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论文

硝酸异山梨醇透皮给药系统的研制

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摘要:

硝酸异山梨醇透皮给药系统(ISDN—TDS)由背衬层、药库、乙烯—醋酸乙烯共聚物(EVA)控释膜、压敏胶及防粘层组成。采用Keshary—Chien体外释药装置,研究了药库组分、基质溶剂、控释膜、压敏胶粘度及透皮给药促进剂氮酮等对药物释放的影响。以释异丁烯、矿物油、EVA控释膜为主要材料制成的ISDN—TDS体外能持续释药72h,0~48h药物按零级动力学经皮透过。平均释药速率为13.76μg·h⁻¹/cm²,而国外类似产品Frandol tape-s按Higuchi模型释药仅24h。

关键词: 硝酸异山梨醇 透皮给药系统 体外释药速率 高效液相色谱法 氮酮

STUDIES ON TRANSDERMAL DELIVERY SYSTEM OF I SOSORBI DE DINITRATE

AM Ji; XT Jiang; HQ Zou; XF Wang

Abstract:

A transdermal delivery system of isosorbide dinitrate (ISDN-TDS)and an HPLCmethod for the measurement of ISDN were developed. The system is composed of backing drug reservoir, control membrane, contact adhesive and protective layer. The influences of drug reservoir, solvent, control membrane, viscosity and penetration enhancerazone on the release of ISDN were investigated. The cumulative released amount of ISDN / time profile indicated that ISDN was permeated through excised skin in a zero--order kinetic in 48 h. The release of ISDN from ISDN--TDS can last 72 h at least. The mean permeation rate is 13.76 μ g·h⁻¹/cm². Releasing ISDN from ISDN--TDS was more stable than that from Frandol tape-s whose release profile was found to follow a linear Q vst^{1/2} relationship with a release flux of 114.39 μ g·h⁻¹/cm².

Keywords: Transdermal delivery system HPLC Azone Isosorbide dinitrate

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