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## HPLC测定他克莫司软膏体外透皮吸收

Determination of Percutaneous Absorption of Tacrolimus Ointment by HPLC

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英文关键词: [tacrolimus](#) [ointment](#) [percutaneous absorption](#) [HPLC](#)

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中文摘要:

目的 建立规格为0.03%的他克莫司软膏体外透皮接收液中药物的HPLC测定方法, 研究0.03%他克莫司软膏的体外透皮量。方法 采用Diamonsil C<sub>18</sub>色谱柱(250 mm×4.6 mm, 5 μm); 流动相: 乙腈-水-磷酸(700:300:1); 流速: 1.0 mL·min<sup>-1</sup>; 检测波长: 215 nm。体外透皮实验采用改良的Franz直立扩散池, 透皮屏障采用实验用离体乳猪皮。将自制软膏与市售软膏的透皮结果进行对比分析, 分别在设定的不同时间点取样测定透皮接收液中他克莫司的浓度, 计算累积透皮量。结果 他克莫司的标准曲线方程为  $A = 16\ 310.263\ C + 3\ 629.783$  ( $r = 0.999\ 97$ ), 线性范围为2.088~20.88 μg·mL<sup>-1</sup>, 平均回收率为99.10%。累积透皮量与时间呈良好的线性关系, 自制软膏与市售软膏的透皮结果无显著性差异。结论 该检测方法操作简便, 快速准确, 是考察他克莫司软膏体外透皮性能的理想方法。

英文摘要:

OBJECTIVE To establish an HPLC method for quantitative determination of tacrolimus in vitro percutaneous solution, and investigate the ability of percutaneous penetration of 0.03% Tacrolimus ointment. METHODS Diamonsil C<sub>18</sub> column(250 mm×4.6 mm, 5 μm) was used as the fixed phase and a mixture of acetonitrile, purified water and phosphoric acid(700:300:1) as mobile phase. The flow rate was 1.0 mL·min<sup>-1</sup>. The detection wavelength was at 215 nm. Improved Franz type diffusion cells were used in vitro permeation studies and excised mini pigs skins in vitro were used as transdermal

barrier. The concentration of tacrolimus in the receptor solution was determined by HPLC to investigate its cumulative permeation quantities at different time respectively and compared with that of the commercial ointment. RESULTS The regression equation of Tacrolimus ointment was linear in the range of 2.088–20.88  $\mu\text{g} \cdot \text{mL}^{-1}$  ( $A=16\ 310.263C+3\ 629.783$ ,  $r=0.999\ 97$ ). The average recovery was 99.10%. A good linear relationship existed between the cumulative penetration quantities and the time. There was no significant difference in the permeation quantities between the self-made and commercial ointment. CONCLUSION The method is simple, rapid, and accurate. It is a good method to evaluate the characteristic of permeation for Tacrolimus ointment.

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