

论文

复方丹参pH依赖型延迟释药微丸在家犬体内的药效动力学

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摘要:

目的制备复方丹参pH依赖型延迟释药微丸填充胶囊并进行家犬体内药效动力学研究。方法分别用HPMC, Eudragit L-30D-55, Eudragit L100/S100 (1:6)包衣制备pH依赖型延迟释药微丸, 测定体外释放曲线, 并用血清药理学方法进行家犬体内的药效动力学研究。结果制备了复方丹参pH依赖型延迟释药微丸, 体外溶出曲线呈pH依赖特征。单剂量给药后自制速释片R的药效动力学参数 T_{max} 为0.58 h, E_{max} 为34.63%, 延迟释药胶囊T1和T2的 T_{max} 分别延长至2.42和3.17 h, E_{max} 分别降低至13.57%和14.52%, 相对生物利用度分别为99.3%和133.6%。多剂量给药后自制速释片R波动度DF 7.32, 延迟释药胶囊T1和T2的波动度DF 3.40和3.03。结论复方丹参pH依赖型延迟释药胶囊体外释放具有pH依赖特征, 体内具有明显的延迟释药作用, 多剂量达到稳态时, 药效动力学波动系数低于普通片。

关键词: 复方丹参 pH依赖型延迟释药微丸 血清药理学 药效动力学

Pharmacodynamics of compound danshen pH-dependent delayed release pellets in dogs

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Abstract:

AimTo prepare the compound danshen pH-dependent delayed release pellets and filled them in capsules and then study thier pharmacodynamics. MethodsThe pH-dependent delayed release pellets were prepared by coating with HPMC, Eudragit L-30D-55 and Eudragit L100-Eudragit S100 (1:6), separately, and mixed in proper proportion to prepare the two pH-dependent delayed release systems T1 and T2. The release of delayed release pellets was determined according to the method of China Pharmacopoeia (2000) in the simulated gastrointestinal pH conditions. The pharmacodynamic parameters were evaluated by serum pharmacology method. ResultsThe compound danshen pH-dependent delayed release pellets were prepared with the characteristics of pH dependent delayed release profile *in vitro*. In single oral dose,the pharmacodynamic parameters of rapid release tablets R E_{max} (%) and T_{max} (h) were 34.63% and 0.58 h, respectively. T_{max} s of delayed-release pellets T1 and T2 were extended to 2.42, 3.17 h and E_{max} s (%) were declined to 13.57%, 14.52%. The relative bioavailabilities of T1 and T2 were 99.3%, 133.6%, respectively. In multiple oral doses of R the pharmacodynamic parameter of DF was 7.32 and those T1, T2 DF were 3.40, 3.03, respectively. ConclusionThe compound danshen pH-dependent delayed release capsules have characteristics of pH dependent releasing *in vitro* and characteristics of delayed release *in vivo*. In multiple oral doses the DF of delayed release capsules was lower than that of rapid release tablet at steady state.

Keywords: pH-dependent delayed release pellet serum pharmacology pharmacodynamics compound danshen

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