Test without Limits!

Overcome the barriers to predicting diffusion in human skin.

Merck Millipore is a Division of MERCK

Experience the Unmatched Predictability of Strat-M™ Membrane

This synthetic, non-animal based model* for transdermal diffusion testing is predictive of diffusion in human skin without lot-to-lot variability, safety and storage limitations.

Diffusion through Strat-M™ membrane is predictive of diffusion through human skin for a wide range of substances:

- Active pharmaceutical ingredients (API)
- Cosmetic actives
- Formulations
- Personal care products
- Pesticides
- Chemicals

In most cases, Strat-M™ membrane correlates more closely to human skin than do animal skin models commonly used for *in vitro* screening of transdermal formulations. And because it is a synthetic test model with low variability and no special storage or hydration requirements, Strat-M™ membrane simplifies experimental design and data analysis.

A perfect fit for Franz cells

By choosing Strat-M™ membrane for Franz cell-based diffusion tests, you can screen actives or rank-order formulations with unprecedented consistency and convenience. Strat-M's predictive performance will allow you to generate meaningful data and focus your research on actives or formulations with the most potential. You will conserve your time, budget, and human skin samples for critical downstream analyses.

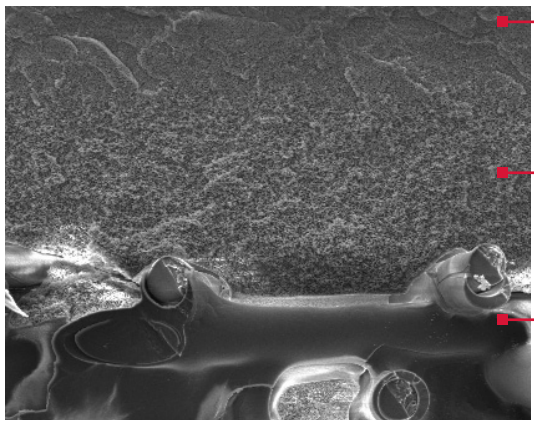
*For research use only.
Not for use in diagnostic procedures.

Strat-M™ Membrane – A Synthetic Transdermal Diffusion Test Model

Engineered for Performance

We've engineered predictive performance into the structure and chemistry of the Strat-M™ membrane. Like human skin, the Strat-M™ membrane has multiple layers with varied diffusivity, as shown in Figure 1.

Strat-M™ is constructed of two layers of polyethersulfone (PES, more resistant to diffusion) on top of one layer of polyolefin (more open and diffusive). These polymeric layers create a porous structure with a gradient across the membrane in terms of pore size and diffusivity. The porous structure is impregnated with a proprietary blend of synthetic lipids, imparting additional skin-like properties to the synthetic membrane.



Total membrane thickness: approximately 300 µm.

Figure 1. The multilayered structure of Strat-M™ membrane matches that of human skin.

Strong Correlation to Human Skin

We observed nearly equivalent flux of 14 test compounds ranging in molecular weight from 162 to 425 with log P values (representing relative lipophilicity) of -0.131 to 6.9 through human skin (split thickness cadaver skin) and Strat-M™ membrane. These data indicate that Strat-M™ membrane has broad chemical compatibility and is an appropriate model for screening compounds with diverse physiochemical properties.

STRAT-M™ MEMBRANE CORRELATION FACTOR TO HUMAN SKIN

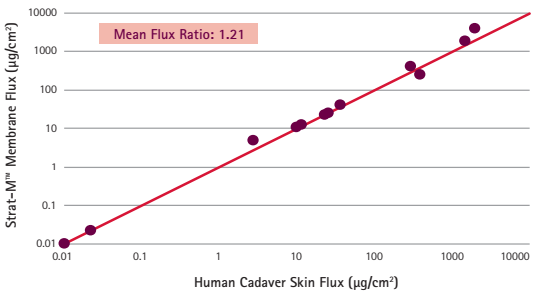


Figure 2. Comparison of flux through human skin vs. through Strat-M™ membrane. Data points are the ratios of average values of cumulative flux for various compounds through Strat-M™ and human cadaver skin, measured at 8 hours. The solid line represents the ideal 1:1 correlation. N = 14

Diverse Compounds, Same High Performance

Below are detailed diffusion data for a few of the 14 compounds we tested. Octocrylene, a slowly diffusing active ingredient in many sunscreens, shows low levels of flux through both Strat-M™ membrane and human skin. For acetylsalicylic acid (aspirin, an analgesic), high flux was measured through both human skin and Strat-M™ membrane; however, flux was lower through porcine skin, indicating that Strat-M™ membrane is a better match for human skin than animal skin models. Finally, we show data for diclofenac, a topical analgesic, whose diffusion through Strat-M™ membrane shows good correlation with human skin; however, the two lots of human skin tested showed high variability. The lot-to-lot consistency of Strat-M™ membrane, therefore, is an advantage in this case.

