Quality Control Methods That Make A Difference

QC Testing

How do you bring consistency to QC testing? Pharmaceutical products that meet manufacturability criteria and provide high level consumer satisfaction undergo a battery of tests before being distributed to the consumer. Using affordable instrumentation to perform QC tests, which certify that tablets, capsules, elixirs, ointments, etc. have the right physical properties, is essential for today's successful business.

Major corporations willingly invest in devices used to test physical properties, such as viscosity of liquids and semi-solids, texture of tablets and capsules, use of syringes for injectable liquids, and flowability of powders. If unfamiliar with the methodology, they contact potential suppliers for help. Can smaller companies expect similar attention from vendors? How expensive is the outlay to bring these test methods in house? Or is it better to use contract labs?

Acceptance and implementation of QC test methodology is an R&D responsibility. In smaller companies, QC and R&D may be one and the same. It's important to make sure that QC has a clear understanding of how the method works, the relevance of the data, and when to question the results.

Here are some examples of instruments that offer solutions.

Number 1: The Challenge of Powder Flowability
Pharma industry formulators come up with new powder mixes on a weekly basis for a variety of reasons. Some relate to new active ingredients, some to additives that will enhance processability, and others because new suppliers are providing replacement raw materials, perhaps at a reduced cost. R&D's task is to make sure that the new formulation works when scaled up for manufacturing.

Reliable flow in gravity discharge through a hopper is a major challenge. Standard test methods are simple to do, but unfortunately inaccurate. Tests using the Flodex Cup, Angle of Repose measurement and Tap Test, do not measure the key parameter that affects flow behavior of powders. Consolidation of powder in the bin due to its own self weight is the primary variable that determines whether the powder will flow. The test instrument known as the shear cell is the proper tool to use because it measures the sliding friction of the powder particles against one another as they discharge from the hopper. See Figure 1.

Number 2: How Tough Is Your Capsule?
Hard shell capsules are produced in large quantity every day in plants around the world. R&D produces a capsule design that will hold up from the time that ingredients fill the capsule through the packaging process to the moment that the consumer swallows it. Measuring the strength of the capsule is the key to qualifying whether it will survive the various forces to which it gets subjected. Texture analyzers are general purpose instruments for compression and tension testing. See Figure 2. They are equipped with an array of probes and fixtures to make these measurements and correctly assess the durability of hard shell capsules. The fixture shown in Figure 3 pulls the capsule shell apart to measure the strength of the capsule wall.

Figure 1: Brookfield Powder Flow Tester with Shear Cell

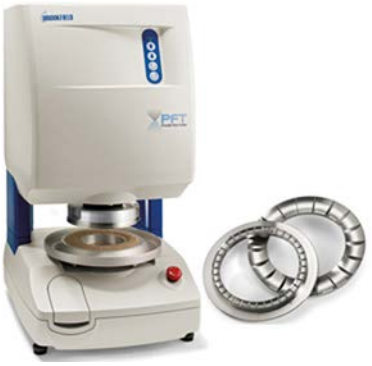


Figure 2: Brookfield CT3 Texture Analyzer

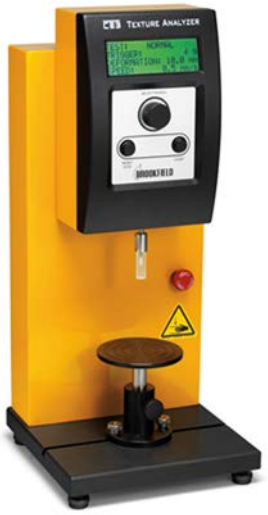
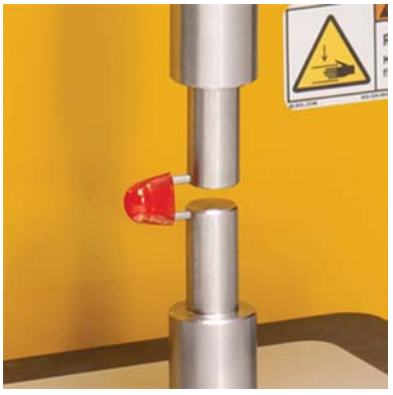


Figure 3: Test Fixture Measures Capsule Wall Strength



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Number 3: Will The Tablet Hold Together?
R&D concentrates on the active ingredients in the tablet to make sure that it fulfills its primary mission of helping customers to get over their sickness. Another facet of qualifying the tablet is to make sure that physical properties, like strength and dissolution rate, are correct. Texture Analyzers have come into prominence by providing an array of fixtures and test methods that ensure tablets behave correctly in a physical sense. These tests ensure that tablets will maintain their integrity from point of manufacture to time of consumption by the customer. Hardness tests, shear tests, and dissolution tests are becoming standard within QC Departments to ensure that performance goals are achieved. Figure 4 shows a fixture used to evaluate the adhesion of a coating to the tablet.

