

基于指纹图谱、化学模式识别和多指标含量测定的金贝口服液质量控制研究^Δ

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中图分类号 R917 文献标志码 A 文章编号 1001-0408(2026)13-1704-06
DOI 10.6039/j.issn.1001-0408.2026.13.08



摘要 目的 基于多波长切换高效液相色谱(HPLC)指纹图谱、化学模式识别和多指标含量测定,建立金贝口服液的质量控制方法。方法 以15批金贝口服液为样品,采用《中药色谱指纹图谱相似度评价系统(2012版)》建立多波长切换HPLC指纹图谱,并进行色谱峰指认和相似度评价。采用聚类分析、主成分分析、正交-偏最小二乘判别分析对15批金贝口服液样品进行化学模式识别分析。采用多波长切换HPLC法同时测定样品中新绿原酸、绿原酸、隐绿原酸、连翘酯苷A、黄芩苷、丹酚酸B、汉黄芩苷含量。结果 15批金贝口服液的指纹图谱中共标定了25个共有峰,并指出其中7个共有峰,各样品相似度均大于0.960。化学模式识别分析结果发现,样品S1~S8聚为第1类,S9~S15聚为第2类,且黄芩苷、汉黄芩苷、新绿原酸、绿原酸、丹酚酸B为质量差异成分。15批金贝口服液中新绿原酸、绿原酸、隐绿原酸、连翘酯苷A、黄芩苷、丹酚酸B、汉黄芩苷的平均含量分别为0.213 7、0.085 3、0.104 9、0.287 3、0.420 1、0.062 1、0.176 0 mg/mL。结论 本研究基于多波长切换HPLC指纹图谱、化学模式识别和多指标含量测定建立的金贝口服液质量控制方法稳定、可靠,可为该制剂的质量标准制定提供参考。

关键词 金贝口服液;多波长切换;指纹图谱;含量测定;化学模式识别;质量标准

Study on quality control of Jinbei oral liquid based on fingerprint, chemical pattern recognition and multi-index content determination

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ABSTRACT **OBJECTIVE** To establish a quality control method for Jinbei oral liquid based on multi-wavelength switching high performance liquid chromatography (HPLC) fingerprint, chemical pattern recognition and multi-index content determination.

METHODS A total of 15 batches of Jinbei oral liquid were used as test samples. The *Similarity Evaluation System for Chromatographic Fingerprint of Traditional Chinese Medicine (Version 2012)* was adopted to establish multi-wavelength switching

HPLC fingerprints, followed by chromatographic peak identification and similarity evaluation. Cluster analysis, principal component analysis and orthogonal partial least squares-discriminant analysis were applied to conduct chemical pattern recognition on the 15 batches of samples. The multi-wavelength switching HPLC method was used to simultaneously determine the contents of neochlorogenic acid,

^Δ **基金项目** 国家重点研发计划-中医药现代化专项(No. 2023YFC3504102);药品监管科学全国重点实验室课题(No. 2025SKLDRS0338);中药监管科学研究项目(No.ZYJGKX202410)

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