

抗疏健骨胶囊中指标成分的溶出度考察*

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摘 要: **目的** 测定抗疏健骨胶囊中三种指标成分的体外溶出度, 为抗疏健骨胶囊的质量评价研究奠定基础。**方法** 采用高效液相色谱法测定淫羊藿苷、 β -蜕皮甾酮和丹酚酸 B 三种指标成分在不同转速、溶出介质、溶出方法中的累积溶出率。**结果** 通过对溶出方法、转速、溶出介质的考察, 建立了适合抗疏健骨胶囊多指标成分溶出度检查方法: 以 0.5% 的 SDS 水溶液作为溶出介质, 以转速 100 r/min 的桨法为溶出方法。**结论** 3 种成分在 90 min 时的溶出几乎达到饱和状态。相同条件下, 同时刻淫羊藿苷、 β -蜕皮甾酮和丹酚酸 B 三种成分中的溶出度比较的结果为: 丹酚酸 B > β -蜕皮甾酮 > 淫羊藿苷, 淫羊藿苷、 β -蜕皮甾酮和丹酚酸 B 的 T50 分别为 10.56 min、9.57 min 和 9.05 min, Td 分别为 13.34 min、12.10 min 和 11.44 min, 三种成分的溶出效果以丹酚酸 B 最佳, 淫羊藿苷最差。

关键词: 抗疏健骨胶囊; 溶出度; HPLC

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Study on the Dissolution Rate of the Index Components in Kangsujiang Capsule

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Abstract: **Objective** To determine in vitro dissolution of three index components of the *Kangsujiang* capsule which provides a basis for evaluation of the quality of *Kangsujiang* capsule. **Methods** cumulative dissolution rate of Icarin, β -ecdysterone and three metrics Sal B component were detected by HPLC in different speeds and the dissolution medium. **Results** Based on the dissolution method, speed, dissolution medium, a multi-index component dissolution test method was established for *Kangsujiang* capsule, 0.5% SDS aqueous solution as a dissolution medium, rotation speed of 100r/min paddle method of the dissolution method. **Conclusions** when at 90min, The three components of dissolution almost reach their saturation. Under the same conditions, the same time the results of the dissolution comparison of icariin, β -ecdysterone and Sal B are Sal B > β -ecdysterone > icariin; the T50 of icariin, β -ecdysterone and Sal B are 10.56min, 9.57min and 9.05min, Td respectively are 13.34min, 12.10min and 11.4min. The comparison of the dissolution effect of the three components, Sal B is best, icariin is worst.

Key words *Kangsujiang* capsule; dissolution; HPLC

抗疏健骨胶囊是由淫羊藿、杜仲、丹参、白术、牛膝等五味药材组成的中药复方制剂, 方中淫羊

藿为君药, 主要用于脾肾两虚, 气血瘀阻导致的骨质疏松症^[1-5]。复方中药是通过多味药材中多种