PERMEGEAR

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H1C Side-Bi-Side Manual Diffusion System

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Introduction

Description

PermeGear's H1C Side-Bi-Side Manual Diffusion System is an apparatus employing a Side-Bi-Side Cell for carrying out testing that enables a researcher to measure the release or permeation of a compound into or through membranes. They are currently in laboratories around the world and used for everything from measuring the migration of molecules through biological membranes to an instrument of measurement in the development of fuel cells. To best mimic *in vivo* conditions, permeation experiments are typically done at near normal body temperature. Therefore, the fluid inside the chambers of a Side-Bi-Side cell is heated and stirred.

Components

PermeGear's H1 Side-Bi-Side Cell Manual Diffusion System includes one Side-Bi-Side Cell, an H1C Stirrer, and a heater/circulator. Each cell half is surrounded by a "jacket" through which heated water is circulated. A cell clamp securely locates the Side-Bi-Side Cell directly above individual stirrers. H1C Stirrers provide easy access for connecting the jackets to a heater/circulator (not shown in the photo below). PermeGear provides heater/circulators, but often these are already available in the users' labs.

Figure 1 - An H1C magnetic stirrer, Side-Bi-Side Cell, and Cell Clamp

Setting up a PermeGear H1C Side-Bi-Side Manual Diffusion System

1 Connect the stirrer to the heater circulator

Install the stirrer on a level surface. Place the Side-Bi-Side Cell into the Cell Clamp supplied with the stirrer. Connect the output tube from the heater circulator to the upper jacket opening on one of the Side-Bi-Side Cell halves. Connect the return tube of the heater/circulator to the upper opening of the other half of the Side-Bi-Side Cell. Finally connect the remaining jacket openings with a third tube. An additional H1C Stirrer can be connected with a pair of Y-connectors and additional tubing. If you wish you can use Quik-Disconnect® fittings which must be purchased from your supplier separately. In either case the cell needs to be removed from the stirrer from time to time for cleaning.

Figure 2 shows all components of a Side-Bi-Side Cell as well as a Cell Clamp. The two white ring Teflon® foam gaskets can be used to prevent leakage between the cell halves and the membrane, if necessary.

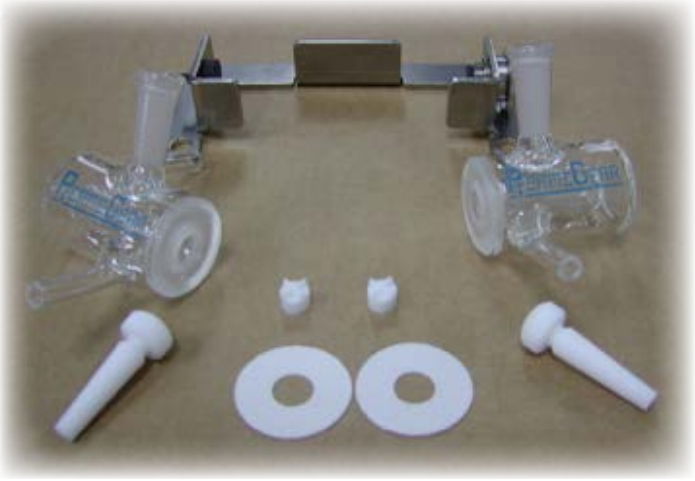

Figure 2 - Components of a Side-Bi-Side Cell

Preparing the PermeGear H1C Side-Bi-Side Manual Diffusion System for use

2 Cleaning Side-Bi-Side Cell

Prior to using the cell, clean the stirbars and stoppers shown by rinsing them with methanol (MeOH) first and then deionized water several times. Let them dry. Fill both chambers with methanol. Then use a disposable plastic pipette to suck and release methanol from the chamber several times to clean both chambers as well as the contact surfaces of the chambers and the sampling ports. Replace methanol with deionized water. Repeat the previous cleaning step. Finally dry the chambers of each cell in the air before use. Repeat the cleaning procedures after use.

Figure 3, Side-Bi-Side Cell

3 IVPT Diffusion Testing

Before testing, the following should be determined based on the project: The composition and concentration of the donor solution, composition of receptor fluid, type of membrane (polymeric or skin), temperature of the receptor fluid, sampling volume, and sampling time points.

Prior to starting, set the temperature of the water bath/circulator to a predetermined value and place a stir bar into both sides of the cell. Place a membrane between the two chambers and clamp the chambers together. If necessary, place Teflon® foam gaskets between the chambers and membrane. Designate one side as the receptor chamber and begin filling with receptor fluid while tilting the clamped cell up to force any bubbles out. Likewise, fill the donor chamber with donor solution. Insert the chamber stoppers and turn on the stirrers.

At each predetermined sampling time, remove the stopper from the sampling port. Withdraw a volume of sample specified in the test protocol by inserting a suitable pipette or syringe needle into the sampling port so that the sample will be removed from the middle of the chamber. The same amount of fresh fluid is refilled into the cell through the sampling port and the stopper is reinserted into the sampling port.

If possible, limit the sample to a volume that avoids introducing bubbles. If bubbles are created during the sampling process, carefully tilt the cell holder up until the bubbles move out to the sample port.

In some applications, the donor chamber may be sampled as well. Follow the same procedure as for sampling the receptor chamber.

4 Q&A

a - Can Side-Bi-Side cells be autoclaved? YES. They can be sterilized in an autoclave.

b - Can I use the mobile phase for the HPLC analysis as the receptor chamber's fluid? YES. In general, you can use any solvent for the receptor chamber's medium as long as the solvent provides "sink" conditions for the test compound. Generally, sink conditions are such that the concentration of the compound remains below 10% of the compound's solubility in the receptor chamber's medium. This ensures the permeation or release profile is not rate-limited by the compound's solubility in the receptor chamber fluid. The effect organic solvents have on the membrane should also be considered.

c - How do I select a membrane for In Vitro release testing? According to the "FDA Guidance for Industry: Nonsterile Semisolid Dosage Forms: Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation, May 1997, SUPAC-SS CMC 7", any "appropriate inert and commercially available synthetic membranes such as polysulfone, cellulose acetate/nitrate mixed ester, or polytetrafluoroethylene membrane can be used." Hydrophilic polymeric membranes with a pore size of .45µm are widely used. After determining a suitable membrane during the IVRT method development phase, the same membrane should be used for the duration of the project.

d - How do I decide how much sample volume to remove, i.e. the entire receptor volume or a couple of hundred microliters? If the study has only one time point, the entire receptor chamber's volume can be sampled out. If sampling more than one time point, any size aliquot is acceptable as long as no air bubbles are introduced at the junction of the cell halves. All of a chamber's fluid may be removed from the chamber, if necessary, but full replacement necessitates having to lift each clamped cell from the H-Series Stirrer to refill the chamber. Sample volume considerations include the maximum volume that can be removed without introducing bubles and the minimum volume required for sample analysis.

Your System Includes:

1. An H1C Stirrer

2. A Side-Bi-Side Cell

3. A Cell Clamp

4. The appropriate power cord

5. A roll of 3/16” ID soft silicone tubing, that the user will use to connect the cell to the manifolds.

6. A Manual with assembly instructions, operation, proper care and cleaning and frequently asked questions/answers.

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