# 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 alternativ to the Vertical Diffusion or Fran 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 25mm diameter membrane.
There are two different types available, which are described in the Pharmacopeia. Model A with an adjustable reservoir for the semisolids and Model B, which has no adjustable compartment, but is less high.
The Immersion Cell is best used with a special 200ml flat bottomed vessel, used in a Small Volume Conversion Kit with Mini-Paddles 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 100ml Vessels on the Dissilio with the special 200ml Small Volume Vessels, adjust the height of the mini-paddles to 1+/- 0,2cm above the surface of the membrane and the temperature to 32,0 +/-0,5°C or 37,0 +/- 0,5°C in the case of vafinal preparations.
For Model A adjust the reservoir to the volume required using the Adjustment Tool provided. 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 samle with the membrane or visceral side of 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.
For Model B see assembly instructions in the next slides.
Note: the membrane should be thouroughly wetted with a suitable wetting agent prior t use unless Strat-M membranes which do not require wetting.

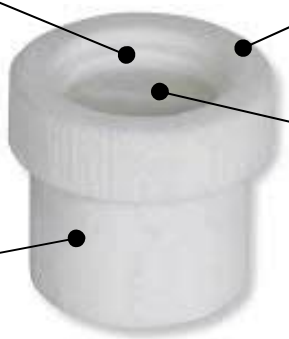
## Running a Test

Place the assembled immersion cell into the bottom of the vessel with the membrane facing up. Use the Installation Rod for Model B.
Add the appropriate amount of preheated and degassed dissolution medium and start the test.
Normally, no fewer than 6 samples are taken over a 6 hour period - for example 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/cm³) 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.

# Immersion Cell Model A

assembly *

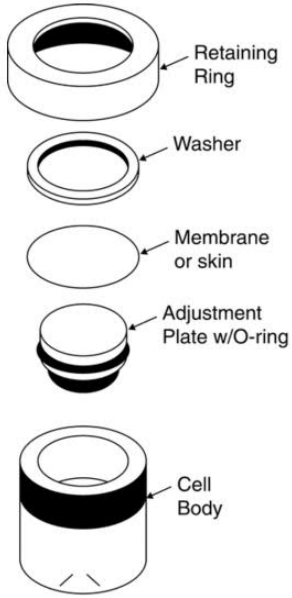
Washer for fixing the membrane;
Washer with defined opening size is included in the assembly



Lock / Retaining Ring

Membrane or Skin

Cell Body with adjustable reservoir

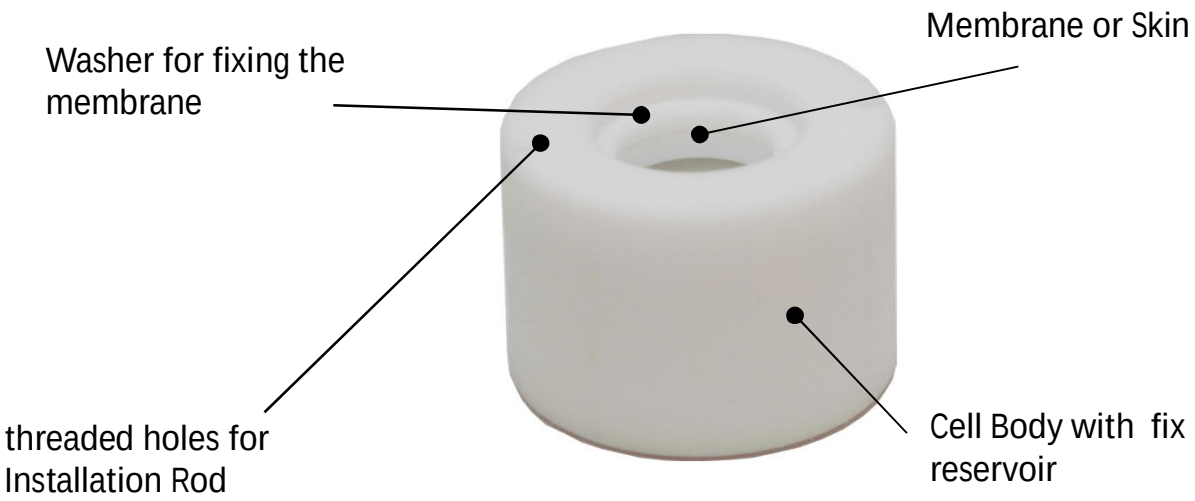


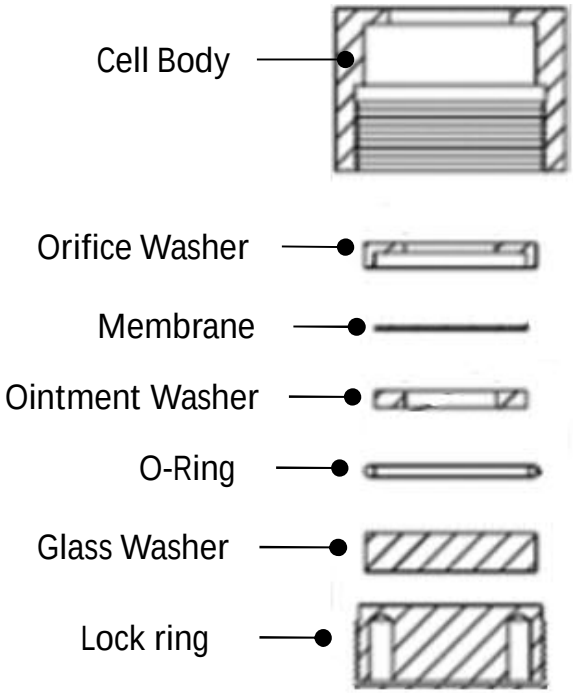

Adjustment Tool

Washers with different opening sizes and their Alignement Tools

# Immersion Cell Model B

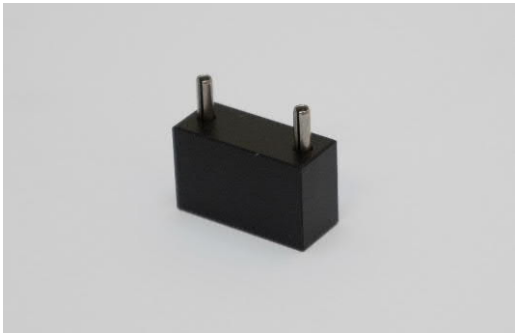
assembly *




Support Tool

Hand Tool



Installation Rod

# Immersion Cell Model B

assembly *

1. Orient the Cell Body upside down, so that the larger opening is faced up.
2. Place the Cell Body on the support tool.
3. Place the orifice washer on the support tool, so that it rests on the top part of the post.
4. Place the membrane in orifice washer.
5. Pleace the ointment washer on top of the orifice washer. The two washers should fit together to hold the membrane in place. Squeeze these together, making sure to keep membrane wrinkles to a minimum.
6. Apply dose to the membrane, inside the circular area in the middle of the ointment washer. Spread the dose to evenly fill the dosage area.
7. Place the O-ring over the washers.
8. Place the glass washer on top of the ointment washer and O-ring.
9. Lift the Cell Body and keep slight pressure on the glass washer.
10. The washers will move to the bottom of the Cell Body. Lift the whole assembly off the support tool and push down gently on the glass washer to ensure the assembly sits at the bottom of the support ring.
11. Close the Cell Body with the Lock Ring using the Hand Tool.

Use the Installation Rod to gently place the Immersion Cell into the Vessel.