

中药药剂学

红景天滴丸成型工艺考察

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摘要

目的 确立红景天滴丸的最佳成型工艺,以提高药物的稳定性,增加生物利用度,方便患者服用。方法 采用熔融法,将药物浸膏分散于辅料中,滴入冷凝液中收缩成丸;以滴丸硬度、圆整度、脱尾情况及溶散时限为指标,采用单因素试验考察载药量及辅料的用量;以综合外观为评价指标考察基质、药物与基质的配比、滴制温度、滴速、滴距、柱长和冷凝液温度对滴丸成型性的影响;以硬度、圆整度等为评价指标,确定红景天最佳用量;结合实际条件,以丸质量差异RSD为评价指标,选用3因素3水平正交设计筛选滴丸的滴制条件。结果 红景天滴丸最佳生产工艺为:药液温度 80℃,载药量质量分数 50%,滴距 4 cm,PEG 4000与PEG 6000的质量比为3:1。结论 该工艺简便,可行,适用于红景天滴丸实验室试验和工业化生产。

关键词 [药剂学](#) [滴丸](#) [正交设计](#) [红景天](#) [熔融法](#) [圆整度](#) [重量差异](#)

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Investigation on the preparation technics of *Rhodiola crenulata* dropping pills

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Abstract

Objective To establish an optimal preparation process for the production of *Rhodiola crenulata* dropping pills in order to enhance the stability and bioavailability of the drug. Method *Rhodiola crenulata* dropping pills were prepared by dispersing *Rhodiola crenulata* extracts into the melted excipients and the molten suspension was dropped into the cooling mixture of polydimethylsiloxane and paraffin liquid. Thereafter the drops contracted, cooled and solidified into dropping pills. A series of tests were performed for the choice of substrate, drug to substrate ratio, the dropping and cooling temperature, and the dropping speed. Using hardness, degree of sphericity and dissolution time as standards, the amount of extracts and excipients were selected via single factor experiments. Subsequently, the dropping condition was optimized on the basis of three factors and three levels orthogonal design. by assessing weight variance of the pill. Result The optimized pill production process was: processing temperature 80℃; loading of the extract 50%, dropping distance: 4 cm above liquid level and weight ratio of PEG 4000 to PEG 6000 was 3:1. Conclusion The optimized preparation method is simple and convenient, and can be used to prepare *Rhodiola crenulata* dropping pills in the laboratory or for industrial production.

Key words [pharmaceutics](#) [dropping pill](#) [orthogonal design](#) [Rhodiola crenulata](#) [fusion method](#) [roundness](#) [weight variation](#)

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