

Suppositories

Background: Suppository Testing

Suppositories, which advantageously avoid the risk of digestion of the active drug in the gastrointestinal tract, are classified as either:

Hydrophilic: made from a water-soluble base such as polyethylene glycol, which dissolves in rectal or vaginal fluids.

Lipophilic: made from a greasy base such as cocoa butter, which melts at body temperature.

There is no single method of drug release testing suitable for all types of suppository formulations.



Suppository Testing

Test Apparatus & Method

The suppository is a more common and accepted dosage form in Europe than in the USA which may explain why references to specific test methods relating to suppositories and associated dosage forms are mainly confined to the European Pharmacopoeia.

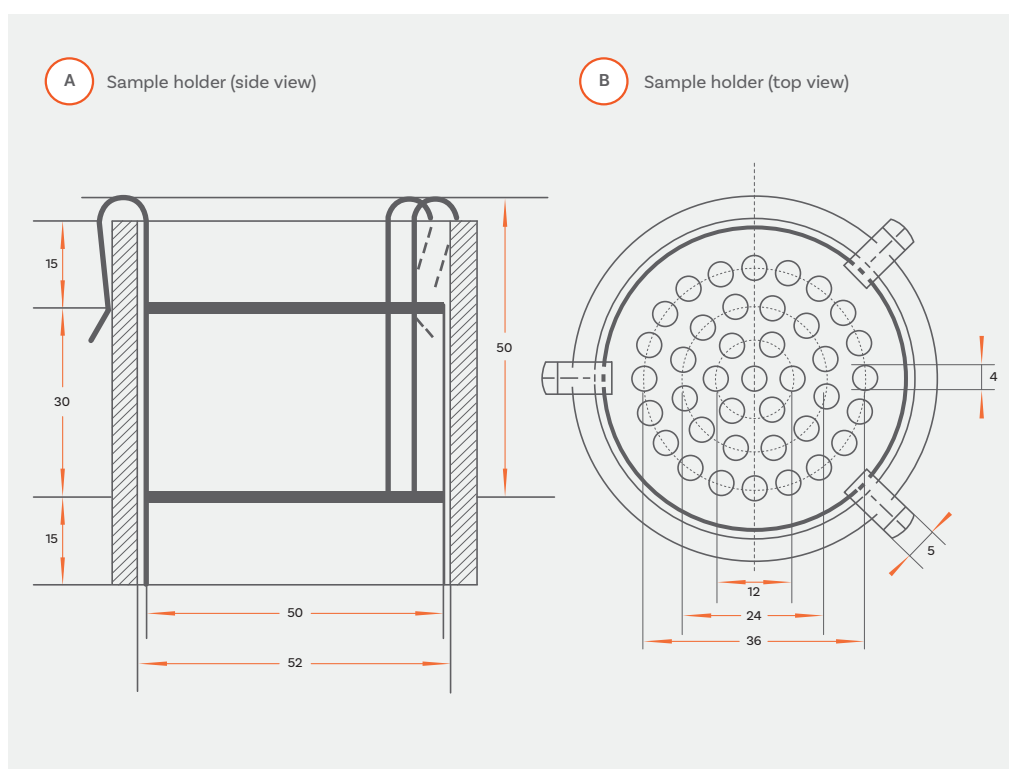
The rate of drug release (dissolution) for hydrophilic suppositories can be measured using the standard basket, paddle or flow through methods described in USP Chapter <711> and Ph. Eur. 2.9.3 (see Page 24-25). Methods for lipophilic suppositories include:

- a modified basket method (see Page 39)
- a paddle method (see Page 24)
- a modified flow method (see Ph. Eur. 2.9.42)

In addition to this, the European Pharmacopoeia references two other technical procedures relating to **disintegration** and **softening** time of suppositories:

2.9.2 Disintegration of suppositories and pessaries

2.9.22 Softening time determination of lipophilic suppositories



Suppository Tester: SDT 1000

Straightforward suppository testing

Designed in accordance with the specifications laid down in Ph. Eur. 2.9.2, the SDT 1000 is a single unit tester optimised for assessing the disintegration properties of suppositories and pessaries and with the appropriate attachment, for measuring the softening time of lipophilic suppositories (as per Ph. Eur. 2.9.22.-2).

The SDT 1000 has a simple design, which uses manual inversion controlled via a water-resistant pulley system. Test parameters including water bath temperature and stirrer speed are easily set using the touch key interfaces.



