MASTER'S THESIS

活血化瘀中成藥處方和製備工藝改進: 雲南白藥劑型的質量比較分析

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活血化瘀中成药处方和制备工艺改进

(云南白药剂型的质量比较分析)

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摘要

目的：云南白药问世之初的半个多世纪都是以散剂供应市场，云南白药最早研制出的剂型是散剂，是一种米黄色或黄白色的粉末。散剂有不易掌握剂量、吞服口感不适的缺点，加上粉末具酸、涩、苦等。随着制药业的发展，不同剂型的需求日显突出。近年云南白药厂为克服本剂型的不足及进一步拓展其临床应用,与有关药厂合作,在白药配方基础上,研制出数种新剂型。云南白药除散剂外，还开发出粉剂、创可贴、酊剂、膏剂、气雾剂等。

方法：利用超高效液相色谱（Ultra Performance Liquid Chromatography，UPLC）探讨不同剂型的云南白药,了解不同剂型的云南白药的成分变化。关于云南白药的含量测定尚未有报道，本文试验采用超高效液相色谱法同时测定云南白药粉剂、创可贴、酊剂、膏剂、气雾剂，解析各种剂型是否有不同成份差异，为中药制剂的产品质量控制提控方法依据和参考。

结果：云南白药的成分秘不外传，但据说主要成分为田七。利用超高效液相色谱分析方法，分析不同剂型的云南白药的成份差异。首先根据云南白药说明书所示最高成份的中药材开始分析，田七中的指标性成份三七皂苷。之后从单因素实验室条件开始考察选择：1.选择流动相的极性选择 2.选择流动相梯度 3.云南白药提取方法 4.提取液中加入某些试剂或溶剂 5. 选择用大孔吸附树脂除去杂质。

结论：由于云南白药中成份多，提取液中加入某些试剂或溶剂，使某些成分溶解度降低而沉淀。因此今后有必要进行多因素考察，通过多因素考察排除非影响条件。石油醚是有机溶剂，易燃，其蒸气与空气混合灼烧能引起爆炸，今后改用大孔树脂法分离云南白药中的成份，可能既便宜而且安全 。

关键词：云南白药 创可贴 酊剂 膏剂 气雾剂 超高效液相色谱。

Abstract

Aim: Yunnan Baiyao powder as a powder has supplied medicinal application over half century. The powder is the longest historical dosage form of Yunnan Baiyao, which is yellow or yellowish white powder. The disadvantage of powder is hardly to measure and uncomfortable, taste not good during swallowing. The powder is sour, bitter and a mouth-puckering taste. Following the development of pharmaceutical science, Yunnan Baiyao needs some other different dosage forms to fulfil the demands of the application. In recent year, Yunnan Baiyao developed its dosage forms and clinical used, by cooperating with pharmaceutics,and produce powder, plasters, tincture , paste, aerosol.

Method : Use UPLC to test the components in the different dosage forms of Yunnan Baiyao, which are powder, plasters, tincture , paste, aerosol, to investigate the coherence between the different dosage forms of Yunnan Baiyao.

Result: The ingredient of Yunnan Baiyao is a secret, but notoginseng is reported as the main component in its formulation by the drugs description of Yunnan Baiyao. UPLC could be used to investigate some ingrediants in different dosage forms of Yunnan Baiyao.
The active ingredient of notoginseng is notoginsenoside. Based on the single factor consideration, experimental condition was measured in the order of, 1. the polarity of mobile phase. 2. Concentration of gradient of mobile phase. 3. extraction conditions of Yunnan Baiyao. 4. extraction method of Yunnan Baiyao. 5. Macroporous Adsorption Resin for extraction.

Discussion: Because of many ingredients of Yunnan Baiya with, lower solubility in some different solvents, the precipitation was used to remove the impurity for separation. In the future, multiple factor consideration is necessary to be used choosing the analysis condition. On the other hand, organic solvent petroleum ether is flammable , explosive solvent, Macroporous Adsorption Resin should be used to separate the ingredients of Yunnan Baiyao, it is a cheaper and safety method.

Key word: : Yunnan Baiyao, plasters, tincture , paste, aerosol. UPLC

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