Preparation Process and Quality Standard of Rougan Huaxian Ointment

Xianyi SHI, Li LONG, Yinghong HUANG, Jiangcun WEI, Bing QING, Wen ZHONG*

Guangxi International Zhuang Medicine Hospital, Nanning 530201, China

Abstract [**Objectives**] To establish the preparation process and quality standard of Rougan Huaxian ointment. [**Methods**] The $L_9(3^4)$ orthogonal test was employed to optimize the preparation process by considering the multiplication of water addition, extraction time, and extraction frequency as influencing factors. The dry paste yield was utilized as the evaluation criterion, in conjunction with the actual production conditions. Thin layer chromatography was employed to identify Radix Astragali, Lycii Fructus, Herba Dendrobii, and Rhizoma Polygoni Cuspidati. Ethanol served as the solvent for the determination of ethanol-soluble extractives using the cold immersion method. [**Results**] The preparation process was conducted as follows: the specified quantity of medicinal materials was combined with water for extraction purposes, performed in two separate stages. In each stage, eight times the amount of water was added. The first extraction lasted for 1.5 h, while the second extraction was completed in 1.0 h. The resulting liquid was then concentrated into a thick paste with a relative density ranging from 1.25 to 1.30 at a temperature of 60 ℃. The thin-layer chromatography analysis of Radix Astragali, Lycii Fructus, Herba Dendrobii, and Rhizoma Polygoni Cuspidati demonstrated distinct spots, effective separation, and the absence of interference from negative samples. Additionally, the ethanol-soluble extractives yielded a minimum of 8.0% in terms of dry weight. [**Conclusions**] The preparation process for Rougan Huaxian ointment is both stable and feasible. Furthermore, the quality standards established for this preparation are unique and reproducible, thereby facilitating effective quality control.

Key words Rougan Huaxian ointment, Preparation process, Quality standard, Orthogonal test, Thin-layer chromatography

1 Introduction

The formulation of Rougan Huaxian ointment is derived from the clinical experience of the Department of Spleen, Gastroenterology, and Hepatology at Guangxi International Zhuang Medicine Hospital. This ointment comprises 11 traditional Chinese medicinal ingredients, including Radix Astragali, Lycii Fructus, Herba Dendrobii, *etc.* It is purported to possess various therapeutic effects, such as nourishing yin, softening the liver, tonifying the kidney, strengthening the spleen, and promoting qi to facilitate water movement, activating blood circulation, alleviating blood stasis, and detoxifying harmful substances. Therefore, Rougan Huaxian ointment may be utilized in the management of hepatitis B, liver cirrhosis, hepatocellular carcinoma, and other chronic liver diseases[1-2]. The formula was initially utilized in clinical settings as a water decoction; however, this method presented challenges for patients in terms of consumption and portability. Consequently, the formula was reformulated into a single-dose, bagged decoction of ointment. To standardize the extraction process of the preparation, enhance production efficiency, ensure the quality of the formulation, and meet the clinical demands for pharmaceuticals, this study integrated the characteristics of the soft extract dosage form, and identified the optimal preparation process for Rougan Huaxian ointment. Grounded in the compatibility of prescription formulation, the study focused on the monarch drug Radix Astragali, alongside the ministerial drugs Lycii Fructus and Herba Dendrobii, as well as the adjuvant Rhizoma Polygoni Cuspidati. Furthermore, it established quality control standards for Rougan Huaxian ointment in accordance with the relevant provisions outlined in the 2020 edition of the *Chinese Pharmacopoeia*.

Received: September 16, 2024 Accepted: November 28, 2024

Supported by Guangxi Key R&D Programme Project (GK AB21196057); National Old Pharmacist Inheritance Studio Construction Project.

* Corresponding author. E-mail: 261822212@qq.com

2 Materials

2.1 Medicinal materials Radix Astragali (20230701), Lycii Fructus (20230202), steamed Rhizoma Polygonati (20230301), Concha Ostreae (20230201), vinegared Trionycis Carapax (20230101), Rhizoma Polygoni Cuspidati (20230601), fried Semen Coicis with bran (20230801), Ycopi Herba (20220902), Endothelium Corneum Gigeriae Galli (20230701), and Jujubae Fructus (20230502) were procured from Guangxi Xianzhu Traditional Chinese Medicine Co., Ltd. Additionally. Herba Dendrobii (23070706) was acquired from Guangxi Jointown Pharmaceutical Co., Ltd.

2.2 Reference materials All reference materials, including dendrophenol (batch No.:111875-201202), Radix Astragali (*Astragalus membranaceus* var. *mongholicus*, batch No.: 120974-201612), Lycii Fructus (batch No.:121072-201611), and Rhizoma Polygoni Cuspidati (batch No.:120980-201706), were procured from the National Institutes for Food and Drug Control.

2.3 Reagents and drugs Rougan Huaxian ointment was formulated by the Zhuang and Yao Medicine Preparation Centre at Guangxi International Zhuang Medicine Hospital, with batch No.: 230901, 230902, and 230903. All chemical reagents utilized in the study were of analytical grade purity.

