Suppositories

INTRODUCTION

Copley Philosophy			
Robust	✓	Reliable	✓
Easy to use	✓	Compliant	✓

The suppository is a more common and accepted dosage form in Europe than in the USA. This probably explains why pharmacopoeial references to specific test methods relating to suppositories and associated dosage forms, are in the main, confined to the European Pharmacopoeia.

With regard to **drug release (dissolution)**, various trials indicate that no single method of dissolution testing is suitable for all types and formulations of suppositories.

Hydrophilic suppositories are made from a water-souble base such as polyethylene glycol, which dissolves in the rectal or vaginal fluids. The rate of drug release (dissolution) of such 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 19).

Lipophilic suppositories, on the other hand, are made from a greasy base, such as cocoa butter, which melts at body temperature. Various methods have been described to measure the rate of drug release (dissolution) from lipophilic suppositories, including a modified basket method (see Page 28), a paddle method (see Page 32) and a modified flow cell method with dual chambers described in Ph.Eur. 2.9.42.

Normally the dissolution medium temperature employed should be at 37 degrees C, however with lipophilic suppositories, the test temperature may need to be raised to ensure that it is above the melting point of the suppository concerned.

In addition, the European Pharmacopeia 7th Edition makes reference to two other technical procedures relating to the **disintegration** and **softening time** of suppositories, namely:

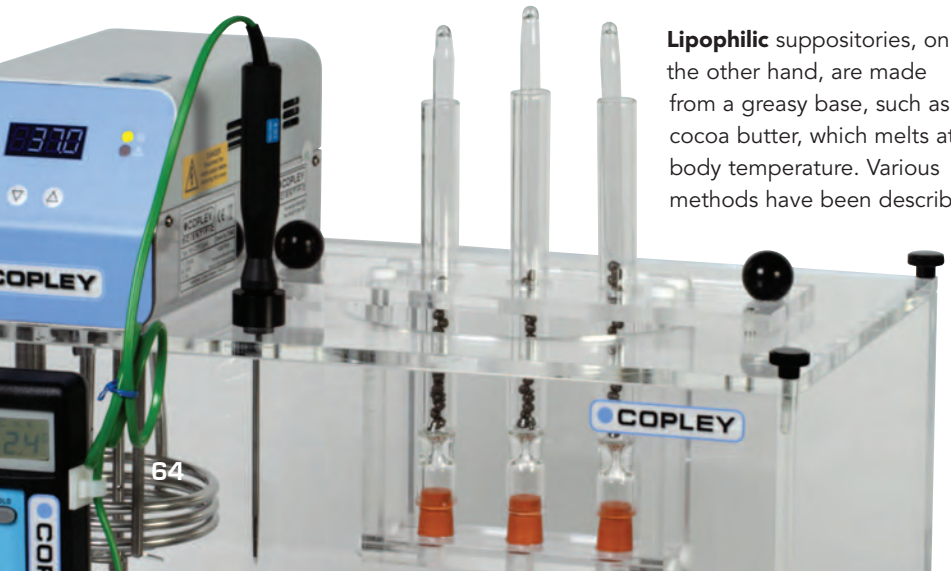
2.9.2 Disintegration of suppositories and pessaries

2.9.22 Softening time determination of lipophilic suppositories

This section describes the apparatus and test methods to be employed in measuring the disintegration of suppositories and pessaries and the softening time of lipophilic suppositories in these two sections.

▲ Digital Timer

Softening Time Attachment ▼



Removing the Test Station

Suppository Disintegration Tester Model SDT 1000

The Suppository Tester SDT 1000 is a single stage unit which has been designed in accordance with the specifications as laid down in the **Ph.Eur. Test 2.9.2 for the disintegration of suppositories, pessaries and vaginal tablets** and with suitable attachments **2.9.22.-2 Apparatus 2 for measuring the softening time of lipophilic suppositories.**

The **disintegration test station** is made up of a 60 mm long acrylic cylinder having an internal diameter of 52 mm into which is inserted the sample holder containing the sample under test. The sample holder comprises two stainless metal disks, 50 mm in diameter and containing 39 x 4 mm holes held 30 mm apart by three spring clips.

Consistent heating of the medium is achieved by immersing the test station into a 4 litre glass vessel contained within a plexiglass water bath. The temperature of the medium is controlled at 36-37 degrees C by an immersion thermostat and measured in the water bath using a PT100 probe connected to a digital display.

During operation, the black knob is rotated through half a turn at 10 minute intervals, which automatically inverts the sample holder through 180 degrees using a water resistant pulley system. The whole test station can be quickly removed from the beaker for cleaning.

Agitation of the test medium is achieved through an electro-magnetic stirrer which, located on a sliding drawer, sits beneath the water bath, directly below the centre of the test station.

The drawer can be withdrawn to allow the setting of the stirrer speed and then retracted during the test. The stirrer speed can be varied between 80 and 2000 rpm at 10 rpm intervals. The stirrer can be removed and used for other purposes if required.

MODE OF OPERATION

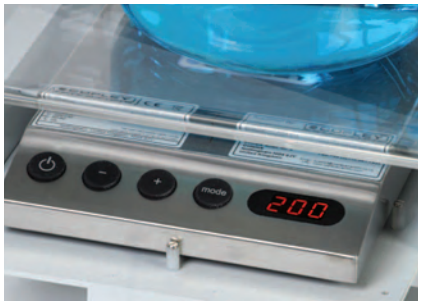
Preheat the test medium to 36-37 degrees C using the combination of the immersion thermostat provided and the slow speed stirrer (optional).

Place a **suppository** or **pessary** in the sample holder, place the latter in the perspex cylinder and secure. Run the test for the time prescribed in the appropriate monograph, inverting the apparatus every 10 minutes using the black knob provided for this purpose. Repeat the test for two more suppositories or pessaries - all samples should disintegrate within the stated time.

The tester can also be used for testing **vaginal tablets.** In this case, only the sample holder is employed. The test station used for suppositories and pessaries should therefore be removed. Place the sample holder on the base of the beaker and adjust the level of the test medium (preheated to 36-37 degrees C) such that it just covers the perforations on the upper plate. Place a tablet on the latter and cover with a suitable glass plate to maintain appropriate conditions of humidity. Repeat the test for two more tablets - all samples should disintegrate within the stated time.

A special attachment designed to be used in place of the disintegration test station and 4 litre beaker containing three glass rods (C1) is available for measuring the **softening time of lipophilic suppositories** (2.9.22.-2).

The unit measures 510 x 280 x 500 mm (w x d x h).



Cat. No.	Description
1704	Suppository Disintegration Tester SDT 1000
1705	Electro-Magnetic Stirrer for SDT 1000 (see photo left)
1706	Softening Time Attachment (Ph.Eur. 2.9.22.-2)
1709	Glass Plate for use with Vaginal Tablets
1708	IQ/OQ/PQ Documentation Pack
1710	Digital Timer with Audible Alarm (including calibration)