Topical and Transdermal Diffusion Cell Systems

FEATURING THE HANSON MICROETTEPLUS™

LEADERSHIP IN DISSOLUTION TECHNOLOGY
50 YEARS

Hanson Research

The Hanson MicroettePlus™ Autosampler

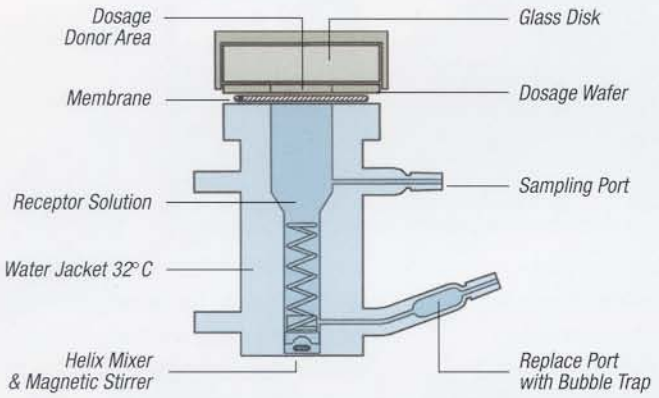
In vitro drug diffusion testing of the transfer rate across a membrane is a technology used for the study of skin transfer kinetics and to establish batch-to-batch uniformity of topical preparations. The procedure employs a diffusion cell that separates a donor compartment from a receptor compartment with a specified membrane. Complete turn-key systems for diffusion cell testing are available from Hanson Research.

The MicroettePlus™ system provides automatic sampling from diffusion cells and collection into HPLC vials for sample analysis. The system automates sampling protocols from groups of six diffusion cells for extensive un-attended tests, and handles surfactants, saline and hydroalcoholic receptor solutions.

The new MicroettePlus incorporates Hanson AutoPlus™ technology, including precision 6-channel syringe pump, Teflon™ valves and sample tubing, Easy-Icon™ programming with graphical display, convenient pop-up menus and help screens, up to 25 test protocols, 21CFR11 compliant firmware, "smart switch" for system communications, automatic media replace at time of sampling, programmable cell dilutions, jacketed media replace beaker, and supply kit. A choice of Hanson precision vertical diffusion cells, 6-cell drive system with stainless stand, MultiFill™ collector with interchangeable HPLC vial racks, validation printer, and heater circulating bath round out the complete system package.

The Vertical Diffusion Cell

The vertical diffusion cell, first popularized by Dr. Thomas Franz, has been applied to a number of skin permeation studies, including topical and transdermal drug delivery formulations, as well as opthalmics, cosmetics, skin care products and pesticides. The vertical diffusion cell system is an ideal tool for quality control of topical preparations (see FDA guideline SUPAC SS). The Hanson vertical diffusion cell is newly redesigned for accuracy and ease of use, based on over fifteen years of rigorous industry, university and regulatory application.

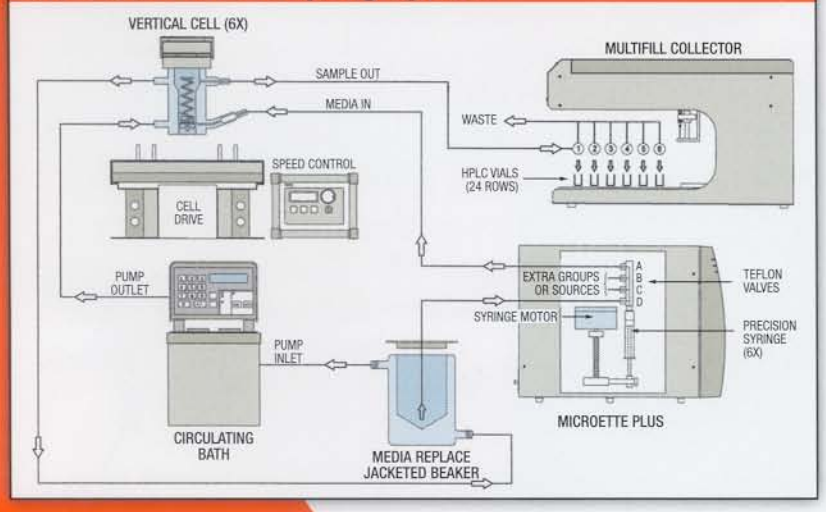


Precision glass cell assemblies include receptor chamber, donor chamber with easy-use clamp, dosage wafer (300 mg "infinite dose" or other volumes available), sampling and media replace ports, outside jacket for temperature control, and Helix™ stirrer. Cells may be manually sampled, or automated with the MicroettePlus. Cells are designed to be "occluded" (sealing the donor from air) to minimize any back-diffusion from automated sampling. Cells include individual serial numbers, and are available in three convenient sizes.

