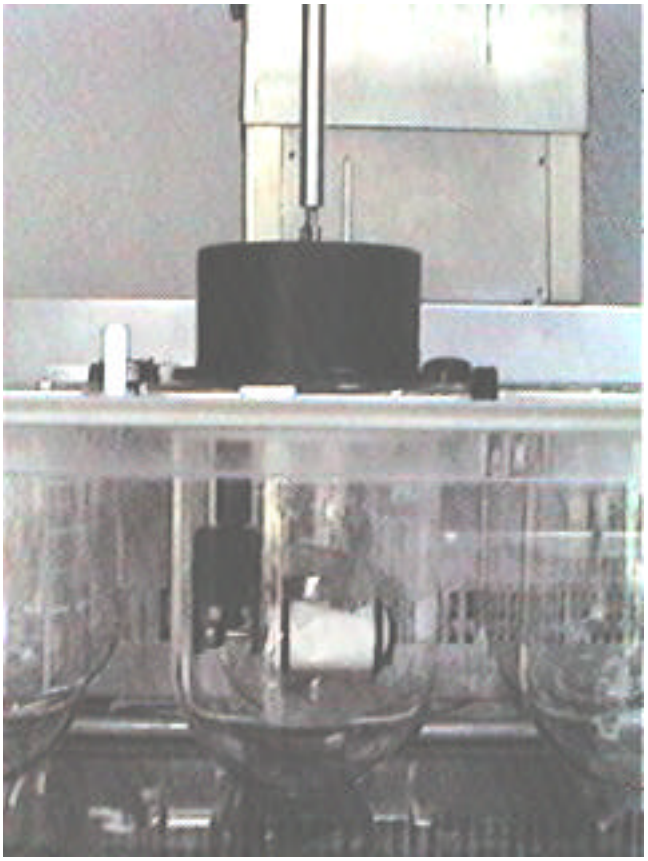
OPERATING MANUAL
Suppository Dialysis Cell
Typ: PTSW - 0



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1.0 General

Most of the international Pharmacopoeias mention today equipment, methods and monographs describing the Dissolution Test of hydrophilic carriers, such as tablets, capsules etc. Also some monographs exist which mention equipment and procedures to test lipophilic carriers, such as suppositories and ovals. Often those methods are difficult to handle due to the melted fatty mass, which creates problems in later analysis.

The PTSW 0 Dialysis Cell handles such kind of problems and offers a suitable solution to determine the active substance release of suppositories and oily suspensions.

The test is suitable for determining active substance release from suppositories, oily suspensions, and soft-gelatine capsules with oily carriers. See also the pulication by H.W. Dibbern and E. Wirbitzki, Pharm.Ind. 45:985-990, 1984 for application examples as well as the Report “Theophylline-Controlled Release Preprations and Fatty Food”, by Silvia K. El-Arini, Gerlad K. Shiu, and Jerome P. Skelly – Pharmaceutical Research Vol. 7, No. 11, 1990.

The following processes must run as a prerequisite for resorption in the case of suppositories or oily suspensions:

- emergence of the undissolved active substance from the liquid or melted fatty mass
- dissolution of the active substance particles dissolved from the fatty carrier in a relatively small volume of gastric juice or in rectal or vaginal secretion, and / or distribute of the particles dissolved in the fat against the above mentioned aqueous phase.