OCTOCRYLENE

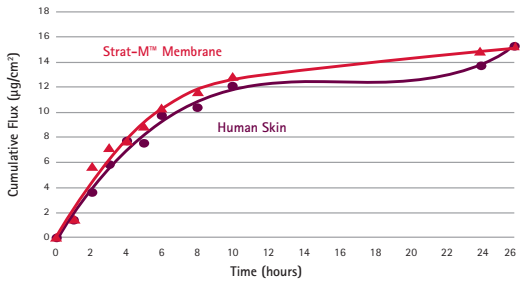


Figure 3a. Octocrylene diffusion. Strat-M™ membrane was tested alongside human cadaver skin in a Franz diffusion cell apparatus (0.635 cm²). Three Franz cells were used for each test model. The donor compartment of each cell was loaded with 500 µL of an octocrylene emulsion (3.5%). Data represent average cumulative flux at each test point.

ACETYLSALICYLIC ACID

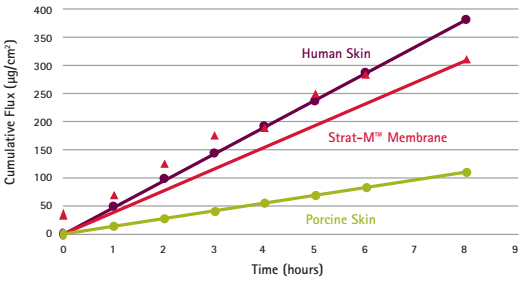


Figure 3b. Acetylsalicylic acid diffusion. The diffusion rate of acetylsalicylic acid through Strat-M™ membrane was measured on a Franz diffusion cell apparatus (0.635 cm²). Six Franz cells were used. The donor compartment of each cell was loaded with 500 µL of a saturated acetylsalicylic acid solution. Diffusion performance was compared to published values for 8-hour cumulative diffusion through human cadaver and porcine skin. Data represent average cumulative flux at each test point.

Sources - Human Cadaver Skin: International Journal of Pharmaceutics, 2006, vol 310, pg 31-36; Porcine Skin: International Journal of Pharmaceutics, 1999, vol 181, pg 255-263

DICLOFENAC

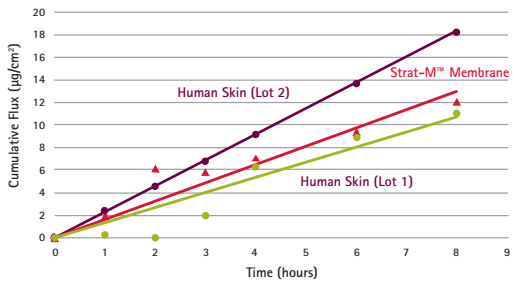


Figure 3c. Diclofenac diffusion. Strat-M™ membrane was tested alongside two lots of human cadaver skin in a Franz diffusion cell apparatus (0.635 cm²). Three Franz cells were used for Strat-M™ membrane and each lot of skin. The donor compartment of each cell was loaded with 500 µL of a saturated diclofenac solution. Data represent average cumulative flux at each test point.

Find Your Match!

Compare diffusion of various compounds through Strat-M™ membrane and other transdermal diffusion models using our interactive Compound Correlation Tool. Click on compounds with lipophilicity and molecular weight that are similar to compounds and formulations you are testing in your lab to see their diffusion properties through Strat-M™ membrane and human skin.

www.millipore.com/StratMtool

Fast or Slow? Accuracy Across All Diffusion Rates

Whether you are safety testing a slowly diffusing sunscreen active, or optimizing a rapidly diffusing NSAID formulation for pain relief, Strat-M™ membrane provides the versatility to generate meaningful data.

