

复方丹参pH依赖型延迟释药微丸的制备和体内外相关性

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摘要

目的 制备复方丹参pH依赖型延迟释药微丸并填充胶囊,用血清药理学方法进行家犬体内药效动力学研究考察体内外相关性。方法 以丹参、三七提取物、冰片 β -CD包合物,用粉末层积法制备含药微丸,用胃溶薄膜包衣剂RT (主要成分为羟丙基甲基纤维素 HPMC)、Eudragit L-30D-55、Eudragit L100-Eudragit S100 (质量比为1:6)包衣制备pH依赖型延迟释药微丸,将不同类型的包衣微丸按一定比例混合、填充胶囊,测定不同溶pH值条件下的溶出度,绘制溶出曲线。用血清药理学方法进行药效动力学研究。结果 制备了复方丹参pH依赖型延迟释药胶囊,体外溶出曲线有明显的缓释特征,药效动力学参数 $AUC_{0\rightarrow t}$ 为 $(95.53\pm 16.05)\%h^{-1}$, t_{max} 为 (3.17 ± 1.83) h。结论 复方丹参延迟释药微丸体内外相关性良好。

关键词 [药剂学](#) [pH依赖型延迟释药微丸](#) [复方丹参](#) [血清药理学](#) [药物相关性](#)

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Preparations and correlation between in vitro and in vivo of compound Danshen pH-dependent delayed release pellets

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Abstract

Objective To prepare the compound Danshen (traditional Chinese medicines) pH-dependent delayed release capsules and study on pharmacodynamics in dogs with serum pharmacology method and correlation between in vitro and in vivo. Methods The pellet containing the extracts of danshen, sanqi and borneol included with the β -cyclohexodextrin were prepared by means of powder layering. The pellets were prepared by coating with HPMC, Eudragit L-30D-55, Eudragit L100-Eudragit S100(1:6), mixed in proper proportion to fill in capsules to produce pH-dependent delayed drug release profile. The pharmacodynamics parameters were evaluated by serum pharmacology method. Results The Compound Danshen pH-dependent delayed release capsules were prepared with the characteristics of delayed release in vivo release profile. The pharmacodynamics parameters $AUC_{0\rightarrow t}$ and t_{max} were $(95.53\pm 16.05)\%h^{-1}$ and (3.17 ± 1.83) h separately. Conclusions There is a good correlation between drug release in vitro and pharmacodynamics in vivo.

Key words [pharmaceutics](#) [pH-dependent delayed release capsules](#) [compound Danshen](#) [serum pharmacology](#) [drug correlationship](#)

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