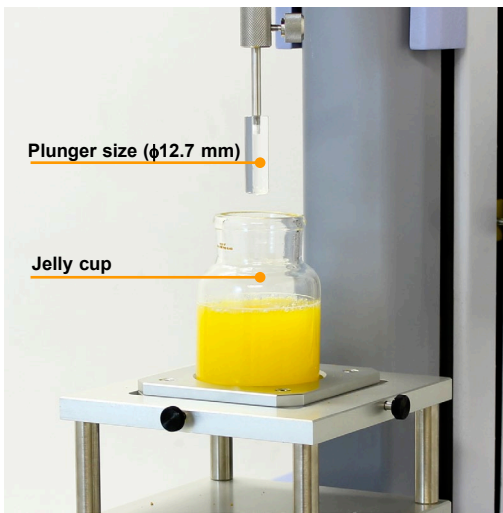


Evaluation of Jelly Strength (Bloom Value)

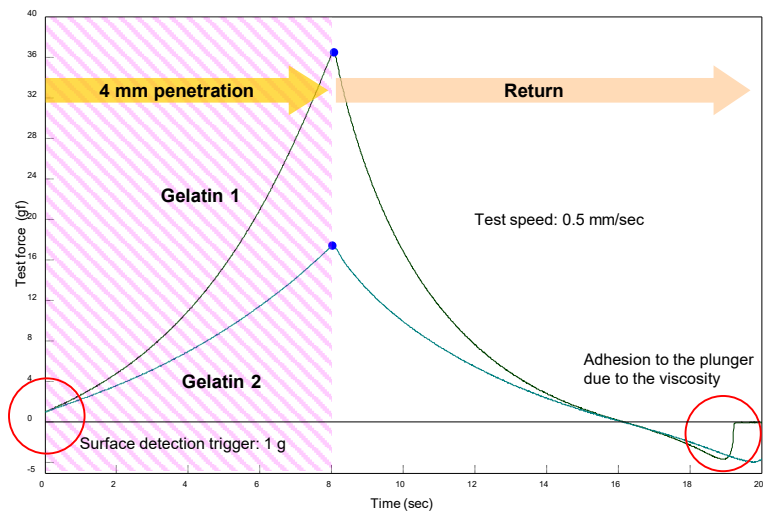
Pharmaceutical and Medical Evaluations

On May 31, 2013, the Japanese Pharmacopeia was partially revised to reflect changes enacted by the issuance of PFSB (Pharmaceutical and Food Safety Bureau) Notification 0531 No. 3. This notification designates the testing procedure for finding the jelly strength (bloom value) of gelatins, and requires gelatin evaluation tests using texture analyzers. An example of a jelly strength test with the procedure as prescribed by the Pharmacopeia is described below. JIS K6503 also prescribes jelly strength tests, in which case the same type of test jigs can be used.

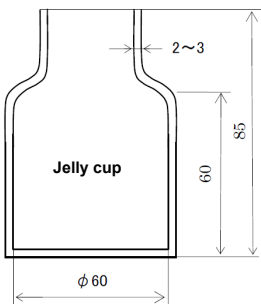
IQ/OQ validation is also supported. Contact Shimadzu for further details.



Jelly Strength Evaluation Test Jig



Example of a Jelly Strength Test Evaluation



- Test speed: 0.5 mm/sec
- Stroke displacement: 4 mm
- Test control: 1 cycle
- Surface detection (elongation origin): 1 g
- Load cell: 10 N
- Jig: Jelly strength evaluation test set
- Test temperature: 10 °C
- Software: Texture

	Max. Test Force (g)	Jelly Strength (g) 80% to 120% of Max. Test Force
Gelatin 1	36.5	29.2 to 43.8
Gelatin 2	17.4	14.0 to 20.9

The trigger test force for detection of the gelatin surface by the plunger was set at 1 g, and an accurate penetration distance of 4 mm from the detected surface was applied. It is also possible to evaluate the viscosity when the plunger separates from the jelly surface.

Jelly Strength (Bloom Value)

Note: Extract from the Japanese Pharmacopeia (translated), partially abbreviated

Determine the load (g) necessary to produce the force which, applied to a plunger 12.7 mm in diameter, makes a depression 4 mm deep in a jelly surface at 10 °C.

(i) The equipment or apparatus is a texture analyzer or other physical measuring instrument with a cylindrical piston 12.7 ± 0.1 mm in diameter, with a plane pressure surface and a sharp bottom edge. The container (jelly cup) is 59 mm ± 1 mm in internal diameter and 85 mm high.

(ii) Place the gelatin in a jelly cup, add 105 mL of water, and allow to stand in a thermostatically controlled bath at 10.0 °C ± 0.1 °C. Then place the cup on the platform of the physical measuring instrument. Center the cup on the platform of the apparatus so that the tip of the plunger contacts the surface of the jelly as nearly at its midpoint as possible, and start the test with 4 mm penetration distance and 0.5 mm/second penetration speed. The jelly strength is 80 % to 120 % of the indicated value.

