

Raft Test

This test will determine the raft strength of Alginate Raft-forming Oral Suspension in accordance with the British Pharmacopoeia.

Alginate-based raft-forming formulations have been marketed globally for over 30 years for treating heartburn and oesophagitis, using a unique mechanism different from traditional antacids. When exposed to gastric acid, alginates form a gel, and with added sodium or potassium bicarbonate, they generate carbon dioxide, which creates a foam that floats on gastric contents like a raft. Studies have shown that these rafts trap carbon dioxide and antacid components, forming a pH-neutral barrier. The raft's strength depends on the amount of carbon dioxide trapped, the alginate's molecular properties, and the presence of aluminum or calcium in the antacid. Measuring the strength of Alginate Raft-forming Oral Suspension is crucial for ensuring its efficacy, consistency, and safety, supporting product development, quality control, and consumer trust.

The raft strength was determined using the CTX Texture analyzer with a 5.0 kg load cell and TA-RT probe.

METHOD

Equipment:

CTX with 5 Kg and Load Cell (CTX)

Fixture Base Table (TA-BT-KIT)

Standard probe TA-RT *Raft Tester*

TexturePro Software (SWL-02-111)

Parameters Set

Load cell	5 Kg
Test Type	Tension
Target type	Distance
Target value	70 mm
Trigger load	0 g
Test Speed	5 mm/s



SAMPLE PREPARATION

The raft was developed as mentioned in the test for Raft Strength in the British Pharmacopeial monograph - Alginate Raft-forming Oral Suspension.

1. Introduce 150 mL of 0.1M Hydrochloric acid into a 250 mL beaker having an internal diameter of 60 to 70 mm.
2. Place in a water bath so the volume of water in the bath is level with the top of the acid in the beaker. Allow it to equilibrate to 36.50 to 37.5°.
3. Suspend an L-shaped probe made of 1 mm diameter 316-gauge stainless steel, with a 90 mm vertical arm and a 20 mm horizontal arm ending in a hook, so that the vertical arm hangs down the center axis of the beaker and the horizontal arm is positioned in the lower third of the acid.
4. Using a syringe (without needle), remove a quantity of suspension, previously shaken, equivalent to one dose. Where a dosage range is specified, use the maximum dose.
5. Wipe the outside of the syringe and add the suspension evenly into the medium (the time taken to add the entire dose is approximately 5 seconds).
6. After 30 minutes, remove the beaker from the water bath, dry the outside of the beaker, and transfer it to a suitable texture analyzer.

PROCEDURE

1. Attach a 5 kg load cell to the CTX Texture Analyzer.
2. Attach the hook adapter and the fixture base table to the base of the instrument. Loosely tighten the thumb screws to enable some degree of mobility.
3. Insert a base plate into the fixture base table and tighten it into position using the side screws.
4. Position the fixture base table centrally under the probe and then tighten the thumbscrews to prevent further movement.
5. Check the temperature of the sample before proceeding with the test.
6. Place the beaker on the fixture base plate.
7. Lower the hook adapter a few millimeters into the beaker. Fit the wire probe in the hook and ensure that the wire probe is raised a few millimeters from the base of the beaker.
8. Once alignment is complete, commence the test.
9. The wire probe proceeds to move upwards, passing through the raft.
10. The force required to break through the raft is a measure of raft strength.

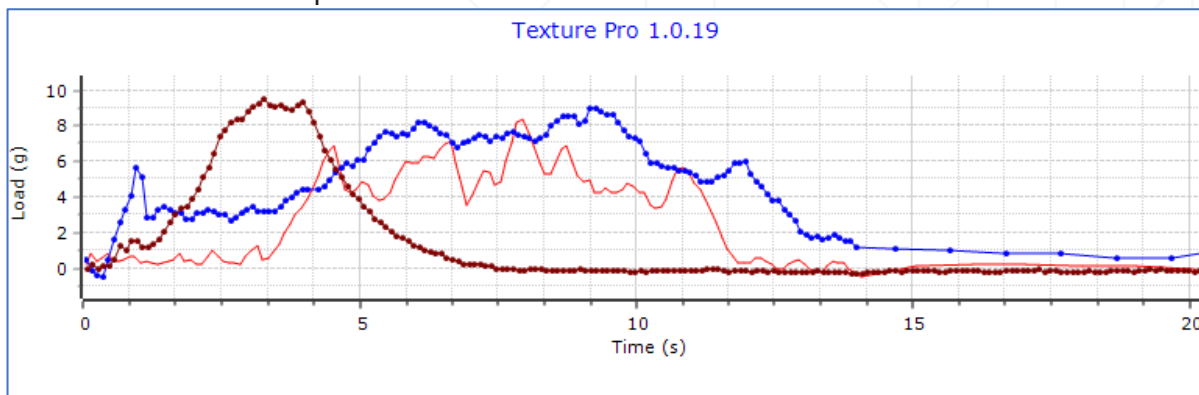
OBSERVATION

When a test is initiated, the probe moves through the developed raft in an upward direction. The Peak Load is the force (g) required to pull the wire probe up through the raft / raft strength. Deformation at Peak Load is the distance value at the Peak Load. Work is the force necessary to break the raft. Test was carried out on three different market samples.

The table below reports the data collected:

Parameters / Sample	Sample 1	Sample 2	Sample 3
Peak Load (g)	9.50	8.40	9.00
Deformation at Peak Load (mm)	16.22	39.62	46.23
Work (mJ)	1.01	1.72	3.47

The Load vs. Time Graph



DISCUSSION

The raft strength test for Alginate Raft-forming Oral Suspension using the CTX Texture Analyzer provided valuable insights into the efficacy and consistency of the product. The data showed variation in peak load, deformation at peak load, and work among different samples, highlighting the importance of precise formulation and preparation.


The peak load values, indicating the force required to break through the raft, ranged from 8.40 g to 9.50 g across the samples. These variations suggest differences in the amount of carbon dioxide entrapped and the molecular properties of the alginate in each sample. Deformation values at peak load and the work required to break the raft also varied, reflecting the mechanical strength and stability of the rafts formed.

This analysis underscores the necessity for stringent quality control and consistency in manufacturing processes to ensure reliable product performance. The accurate measurement of raft strength is critical for maintaining consumer trust and ensuring the suspension effectively prevents acid reflux. The use of the CTX Texture Analyzer and adherence to the British Pharmacopoeia standards are essential for achieving reproducible and reliable results in product testing and development.

DATA REPORT

TexturePro Software is used to program and control the CTX during experimental tests. It automatically measures peak load values which indicate the raft strength of Alginate Raft-forming Oral Suspension.



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CONCLUSION

The test results can be used to determine the raft strength of Alginate Raft-forming Oral Suspension as per the British Pharmacopoeia.

The test procedure, sample preparation, and equipment setup must be adhered to for reproducible test results.

For repeatability and reproducibility of results, the following must be considered:

1. Sample preparation.
2. Position of placing the probe in the samples.
3. Temperature to be maintained during raft preparation and testing.

