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Certificate for New Medicine and Approval for Putting into Production  
(94)Z-76

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Name of the new medicine                      Shuanghuanlian powder

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Category                                      The 4th, powder in ampule for injection, 600 mg

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The unit developed the medicine                      Harbin Second Traditional Chinese Medicine Factory

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The unit applied for production                      ditto

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File No. of the application                      (93)Heyaoshenchan No.12

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Date of application                              1993.7.3

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Conclusion of examination                      It is approved for production after our examination. The standard shall be further improved in the criterion for quality. The content of glucoside of scutellaria baicalensis and chlorogenic acid in herb, semi-finished product and the product should be further studied, so as to assure the accuracy of the prescription and the uniformity of the product. Suggest to add the measurement of the material leached out, so as to improve the standard for the injection.

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No. of New Medicine certificate                      (94)WYZ-66

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No. of ratification                              (94)WYZAHUN-73

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Duration of protection                      Three years, from 1994.10.25. to 1997.10.11

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Sent to    Heilongjiang Provincial Public Health Department

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Copy for

The Pharmacopeia Society under the Public Health Ministry, Chinese Drugs and Bio - products Examination Institute, Department of Public Health and Medicine Examination Institute of All the Provinces and Harbin Second Chinese Traditional Medicine Factory

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Dated:1994.10.12

Ministry of Public Health  
of

The People's Republic of China  
(The Seal)

# 中华人民共和国卫生部

## 新 药 证 书 及 生 产 批 件

(94)Z-76号

新药名称	正式品名:双黄连粉针剂 拉丁名: 汉语拼音:Shuanghuanlian Fenzheji				
类 别	中药第四类	剂 型	粉针剂	规 格	600mg
研究单位	哈尔滨中药二厂				
申请生产单位	哈尔滨中药二厂				
申请编号	(93)黑药申产字第12号	申请日期	1993年7月3日		
审评结论	经审查,同意批准生产。标准试行期间,进一步完善质量标准。继续研究黄芩甙、绿原酸在药材、半成品、成品间量的关系,以保证处方的准确性和成品的稳定性。建议增加某溶剂浸出物的量测以提高注射剂的标准水平。				
新药证书编号	(94)卫药证字8-66号				
批准文号	(94)卫药准字Z-73号				
保护期	3年,自1994年10月12日至1997年10月11日				
附 件	双黄连粉针剂质量标准及使用说明书				
主送单位	黑龙江省卫生厅				
抄送单位	卫生部药典会,中国药品生物制品检定所,黑龙江省(自治区、直辖市)卫生厅(局)及药品检验所,中国人民解放军总后勤部卫生部药品检验所,哈尔滨中药二厂				