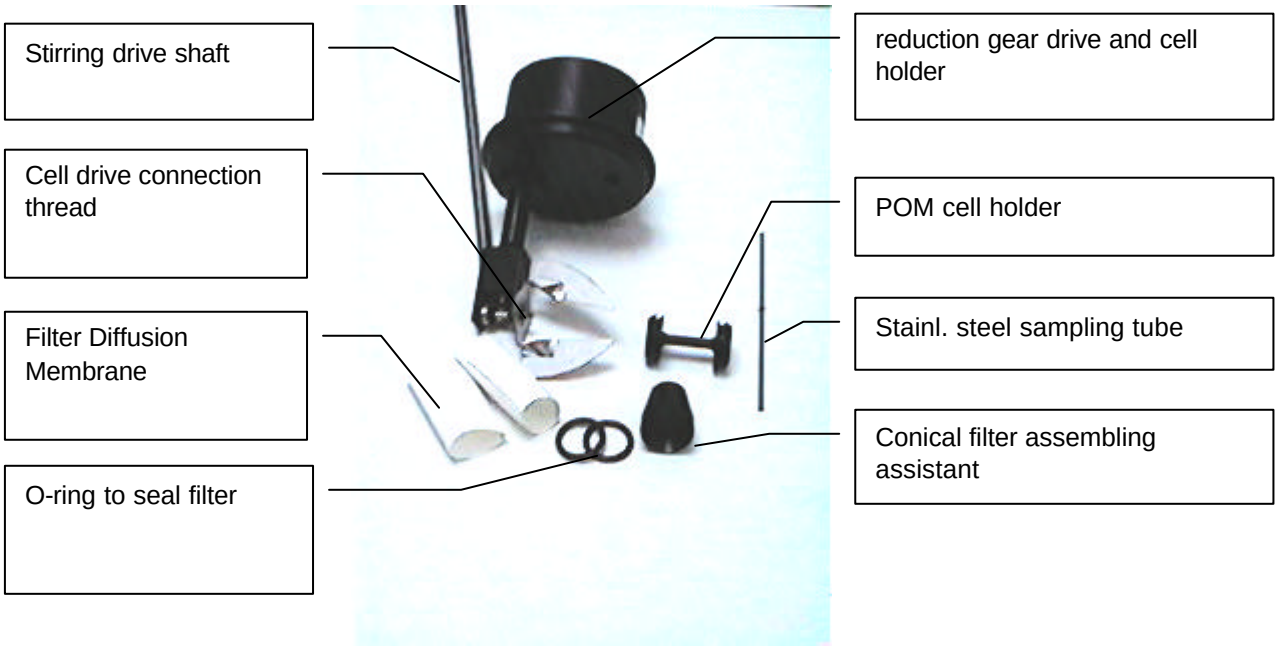
This passage from a liquid carrier into an aqueous phase required a sufficiently large and renewing interface, which is achieved in vivo by dispersion into the GI tract or in the rectum.

In the PTSW 0 apparatus the interface renewal is achieved by continuously circulating the liquid fatty phase in a cylinder rotating around the horizontally placed axis together with a small volume (up to about 5ml) of an aqueous phase. A rapid and in the presence of a suitable distribution coefficient also an almost complete substance transfer from fat to water is thereby made possible. A dialysis tube or hydrophilic membrane filter i used as a cylinder wall. These membranes prevent the emergence of fat droplets from the inner phase. The rotating cell is immersed in an outside aqueous phase of greater volume (up to about 1000 ml), the use of a USP/EP round bottom glass vessel is recommended. The active substance at first dissolved in the aqueous phase in the cell interior migrates to the outer phase because of the existing concentration gradient and can be determined in it in stages at desired time intervals of continously if desired.

