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论文

微孔渗透泵片的药物传递机制

赵学玲;李强;龚显峰;李三鸣

1. 黑龙江大学 制药科学与工程系， 黑龙江 哈尔滨 150080； 2. 沈阳药科大学 药学院， 辽宁 沈阳 110016

摘要：

关键词： 微孔渗透泵 渗透压 体外释放 盐酸曲马多

The delivery mechanism of micro-porous osmotic pump tablets

ZHAO Xue-ling; LI Qiang; GONG Xian-feng; LI San-ming

Abstract:

To investigate the delivery mechanism of micro-porous osmotic pump tablets (MPOP), taking tramadol hydrochloride (TR) as the model drug, tramadol hydrochloride micro-porous osmotic pump tablets (TR MPOP) were prepared with compressible starch as diluent, cellulose acetate as coating material, polyethylene glycol 400 as pore-forming agents. The equilibrium solubility and osmolality of TR were determined. The effects of fillers in tablet cores, coating levels, and osmotic pressures of release media on expansion behavior of preparations were described. The influences of the category, osmolality, and pH value of release media, release methods, and release conditions on release curves of tablets were evaluated. Based on several models, the delivery pattern of TR MPOP was fitted. The equilibrium solubility in water and osmolality of TR were (775.8±17.7) $g \cdot L^{-1}$ and 4.036 $Osmol \cdot kg^{-1}$, respectively. During the drug-release period, it was observed that the tablets expanded markedly in response to the expansion characteristics of compressible starch and the osmotic pressure difference across the membrane. When osmotic pressure of release media increased, the significant change of the equilibrium solubility of TR was not found, but the release rates of TR MPOP decreased significantly. The delivery rate was not influenced by the pH of release mediums, dissolution methods and paddle stirring rates. The drug release profile conformed to the model of zero order in 8 h. The pore-forming agents were dissolved in release medium, which caused micro-pores. The expansion of tablets made the size of micro-pores bigger, and then the drug-releasing pores were obtained. It was proved that the drivers of drug delivering from TR MPOP were mainly the difference of osmotic pressure, and secondly the difference of solubility. TR MPOP were the controlled-release preparation.

Keywords: osmotic pressure *in vitro* dissolution tramadol hydrochloride micro-porous osmotic pump

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通讯作者: 李三鸣

作者简介:

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