BROAD COMPATIBILITY

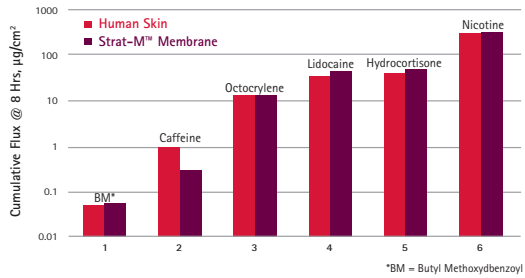


Figure 4. Correlation between human skin and Strat-M™ membrane across diffusion rates that vary over four orders of magnitude. Transdermal diffusion testing was performed for several formulation types commonly used for transdermal delivery. Six Franz cells were used for each formulation—three with Strat-M™ membrane and three with human cadaver skin. The donor chambers were loaded with 500 µL of the formulations. Samples were collected hourly and analyzed by HPLC.

Formulation Development

Strat-M™ membrane exhibits differential permeability in the presence of enhancers, so it is appropriate for use during formulation optimization.

Strat-M™ membrane is compatible with common formulation formats:

- Solutions
- Cream
- Gel
- Patch
- Foam
- Emulsion

ENHANCER SENSITIVITY

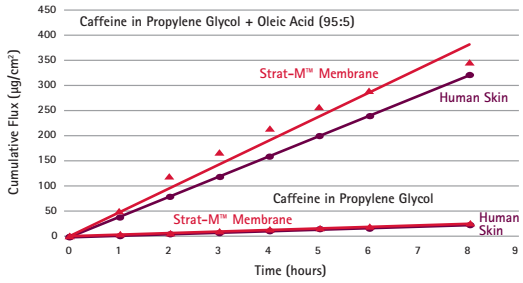


Figure 5. Caffeine solution in propylene glycol shows quantitatively similar increase in diffusion through human skin and Strat-M™ membrane upon addition of a permeation enhancer (Oleic acid) to the formulation.

Low Variability, Reproducible Data

With skin-based models, you need to repeat testing each time a new lot of skin arrives in the lab. In contrast, Strat-M™ membrane is a highly consistent, engineered material that enables you to compare today's diffusion data with data you will generate next week, or next month.

LOT-TO-LOT VARIABILITY

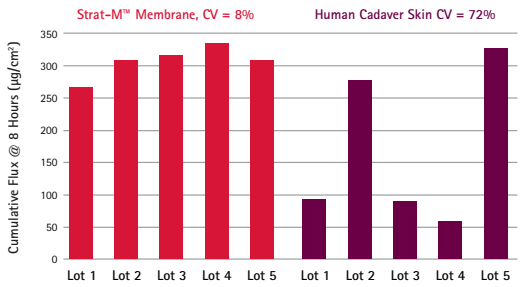


Figure 6. Measured flux rate of a caffeine solution through **Strat-M™ membrane (left) shows greater lot-to-lot consistency than through human cadaver skin (right).** Flux rates were measured for five different lots of Strat-M™ membrane and eight different lots of human cadaver skin. The diffusion test was conducted in a Franz cell with a 500 µL saturated caffeine solution. Data represent average 8-hour cumulative flux values for four samples per lot of membrane or skin. The average flux for Strat-M™ membrane was 304.0 µg/cm^2, with CV = 8%. The average flux for human cadaver skin was 168.8 µg/cm^2, with CV = 72%. Strat-M™ membrane used in this study was pre-validated material.

Ultimate Experimental Convenience

- Strat-M™ is shelf-stable and does not require any special storage considerations.
- Strat-M™ membrane is individually packaged as precut discs to simplify setup of your Franz cells. Strat-M™membrane discs come in two sizes to accommodate most Franz cell dimensions: 25 mm (4.9 cm^2) and 47 mm (17.3 cm^2).
- Unlike skin, Strat-M™ membrane does not need to be hydrated prior to use. Simply remove the Strat-M™membrane disc from its pouch and load into a Franz cell.

Ordering Information

Description	Catalogue No.
Strat-M™ Membrane, 25 mm, 60/pk	SKBM02560
Strat-M™ Membrane, 47 mm, 60/pk	SKBM04760

Related Products

For information about cosmetics raw materials please visit:
www.merck4cosmetics.com

Visit www.millipore.com/StratmTool to see how Strat-M™ membrane performs.

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