How the System Works

1. The diagram illustrates sampling from one diffusion cell. The MicroettePlus system simultaneously samples and collects from groups of six cells.
2. The system is set up by filling each diffusion cell with heated deaerated receptor solution from the media beaker. A measured volume and thickness of drug formulation is then placed on the membrane in the cell donor chamber to start the test.
3. The MicroettePlus saves up to 25 protocols for sampling volumes and time points, including advanced routines for cell dilution and other requirements. A given protocol is activated to initiate the start.
4. On program command, the Helix stirrer stops, and a selected aliquot of fresh replacement media is injected from the precision syringe pump into the capillary media replace port of the receptor cell. This forces an exact equal amount from the cell to be extracted through the sample port to the collector.
5. Sample aliquots are collected and archived in sealed-septum HPLC vials in the MultiFill collector. When each sampling point is complete, the Helix stirrer starts again to restore homogeneity.
6. A rinse cycle just before each sampling cycle ejects contents of the sample tube to waste. This cleans the sample lines prior to sampling and collection.
7. This sampling and collection sequence continues for each programmed time point until the end of the test. The validation printer provides an on-going status report of all test operating conditions.
8. The use of advanced "scripting" allows for special protocol routines, including cell dilution at selected time points.
9. Throughout the test, the heater circulating bath maintains controlled temperature in the media replacement beaker and each diffusion cell (typically 32°C for skin permeation studies).
10. Collected samples archived in interchangeable racks may be removed at the convenience of the scientist for HPLC and other method analysis.

MicroettePlus Sampling System



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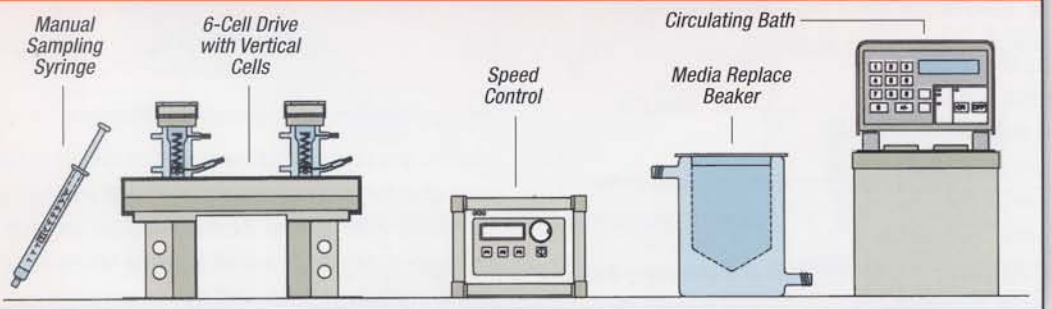
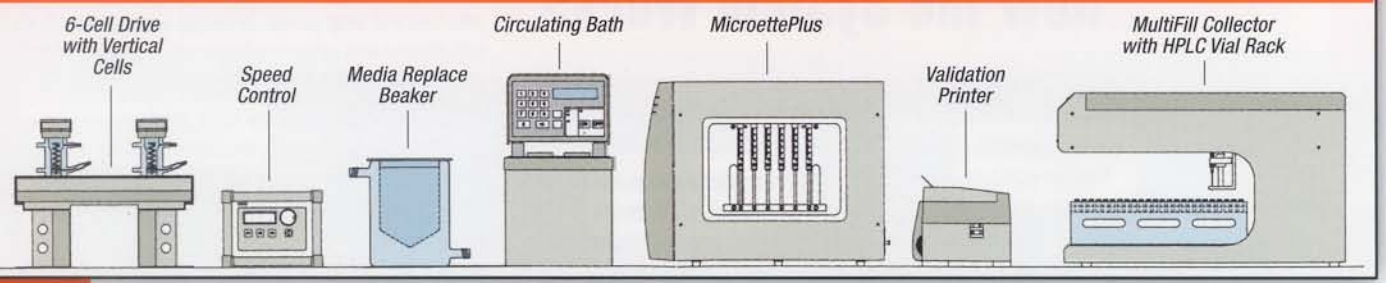
System Configurations

Manual Start-up System



The Manual Start-Up System provides everything you need for drug percutaneous diffusion cell experiments with manual sampling. The system package includes six complete diffusion cell assemblies, 6-cell drive with programmable control, stainless stand and manual sampling syringe. The jacketed beaker pre-heats replacement media, and the optional circulating bath delivers precision temperature control for the system.

MicroettePlus System



The MicroettePlus System provides full automation for unattended sampling and collection protocols. With an easy connection to the Start-Up System, the MicroettePlus automatically samples from groups of 6 cells, simultaneously replaces media, and archives samples in the MultiFill™ Collector. Extensive experimental routines are easily programmed and validated. The Validation Printer provides a hardcopy report of all test operating conditions.

Ordering Information

Hanson MicroettePlus™ technology provides everything required for automated percutaneous diffusion cell studies.

- Model 58-6A MicroettePlus™ autosampler
- Choice of vertical diffusion cells
  - ✓ "Small" 9 mm orifice & 4 mL volume
  - ✓ "Standard" 15mm orifice & 7 mL volume (recommended by FDA for SUPAC SS)
  - ✓ "Large" 15 mm orifice & 12 mL volume
- 6-Cell drive system with stainless stand
- MultiFill™ collector with HPLC vial racks
- Hanson Q-Pak™ validation guideline
- Optional validation printer
- Optional heater circulating bath
- Model 58-6M manual "start-up" system
  - ✓ Includes choice of vertical diffusion cells
  - ✓ MicroettePlus™ may be added later

I.S. EN ISO 9001

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