BROOKFIELD

TEXTURE APPLICATION NOTE:

GELATINE CAPSULES

TEST PRINCIPLE

Evaluation of the tensile strength and extensibility of two types of hard gelatine capsules.

BACKGROUND

Capsules have become a common form of drug administration due to their size and shape along with their smooth and flexible texture making them easy to swallow. The capsule also masks the taste and odour of specific medical compounds thus improving patient drug compliance.

When formulating a drug, one key element a manufacturer needs to consider is whether the drug substance is compatible with the gelatine shell. The gelatine shell consists of a mixture of water-soluble proteins. Drugs substances containing reactive aldehydes (e.g., Formaldehydes) can react with the gelatine forming cross-linkages with lysine residues within and between gelatine strands consequently stiffening the gelatine structure.

The water content of the gelatine shell is another determining factor for the choice of filling. A highly hygroscopic filling may absorb water from the capsule shell causing the shell to become brittle and prone to breakage under mechanical strain.

The CT3 capsule accessory quantifies the mechanical strength of the capsule shell enabling manufacturers to identify the effects of fillings on the strength and stability of the capsule.

This method can be applied on other capsule materials or loop samples. For samples with higher mechanical strengths, a larger capacity load may be required. Likewise, for samples with a higher elastic component, an increased test distance may be required.

METHOD

EQUIPMENT CT3 with 4.5kg load cell
Capsule Tensile Accessory

SETTINGS		
	Test Type:	Tension
	Pre-Test Speed:	0.5 mm/s
	Test Speed:	0.5 mm/s
	Post-Test Speed:	4.5 mm/s
	Target Type:	Distance
	Target Value:	15 mm
	Trigger Force:	5g

Note: It is recommended that the pre-test speed be the same as or less than the test speed for accurate trigger detection; for example, 1mm/s test speed will require ≤1 mm/s pre-test speed.

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SAMPLE PREPARATION

Separate capsules into two halves (body and lid) and empty the contents. Select the smaller half of the capsule (lid) for testing.

PROCEDURE

1. Lock into position the upper holding fixture into the load cell.
2. Position the lower holding fixture on the base of the instrument and loosely tighten the screws to enable some degree of mobility.
3. Move down the instrument arm such that the upper arm of the tensile accessory is close to the lower arm by approximately 2 mm.
4. Re-position the lower fixture to align the top and bottom arms.
5. Tighten the screws of the lower holding fixture to securely fasten it to the fixture base table.
6. Push the gelatine capsule over the fixture holding pins.
7. Commence the test.

OBSERVATIONS

The upper fixture moves away from the lower fixture at a pre-test speed of 0.5 mm/sec until a trigger force of 5g is detected. At this point, the test commences. The capsule is extended with increasing force to a point where the sample can no longer support the applied force and breaks. The breaking point is an indication of the hardness of the sample.

RESULTS

A typical plot of a tension test on two types of hard gelatine capsules.

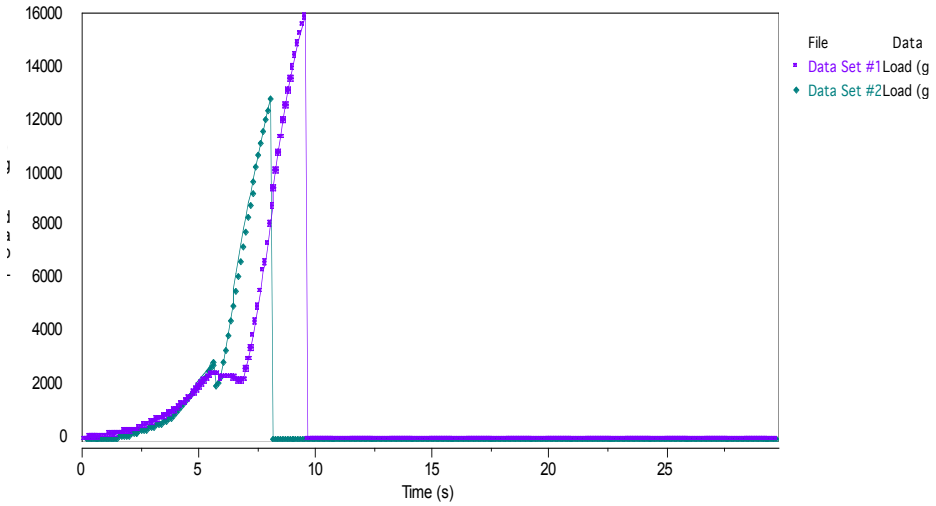

Figure I

GELATINE CAPSULES

The figure 1 graph shows the tension force for gelatine capsules

Data Set #1: Sample A (Green Gelatine Capsule 9 mm in diameter)
Date Set #2: Sample B (White Gelatine Capsule 6 mm in diameter)

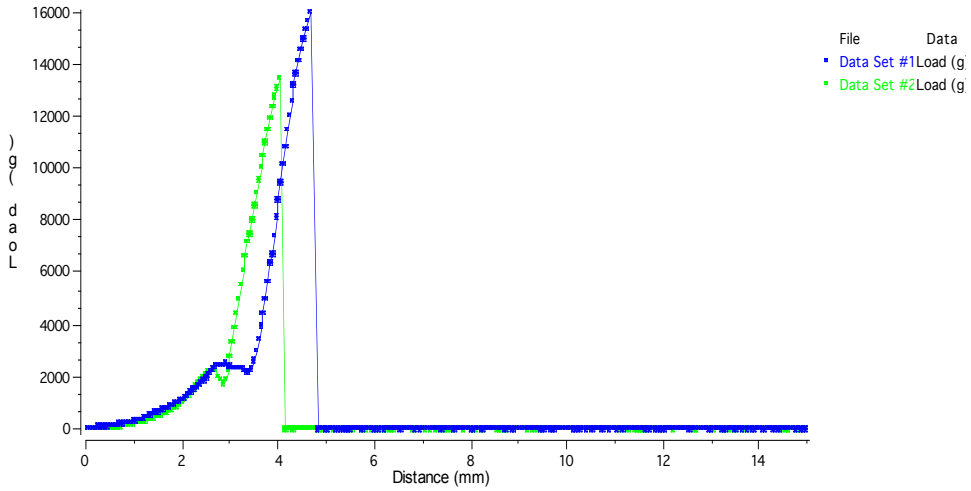

Figure II

The graph in figure 2 shows the tension force of a gelatine capsule.

Data Set #1: Sample A (Green Gelatine Capsule 9 mm in diameter)
Date Set #2: Sample B (White Gelatine Capsule 6 mm in diameter)

Figure 1 shows that Sample A is much harder than Sample B. This is supported by the mean Work Done values (see Table 1) where the value for Sample A is twice that of Sample B.

Table I

Sample	Peak Load (g)	Deformation at Peak Load (mm)	Work Done (mJ)
Green Gelatine Capsule	16585 ± 163	5.13 ± 0.44	218.8 ± 91.2
White Gelatine Capsule	12813 ± 239	4.06 ± 0.38	114.8 ± 37.9

Mean values (n=10) for the green and white gelatine capsules