Number 4: Does the Ointment Hurt?
Patients are quick to complain when a medical ointment stings after application. But there may be another reason for dissatisfaction if the ointment is too thick. Not only is it hard to get out of the tube; it has a rough feeling to the skin as you try to rub it on.

The ointment may well have been tested for viscosity, the resistance to flow, by the manufacturer and passed the QC check. But the test method may not have correctly simulated how the customer will rub the ointment onto the skin. Single point viscosity checks are standard in the QC world, but may not be sufficient to qualify the flow behavior of ointments. It's important to choose shear rates (rotational speeds) that measure viscosity and properly simulate the rubbing action of the customer. Figure 5 shows a rheometer used by many pharmaceutical companies to evaluate viscosity and yield stress.

Number 5: Is the Elixir Easy To Swallow?
Medicinal syrups should not only taste good, they should be swallowed without difficulty. Performing a viscosity test that simulates swallowing action is a must. Shear rates between 10 and 100 reciprocal seconds are customarily used to make this assessment. The apparatus shown in Figure 6 shows the test set up that accomplishes this test using a standard bench top viscometer.

SUMMARY
Simple QC tests with the proper test equipment can guarantee consistency in your product. If you have been thinking that it's time to investigate what's available, search the internet using phrases like "powder flow behavior", "capsule strength", "tablet coating adhesion", "ointment viscosity", and "liquid dose swallow test". You will learn that, not only are there many vendors to choose from, there are many new test methods available to you.

Figure 4: Test Fixture Measures Coating Adhesion

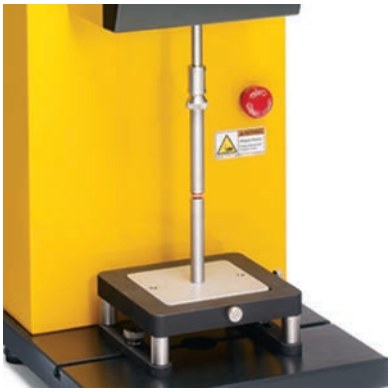


Figure 5: Brookfield RS Cone Plate Rheometer Measures Flow Behavior of Ointments

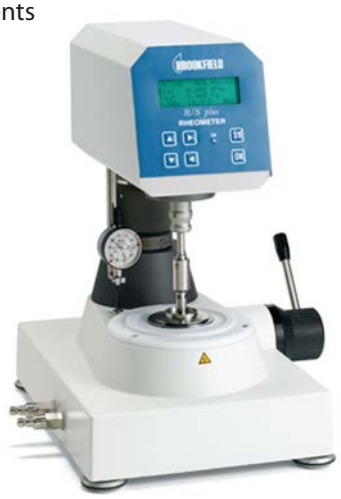
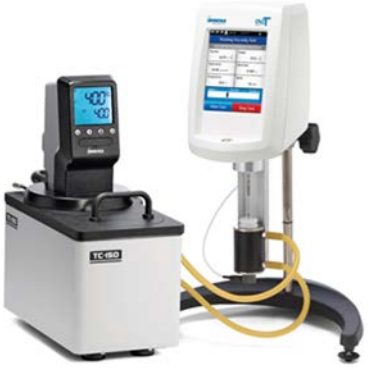


Figure 6: Brookfield DV2T Viscometer with Small Sample Adapter



Author: Robert G. McGregor, General Manager – Global Marketing
Brookfield Engineering Laboratories, Inc., 11 Commerce Blvd., Middleboro, MA 02346
Tel: 1.508.946.6200 Fax: 1.508.946.6262
Email: r_mcgregor@brookfieldengineering.com Website: http://www.brookfieldengineering.com