

Damaged Goods - Whose Responsibility?

tablets and capsules

Tablets and capsules that fall apart prematurely is a problem that we have all experienced as consumers. Who is responsible for the failed product? Should Quality Control receive production batches from manufacturing and be able to detect potential failures before they reach the customer? What tools does R&D provide to QC for identifying potentially weak capsules and tablets?

Texture Analyzers are instruments that measure materials using compression or tension and are becoming popular for use in measuring the durability of tablets and capsules. Figure 1 shows a Texture Analyzer with a cylinder probe that is pushing downward on a jar of gelatin. This standard procedure is called the Bloom Test and has a prescribed protocol for type of probe (cylinder with defined cross-sectional area), speed of probe downward movement (0.5mm/sec), and depth of penetration (4mm). The test determines the firmness of the gelatin and is ultimately used to value each batch of gelatin for its commercial worth. Manufacturers of gelatin capsules use this procedure to confirm that the gelatin has the desired strength rating they need for producing their capsules.

There are several advantages afforded by Texture Analyzers over traditional universal testers that provide tension and compression test capability. Texture Analyzers can work in standalone mode or under PC control. This means that characterization work performed by R&D using a PC to evaluate different formulations of a specific product can be transferred to QC as a discrete test method that is performed in standalone mode. The investment in equipment by QC is limited to the instrument and the probe needed to run the test. Typical expenditure for R&D to purchase a Texture Analyzer is under \$10K, while QC can spend a little over \$5K to implement the test method. The operation of the Texture Analyzer in standalone mode is relatively easy and can be taught in a matter of minutes to QC technicians.

Examples of other simple tests performed by QC to confirm durability of tablets and capsules include the following:

- The Capsule Loop Tensile Test Fixture in Figure 2 gives a measurement of the wall strength of the gelatin capsule. The half shell of a capsule is placed over two prongs that are moved away from each other at a low speed, perhaps 0.5mm/sec. The stretching action continues until the capsule wall ruptures, which by definition is the capsule wall strength.
- The Tablet Coating Adhesion Fixture in Figure 3 measures the force needed to remove the coating from a tablet. The fixture consists of two cylinders that have slightly concave surfaces with sticky pads affixed. The cylinders cradle the capsule using a low compressive force. Then

Figure 1: Brookfield Texture Analyzer Tests Gelatin in a Bloom Jar



Figure 2: Capsule Loop Tensile Test Fixture

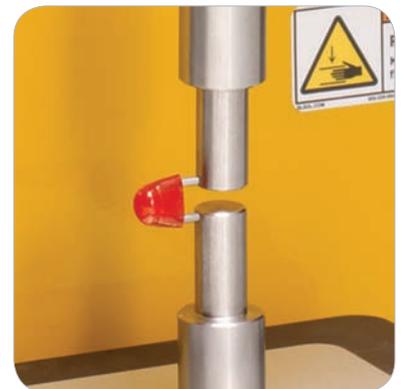


Figure 3: Tablet Coating Adhesion Test Fixture



the cylinders are pulled apart and the force needed to pull the coating off of the tablet is measured.

c) Crush and cutting tests on tablets and capsules are performed with blades and punches that measure the compressive force needed to break the product. Capsules with filler liquid, for example, may resist up to a 50kg load or higher, proving that they have the durability to survive in large containers of capsules that feed packaging machines.

d) Two part tablets can be tested for how well they stick together using a Bilayer Shear Fixture shown in Figure 4. The blade comes down on the joint where the tablet halves join together. The strength needed to separate them is measured.

e) The Blister Pack Support measures the force needed to expel the tablet or capsule from its packaging. While this test is more related to ensuring that customers can extract the product, it is still useful in verifying that the item holds together during the extraction process.

The above examples illustrate how Texture Analyzers are becoming commonly used tools for QC testing in tablet and capsule production. The good news is that this equipment is not expensive. It sets up quickly and technicians become proficient within a matter of minutes. There is no good reason not to use a Texture Analyzer if you are in the tablet and capsule manufacturing business.

Figure 4: Bilayer Shear Test Fixture



Figure 5: Blister Pack Support Test Fixture



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