablet's mechanical strength. The types and compositions of binders, other excipients, and APIs can influence hardness. Binders can interact with other components in a mixture to form a wetter or drier mix, affecting a drug product's texture as well as its physical and chemical stability.

During manufacture, the way that operators use equipment as well as the manufacturing conditions—such as the tablet press speed, the hopper angle for granulation flow, and any form of aeration introduced—can affect a finished product's hardness.

During quality control, standardized test settings and sample sizes are important. Tablet hardness depends not only on the drug product's formulation and processing but also on the dimensions of the tablets being tested, the type of probe used for testing, and the compression force or distance applied.

Capsule shells. Various factors can affect capsule shell hardness. Formulation ingredients that contain reactive aldehydes, such as formaldehydes, can react with a gelatin shell. This reaction forms cross-linkages with lysine residues within and between the gelatin strands, consequently stiffening the gelatin structure.

A gelatin shell's water content is also a factor in determining its compatibility with a formulation. A highly hygroscopic formulation can absorb water from the capsule shell, causing the shell to become brittle and prone to breakage under mechanical strain.

Methods of testing hardness

Testing tablet and capsule-shell hardness is necessary in R&D for new formulations and in quality control (QC). You can test the hardness of tablets and capsules in numerous ways using a texture analyzer with various probes.

Tablet testing. A texture analyzer can perform bend testing for break strength, crush testing for bond strength, and shear testing for the seal strength of bilayer tablets (Figures 1 and 2). Results are obtained within minutes, making the device ideal for R&D and QC.

Capsule testing. A texture analyzer can quantify the mechanical strength of a capsule shell to identify the effects of formulations on the capsule's strength and stability (Figure 3). The analyzer can also quantify the elasticity of a gelatin capsule shell by measuring its deformation at peak load.

A texture analyzer can also conduct a quick penetration test using probe to determine the film strength or rupture point of soft common test method can also measure points of weakness in a manufacturing, simulating circumstances in which a capsule may and transport. You can also determine a capsule's seal strength using a compression probe with a larger diameter than the capsule. Position the seal perpendicularly to the probe and measure the force required to break the seal.



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