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Enhancer Cell Assembly Operator's Manual

P/N 70-9027
November 2010
Revision G

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Chapter 1 Introduction

The Enhancer Cell Assembly, designed for research, quality control, and product development laboratories, is a Teflon cell with adjustable volume and a screw cap to retain the skin or artificial membrane. The assembly can be used with any dissolution tester and is available with 4.0, 2.0, or 0.5 cm^2 surface area. Using the Paddle-over-Enhancer-Cell method (see Figure 3, “Paddle over Enhancer Cell,” on page 9) provides release rates comparable to Franz Cell technology. It provides release rate data for quality control of topicals using readily available dissolution apparatus, including 200 mL or standard 900 mL dissolution vessels.

The alignment tool (see Figure 1, “Enhancer Cell Assembly,” on page 8) is used to hold the membrane in place and ensure the washer is centered properly while using the adjustment tool to set the volume with the adjustment plate. When purchasing more than one Enhancer Cell Assembly, one alignment tool is required per size. The adjustment tool is universal and fits all sizes. Both the alignment tool and the adjustment tool are required and must be ordered separately. The Enhancer Cell Assembly does not include the vessel, paddle, or membrane / skin.

FIGURE 1. Enhancer Cell Assembly

*not provided—for illustrative purposes only.

FIGURE 2. Enhancer Cell Assembly Surface Areas

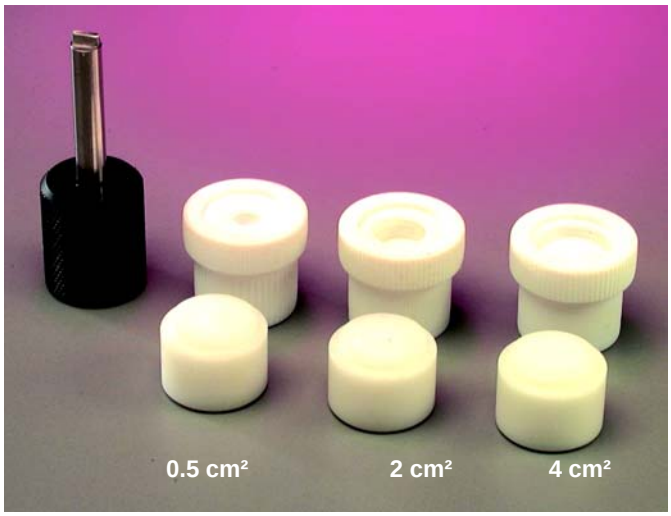


FIGURE 3. Paddle over Enhancer Cell

Assembly Components

The Enhancer Cell Assembly consists of the following components (see Figure 1, "Enhancer Cell Assembly," on page 8):

- Retaining ring – secures the membrane or skin sample to the cell body and ensures full contact with the sample.
- Washer – provides a leak-proof seal between the membrane, retaining ring, and cell body.
- Membrane (not provided) – retains the sample in the sample compartment. Usually an artificial membrane although some tests use skin samples.
- Adjustment plate – allows control of the volume of the reservoir within the cell body. This threaded part can be placed at the appropriate height for each test and can be completely removed for easy cleaning. A Viton O-ring prevents leakage.
- Cell body – provides a variable depth reservoir for the sample (semisolid, solution, suspension, or emulsion) being tested.

Two additional tools are required to properly use the Enhancer Cell Assembly and must be ordered separately:

- Adjustment tool – to move the adjustment plate.
- Alignment tool – to ensure the membrane is in proper contact with the sample and the washer is properly centered.

This product is warranted to be free from manufacturing defects at the time of delivery. Please report any problems upon receipt of merchandise to Dissolution Systems Customer Service at 800.229.1108 (inside the US) or 919.677.1108 (outside the US).

Unpacking Your Enhancer Cell Assembly

Step 1. Carefully remove the Enhancer Cell Assembly.

Step 2. Ensure all of the following items were shipped with your Enhancer Cell:

- *Enhancer Cell Assembly Operator's Manual*
- Retaining ring
- Washer
- Adjustment plate with O-ring
- Cell body

Included if purchased separately:

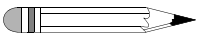
- Adjustment tool
- Alignment tool

If any item is damaged or missing, contact the Dissolution Systems Service Department or your local Varian representative for replacements.

Chapter 2 Operation

To use the Enhancer Cell Assembly, follow these steps:

Note



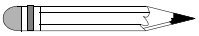
Always use care when disassembling, assembling or tightening any part of the Enhancer Cell Assembly. The Teflon parts are delicate and could be damaged by extreme force.

Step 1. Using empty dissolution vessels and empty Enhancer Cell Assemblies, set the appropriate paddle height. The recommended distance from the top of the cell to the bottom of the paddle is 25 mm.

Step 2. Ensure the Viton O-ring is in place on the adjustment plate.

Step 3. Insert the adjustment plate into the cell body. Ensure the slot on the bottom of the adjustment plate is oriented toward the bottom of the cell body.

Step 4. Using the adjustment tool, carefully screw the adjustment plate into the cell body until the reservoir formed at the top is the approximate volume necessary for the test.



Note

Use only the special adjustment tool designed for use with the adjustment plate. Using another type of tool or screwdriver may damage the adjustment plate.

Step 5. Fill the reservoir with the sample to be tested. Ensure the reservoir is filled to the top in order to minimize the possibility of an air bubble forming between the sample surface and the underside of the membrane. For semisolids, a uniform surface can be obtained with the aid of a laboratory spatula.

Step 6. Place the membrane over the top of the sample compartment. It should be large enough that the edges overlap the top of the cell body (between 2.5 and 2.8 cm). Ensure the membrane is free of wrinkles (which can occur if the membrane is too large).

Step 7. Place the washer on top of the membrane, positioning it over the top edge of the cell body. Place the retaining ring onto the cell body and *carefully* screw it on the body until it just touches the washer*. Do not fully tighten at this point.*

Step 8. Carefully insert the end of the alignment tool with the indented edges into the retaining ring until it is level and evenly seated. This process ensures the washer is properly centered and presses the membrane tight against the sample in the reservoir to prevent bubbles.

Step 9. With the alignment tool still in place, insert the adjustment tool in the adjustment plate. Tighten the retaining ring until it is hand tight while giving a slight clockwise turn with the adjustment tool. Remove the alignment and adjustment tools.

Step 10. Carefully place the completed assembly into the bottom of the dissolution vessel, with the membrane facing up. Add the appropriate preheated medium and begin the test.

Membrane Selection Information for the Enhancer Cell

Ideal Characteristics for a Membrane

Minimize resistance to drug transport

- High porosity
- Minimal thickness
- No drug binding

Examples of Membranes Used for In Vitro Release Tests

- Regenerated cellulose (Dialysis membrane)
- Silastic membrane - polydimethyl siloxane
- Fluoropore FHLP hydrophobic membrane
- Ethylene vinyl acetate (Cotrans 9702)
- Skin (human, rat, rabbit, porcine, mouse)
- Cuprophan
- Carbosil
- Polysulfone

Sources for Membranes

3-M Drug Delivery Systems
3M Center, Building 275-3E-10
St. Paul, MN 55144-1000
USA 1.800.643.8086

GE Osmonics
5951 Clearwater Drive
Minnetonka, MN 55343-899
USA 1.952.933.2277

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