Ph. Eur. compliant



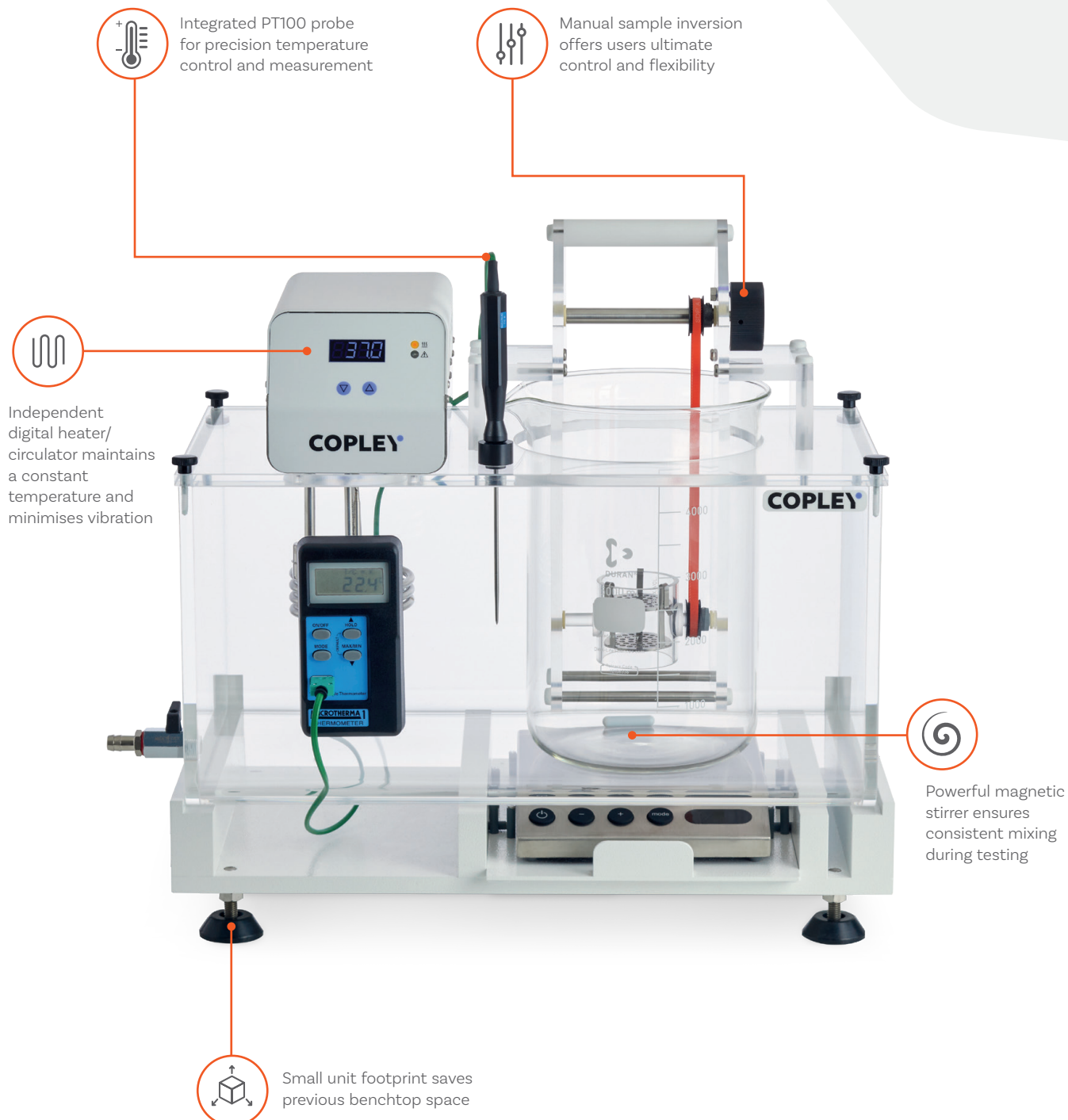
Easy-remove
components for
straightforward
cleaning



Single unit assesses
both disintegration
and softening time
(with necessary
attachments)

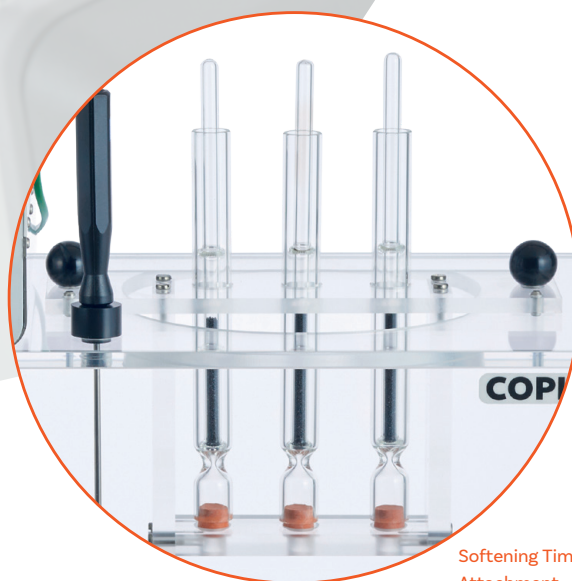


SDT 1000: Key Features



Softening Time Attachment

A special attachment is used in place of the disintegration test station, in combination with a 4-litre beaker containing three glass rods (C1) for measuring the softening time of lipophilic suppositories, in accordance with Ph. Eur. 2.9.22.-2.



Softening Time Attachment



SDT 1000

Cat. No.	Description
1704	Suppository Disintegration Tester SDT 1000
1705	Electro-Magnetic Stirrer for SDT 1000
1706	Softening Time Attachment (Ph. Eur. 2.9.22.-2)

SDT 1000: Technical Specifications

Pharmacopoeial Compliance	Ph. Eur. Test 2.9.2 Ph. Eur. 2.9.22.-2 (with suitable attachments)
User Interface	Touchpad buttons, LED display
Test Stations	Disintegration: 1 Softening Time: Up to 3
Temperature Range	Ambient - 50 °C
Sample Inversion	Manual
Stirrer Speed	80 - 2000 rpm (in 10 rpm intervals)
Unit Dimensions (w x d x h)	510 x 280 x 500 mm



SDT 1000 Accessories

Cat. No.	Description
1707	Qualification Tools
1712	Re-calibration of Qualification Tools
1708	IQ/OQ/PQ Documentation
1710	Digital Timer with Audible Alarm (including calibration)

Vaginal Tablet Tester (VTT)

Using the same sample holder as the SDT 1000 together with a low form beaker and heater/stirrer, Copley's VTT is a reliable, easy-to-use and compliant (Ph. Eur. 2.9.2) solution for assessing the disintegration properties of vaginal tablets.

Vaginal Tablet Tester

Cat. No.	Description
1800	Vaginal Tablet Tester (VTT)
1709	Glass Plate for use with Vaginal Tablets

