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论文

# 关节腔内注射用氟比洛芬明胶微球

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摘要:

目的:制备关节腔注射用氟比洛芬明胶微球。方法:按均匀设计法筛选乳化冻凝法制备氟比洛芬明胶微球(FP GMS)的最佳制备工艺。结果:微球粒径范围为2.5～12.3μm,平均粒径为7.53μm,氟比洛芬含量为5.02%(w/w)。其体外释药符合Higuchi方程,稳定性实验表明,FP-GMS的稳定性良好,兔关节腔内注射后,与溶液剂对照组相比氟比洛芬体内平均驻留时间(MRT)显著延长($P$<0.01),峰时比对照组延长2.03倍,峰浓度比对照组减小5.57倍。体内外相关性研究表明,FP-GMS体外累积溶出百分率与兔体内药物吸收分数呈显著相关($P$<0.01)。结论:本法制备的氟比洛芬明胶微球粒径分布集中,粒径大小符合设计要求,体内外释药结果表明氟比洛芬明胶微球具有明显的缓释作用。

关键词: 氟比洛芬明胶微球 关节腔注射 稳定性 药代动力学

## FLURBIPROFEN GELATIN MICROSPHERES FOR INTRA ARTICULAR ADMINISTRATION

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Abstract:

AIM: To prepare flurbiprofen gelatin microspheres for intra articular administration. METHODS: An optimum procedure was established by uniform test for preparing flurbiprofen gelatin microspheres (FP-GMS) with emulsion congealing method. RESULTS: The particle size focused on 2.5～12.3 μm, the mean size was 7.53 μm, drug content was 5.02% (w/w). The dissolution profiles of the FP-GMS followed Higuchi kinetics. The stability of FP GMS was excellent. In rabbits the mean retention time (MRT) of FP GMS was prolonged *vs* that of the injection group ($P$<0.01), after intra articular cavity administration with FP GMS. The $T_{max}$ was prolonged 2.03 times and the $C_{max}$ was decreased 5.57 times *vs* that of the injection group. Significant linear correlation exists between the dissolution *in vitro* and absorption *in vivo* ($P$<0.01). CONCLUSION: The size distribution of FP-GMS was focalized, and the FP-GMS showed obvious sustained effect both *in vitro* and *in vivo*.

Keywords: intra articular administration stability pharmacokinetics flurbiprofen gelatin microspheres

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