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厄贝沙坦胃滞留夹芯渗透泵片的制备及体外释放度考察

Preparation and Dissolution Test *in Vitro* of Intragastric Floating Sandwiched Osmotic Pump Tablets of Irbesartan

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作者	单位	E-mail
方瑜	河北医科大学药学院, 石家庄 050017	tri99@126.com
潘振华	河北医科大学药学院, 石家庄 050017	
曹德英	河北医科大学药学院, 石家庄 050017	

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中文摘要:

目的 对厄贝沙坦胃滞留夹芯渗透泵片(SOPT)的制备方法进行研究,并考察其体外释放度。方法 分别以膨胀速度、水渗透速、低剪切黏度、屈服应力及释放度为评价指标,确定处方中膨胀剂材料、致孔剂、助悬剂、促渗剂的用量。结果 最佳处方:膨胀剂为(Mw 5 000 000)与HPMC混合物(4:1),用量70 mg;促渗剂氯化钠用量为25 mg;包衣液致孔剂PEG400用量8%;助悬剂PEO(Mw 200 000)用量为厄贝沙坦的1/4。释药行为符合零级方程,具有明显的控释特征。结论 SOPT具有良好的体外控释效果,可进一步进行体内释药行为考察。

英文摘要:

OBJECTIVE To study prescription and technique of intragastric floating sandwiched osmotic pump tablets (SOPT) of irbesartan and inspect release property in vitro. METHODS The swelling rate, permeation rate of water, shear viscosity of slow-speed revolution, yield stress and release property was inspected to determine the dosage of the swelling agent, porous agent, suspending agent and osmotic agent. RESULTS The optimization of prescription and technique were defined: swelling agent was a mixture of PEO(Mw 5 000 000) and HPMC as a ratio of 4:1 (the dosage was 70 mg); osmotic agent sodium chloride was 25 mg; porous agent PEG 400 was 8%; the ratio of suspending agent PEO(Mw 200 000) and irbesartan was 1:4. The release behavior of SOPT coincided with zero-level equation well and the character of controlled-release was transparent. CONCLUSION SOPT has good controlled-release in vitro and the release behavior in vivo need to be investigated.

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