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BROOKFIELD
AMETEK
Instrumentation & Specialty Controls Division

Physical Properties Tests for the Pharmaceutical Engineer

Products packaged for consumer use by the pharma industry go through a battery of tests related to how the user applies the product. Creams and ointments, for example, are filled into tubes and jars; the effort needed to extract them from their container and spread on skin is the appropriate test. Medicines injected into the body via syringe have variable consistency depending on nature of the formulation; measuring the force needed to expel the fluid from the cartridge is the test that makes sense. Inhalers are designed for various ages of potential users – youth, adults, seniors; the actuation force to trigger flow must not exceed the average customer's strength, therefore test the plunger.

Figure 1: Texture Analyzer with Tube Extrusion Fixture

Basic test instruments called Texture Analyzers have come into widespread use to make these measurements. Figure 1 shows the device with a fixture mounted on its base holding a tube of ointment. The probe attached to the instrument is a rounded-edge blade that pushes down on the tube to squeeze ointment out the opening. The instrument controls speed of probe descent and distance of penetration while measuring load resistance as the tube is squeezed between the blade and fixture. The extrusion force needed to expel ointment must fall between pre-established min/max load limits for product to pass the test.

Figure 2 shows the graph of load vs. time for the tube extrusion test on two different materials. The measured force climbs to a peak value until steady state flow is achieved. The force remains relatively constant as flow continues. R&D will run tests on multiple tubes to establish performance limits for acceptable squeezing force. Once the test is established, Quality Control carries out the same test procedure running the instrument in standalone mode. The instrument display reports measured peak load which must fall between min/max limits established in R&D. In this fashion, a random selection of tubes from a production run are tested to verify that tube performance will meet customer expectation.

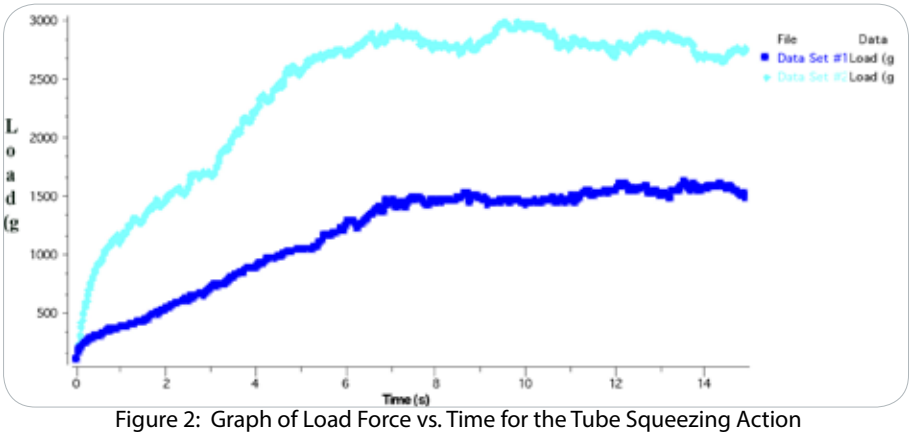

Figure 2: Graph of Load Force vs. Time for the Tube Squeezing Action

Syringes are widely used by medical personnel and consumers as well to administer medicinal dosage. Patients suffering from common diseases like diabetes are an example of the latter category. The design of the syringe (material make up, size, shape, and thickness) and the fluid viscosity will determine the force required to draw or eject a fluid. These factors can either hinder or ease user comfort, administration force, and ability to express a full dose.

Figure 3: Syringe Test Fixture

Actuation force for the plunger must fall between established limits to satisfy user expectation for acceptable performance. Figure 3 shows a special fixture that holds the syringe in a vertical position beneath the drive mechanism on the Texture Analyzer. A special probe affixed to the Texture Analyzer attaches to the syringe plunger and drives it downward at defined speed through an established distance. This action expels the fluid in the syringe. The Texture Analyzer measures the expulsion force to drain the fluid from the syringe. Pass/fail limits are established by R&D for use in QC. Random syringes selected from each production run are tested in a similar fashion to confirm acceptability.

Inhalers have become a vital tool for people suffering from asthma and other respiratory diseases. Inhalers involve self-administration and as such the dosage expressed must be precise/accurate and reproducible to the lungs or nose. A change in formulation by implementing a new propellant system will ultimately necessitate redesign of the valve system for successful drug delivery. The CT3 can be used in objectively redesigning the valve system and monitoring consistency and functionality of the inhaler.

Figure 4: Metered Dose Inhaler Fixture

The actuation force that triggers release of the medicinal ingredients within is carefully defined by R&D during initial product formulation and engineering. Figure 4 shows the fixture used to hold the inhaler in position for testing by the Texture Analyzer. A finger-shaped probe attaches to the Texture Analyzer, moves downward at defined speed, contacts the actuator on the inhaler, and depresses it through a defined distance. The measured load is typically highest at the outset when the probe first makes contact, then reduces as the actuator moves steadily downward. R&D will evaluate the graph of load vs distance to make sure that the initial actuation force falls between pre-established min/max limits and then remains smooth after initial triggering. QC will monitor test performance for similar data when the instrument is used in standalone mode.

The utility of the Texture Analyzer is its robust capability to provide detailed graphical information for R&D. Using this data, the QC test can be fine-tuned for the specific performance parameter(s) that will guarantee customer acceptance.

Authors: Robert McGregor, Director - Global Marketing/High-End Lab Instrument Sales
Chris Freeman - Sales Manager Texture Analyzer
Email: chris.freeman@ametek.com
AMETEK Brookfield, Inc.
INSTRUMENTATION & SPECIALTY CONTROLS DIVISION
11 Commerce Blvd. | Middleboro, MA 02346
Tel: 508.946.6200 | Fax: 508.946.6262 | Website: www.brookfieldengineering.com