RIGGTEK
Dissolution Test Systems

IMMERSION CELL
SHORT INSTRUCTION

This short instruction is no replacement for the guidelines in any Pharmacopeia and is just for the first introduction to the immersion cell use.

Design

Another alternative to the Vertical Diffusion or Franz Cell for testing semisolids is the Immersion Cell.

The **Immersion Cell** is used with the conventional USP Apparatus 2.

The PTFE Immersion Cell is designed to accommodate a 25 mm diameter membrane. It comprises four main parts:

1. A retaining ring which secures the membrane to the cell body
2. A washer which holds the membrane in contact with the sample
3. The membrane or skin
4. The cell body which contains the compartment in which the sample to be tested is placed

The cell is also provided with an alignment tool and an adjustment tool that allows the user to vary the volume of the reservoir within the cell.

The Immersion Cell is used with a special flat bottomed version of the **200 mL Small Volume Conversion Kit** (*special shaft, paddle, vessel*) in order to avoid the issue of dead space under the cell, were a round bottomed vessel to be used.

Sample Preparation

Replace the conventional 1000 mL Vessels on the Dissolution Tester with the 200 mL Small Volume equivalents, adjust the height of the mini-paddles to 25 mm above the surface of the membrane and the temperature to 32 +/- 0.5 degrees C (37 +/- 0.5 degrees C in the case of vaginal preparations).

Adjust the reservoir of the cell body to the volume required using the Adjustment Tool provided for this purpose.

Now fill the reservoir with the sample under test, removing any excess with the aid of a spatula.

Finally, place the artificial membrane (or excised skin) over the top of the sample with the membrane or visceral side of the dermis (the underneath of the skin sample) facing upwards, such that when the cell is placed in the vessel this side is bathed with receptor medium and secure it with the washer and retaining ring.

Note: the membrane should be thoroughly wetted with a suitable wetting agent prior to use unless Strat-M membranes which do not require wetting are employed.

Running a Test

Place the assembled cell into the bottom of the vessel with the membrane facing up.

Add the appropriate amount of preheated and degassed dissolution medium (see Page 35) and start the test.

Normally, no fewer than 6 samples are taken over a 6 hour period, say, 0.5, 1, 2, 4, 5 and 6 hours and analysed using HPLC or similar analytical technique. The results are expressed as the amount of drug released per unit membrane area (mcg/cm^2) vs square root of time (minutes) which should yield a straight line. The slope of the line (regression) represents the release rate of the product.

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