HB Instrument

经皮水分流失测量仪

瑞士进口SKT品牌，品质保证，让实验结果更可靠

研究表明，离体皮肤的评价受皮肤新鲜度、厚度、质量和皮肤屏障完整性等因素的影响。皮肤屏障完整性评价作为皮肤模型的质量重要控制手段，可通过测定经皮水分流失方法确定。经皮水分流失的测试是通过测定皮肤外表面附近的水分(蒸汽)，从而评估水分从皮肤下通过皮肤屏障的速率。

测定时，将皮肤安装到扩散池中间(夹在供给室和接收室之间)，使皮肤下侧与接收室中的接收介质(如PBS/PH7.4)接触，然后将皮肤表面温度平衡至32℃±1℃。如果皮肤切片的直径比较大， 能盖住扩散池内皮肤安装位置的法兰，可在皮肤表面温度平衡至32℃±1℃几小时后，在不破坏皮肤切片和下部的扩散池法兰粘附的情况下，将供给室轻轻移去，此时可将TEWL探头直接放置在皮肤表面测试TEWL，而不用放置在供给室的顶部。通常，测试结果稳定后每个皮肤切片需至少重复测定3次，并记录相关结果。

- 采用封闭腔体内湿度变化量测定方法
- 可测定TEWL
- 测量范围广，可达-100~300g/m²/h,测量精度0.1
- 0~50℃下可正常运行，温度精度0.1℃
- 湿度运行范围10%~80%
- 用测量探头的开口部位轻轻的压在皮肤上，按下按键:在 13 秒以内便可测出数值。

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In Vitro Permeati
Test Studies for Topi
Drug Products
Submitted in ANDAs
Guidance for Industry

DRAFT GUIDANCE

202 *1. Trans-Epidermal Water Loss Skin Barrier Integrity Test*
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204 A TEWL skin barrier integrity test involves a measurement near the outer surface of the skin of
205 the rate at which water (vapor) is fluxing through the skin barrier from the underside of the skin
206 section. For the test, the skin section is mounted in a diffusion cell (e.g., clamped in place
207 between the donor and receptor compartments), with the underside of the skin in contact with the
208 receptor solution in the receptor compartment (e.g., phosphate buffered saline, pH 7.4), and
209 equilibrated to a skin surface temperature of 32°C ± 1°C. If skin sections are cut large enough to
cover the flange of the diffusion cell in which they are mounted, then after they have equilibrated
for several hours at a skin surface temperature of 32°C ± 1°C, it may be feasible to gently
ove the donor compartment without disrupting a skin section's adherence to the lower flange
iffusion cell, thereby allowing the TEWL probe to be placed directly on the skin surface,
ing placed atop the donor compartment. Typically, a minimum of three replicate
made on each skin section, which are recorded after the measurements have

USP 40 *General Information* / ⟨1724⟩ Semisolid Drug Products 2055

⟨1724⟩ SEMISOLID DRUG PRODUCTS—PERFORMANCE TESTS

MEMBRANE INTEGRITY

The skin barrier integrity in each diffusion cell should be confirmed prior to dosing by using techniques such as transepidermal water loss (TEWL), electrical impedance/conductance or tritiated water permeation; only skin sections with acceptable barrier integrity results should be dosed. TEWL is often a preferred method because, unlike the other methods, it measures the flux of water through the skin barrier while it is dry and in contact with the air, as it is in the normal in vivo state, and TEWL is relatively rapid and convenient.

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