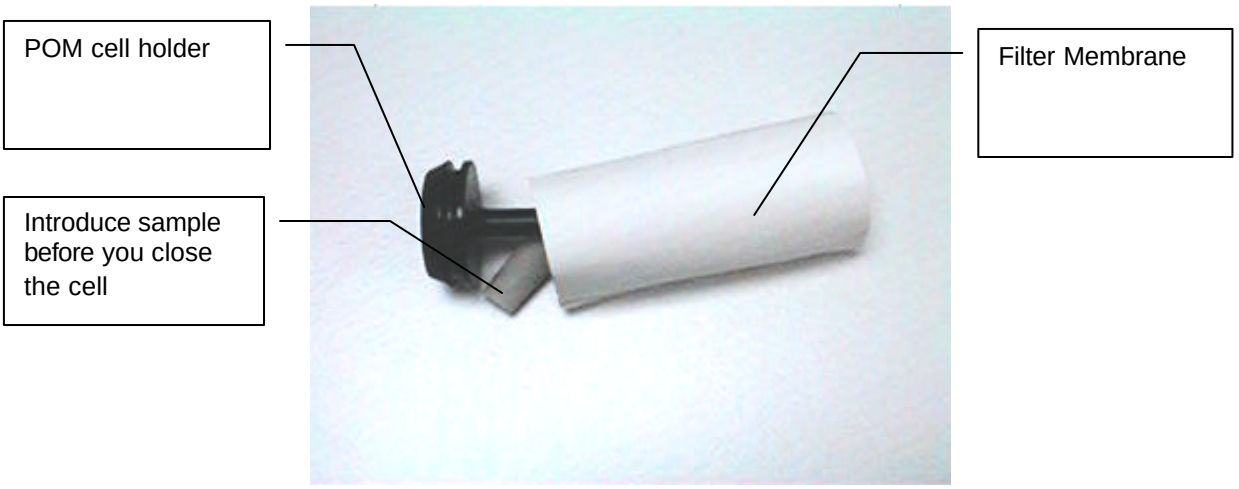
2.0 Cell Assembly

The PTSW 0 cell is made from:

- 1 reduction gear drive incorporating the cell holder
- 1 POM cell
- 2 O-ring
- 1 conical filter assembling assistant
- 1 stainl. steel sampling tube



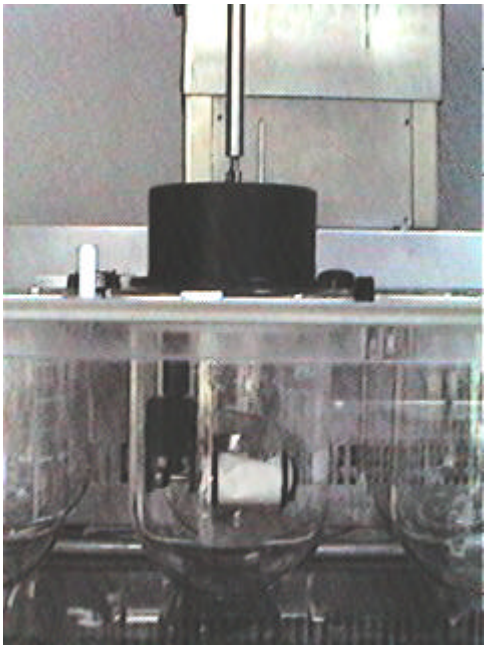
Place the cell onto your bench. Use the conical filter assembly assistant and push the filter tube carefully onto the cell. Allow some space to introduce the sample into the cell before you close the cell completely. Close and seal the cell by means of the supplied O-ring. One is placed from to each side of the cell and remains in the U-gap inside the cell. Use the conical assembly assistant for easier introduction.



Screw the POM cell onto the cell holder and tighten carefully (by hand only, do not use any tools).

2.1 Introduce the Cell into a Dissolution Vessel

Fill up a dissolution vessel and pre-heat the water to 37°C ± 1°C. When the temperature inside the vessel is equilibrated introduce the complete PTSW 0 cell into the vessel. Pull the drive shaft through the drive assembly of the dissolution bath you use and tighten it. Adjust the speed of the drive unit, remember the gear drive of the PTSW 0 steps the seed in a ration 4:1.



Use the supplied sampling tube, which allows the sampling inside the outer phase using either a peristaltic pump or a pipette.
instruments are switched off.

2.2 Membrane

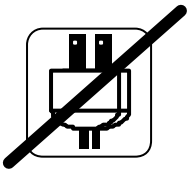
The membrane to be used depends on the application, also see the above mentioned literature. Often the cylinder has to be manually made using welding apparatus also used to seal PP bags. We recommend the use of a 0.45 µ Millipore Filter Sheet KVP.

3.0 Maintenance and Cleaning

All Plexiglas parts should be cleaned daily. Please do not use and detergent containing alcohol, methanol or similar, this will destroy the Plexiglas. Use a soft towel and warm water only.

Usually the filter is a one way type and has to be replaced by a new one for a consequent test.

Clean the s.s. part using cleaning oil, which has been included with the shipment. The oil is in compliance with the German Pharmacopoeia monograph DAB 7.



The instrument does not include any other parts which the user can maintain or repair. Repair works should be done by authorised service agents only.

In case the instrument cannot be operated anymore without the possibility to damage or harm anybody it has to be stopped from operation immediately. This is valid always when:

- The instrument mains cable or socket shows visible damages
- The instrument shows visible damages or does not work
- Any cable shows visible damages