2.4 Experimental instruments The DHG-9145A electric blast drying oven was manufactured by Shanghai Yiheng Scientific Instrument Co., Ltd. The HWS-26 electro-thermostatic water bath was produced by Shanghai Qixin Scientific Instrument Co., Ltd. The ZF-7N intelligent dark box three-purpose ultraviolet analyzer

was developed by Shanghai Jiapeng Technology Co., Ltd. The ME204 analytical balance was produced by Mettler Toledo Instrument Co., Ltd., while the JJ2000B electronic balance was manufactured by Changshu G&G Measurement Plant.

3 Results and analysis

3.1 Optimization of the extraction process

3.1.1 Determination method of dry paste rate[3-4]. Following the cooling of the extracted liquid, a measuring cylinder was employed to determine the volume, ensuring thorough mixing. Subsequently, 50 mL of the liquid was precisely absorbed and transferred to an evaporating dish, which was then dried to a constant weight. The sample was evaporated in a water bath and subsequently placed in an electric blast drying oven at 105 ℃ for 5 h. After this period, the sample was transferred to a desiccator and allowed to cool for 30 min. It was then weighed precisely and subjected to an additional drying period at 105 ℃ for 1 h. The sample was allowed to cool again and weighed repeatedly until the difference between two consecutive measurements did not exceed 5 mg. The dry paste rate was calculated using the following formula.

Dry paste rate (%) = (Weight of dry paste × Total volume of the liquid)/(Total weight of medicinal materials × Sampling volume) × 100%

3.1.2 Design of factor levels. In accordance with the relevant literature[5-6], the multiplication of water addition (A), extraction time (B), and extraction times (C) were selected as the key influencing factors for the formulation of Rougan Huaxian ointment. The extraction process was optimized utilizing an $L_9(3^4)$ orthogonal experimental design. The factor level design for the experiment is presented in Table 1.

Table 1 Factor levels of the extraction process

Level	Factor		
	Multiplication of water addition (A)	Extraction time (B)//h	Extraction frequency (C)//times
1	6	0.5	1
2	8	1.0	2
3	10	1.5	3

3.1.3 Orthogonal test. The dry paste rate served as the evaluation indicator for this study. The experiment was conducted in accordance with an orthogonal test arrangement, and the extraction process was optimized based on the findings from visual analysis (Table 2) and the analysis of variance (Table 3) pertaining to the evaluation indicators. The results indicated that extraction frequency (C) significantly influenced the dry paste rate ($P<0.05$). In contrast, the multiplication of water addition (A) and extraction time (B) did not demonstrate a significant effect on the dry paste rate ($P>0.05$). The order of factors impacting the dry paste rate was established as follows: C > B > A, indicating that extraction frequency had the greatest effect, followed by extraction time, and finally, the multiplication of water addition. Based on the findings from the intuitive analysis, the optimal parameters for the extraction process were determined to be $A_3B_3C_3$, which corresponded to the addition of 10 times the amount of water and three extraction cycles of 1.5 h each.

Table 2 Orthogonal test results of the extraction process

No.	Factor				Dry paste rate//%
	A	B	C	D (blank)	
1	1	1	1	1	16.08
2	1	2	2	2	25.20
3	1	3	3	3	28.95
4	2	1	2	3	24.34
5	2	2	3	1	28.25
6	2	3	1	2	20.62
7	3	1	3	2	28.25
8	3	2	1	3	20.90
9	3	3	2	1	26.51
K_1	23.41	22.89	19.20	23.61	
K_2	24.40	24.78	25.35	24.69	
K_3	25.22	25.36	28.48	24.73	
R	1.81	2.47	9.28	1.12	

Table 3 Analysis of variance of orthogonal test results

Source of error	*SS*	*f*	*S*	*F*	*P*
A	4.93	2.00	2.46	2.05	>0.05
B	10.02	2.00	5.01	4.16	>0.05
C	133.82	2.00	66.91	55.58	<0.05
Error	2.41	2.00	1.20	–	–

3.1.4 Validation of the extraction process. The production of the preparation must also take into account economic factors, particularly in terms of energy conservation and cost-effectiveness. In reference to the pertinent literature[7], it is recommended that the extraction process should be conducted as follows: the specified quantity of medicinal materials should be combined with eight times the volume of water for two extraction phases. The first extraction should last for 1.5 h, while the second extraction should be conducted for 1.0 h. This study compared the proposed process combination with the optimal process combination for verification purposes. The results indicated that the dry paste rate obtained from the optimal process combination was 30.17%, while the dry paste rate derived from the proposed process combination was 26.61%. The difference between the two rates was minimal (Table 4). In comparison to the optimal process combination, the proposed process combination demonstrated a reduction in the extraction frequency, a decrease in extraction time, lower energy consumption, and enhanced adaptability to actual production conditions. Consequently, the extraction process for this product was established as follows: the specified quantity of medicinal materials was subjected to two extraction cycles, with each cycle involving the addition of eight times the amount of water. The first extraction lasted for 1.5 h, while the second extraction was conducted for 1.0 h.

Table 4 Validation results of the extraction process

Process combination	Dry paste rate//%			Mean	*RSD*//%
	1	2	3		
Optimal process	30.22	30.52	29.77	30.17	1.25
Proposed process	26.30	26.70	26.84	26.61	1.05

3.2 Investigation of the concentration process The 2020 edition of the *Chinese Pharmacopoeia* mandates the assessment of the relative density of the soft extract. A high relative density indicates low water content and poor fluidity, which can hinder the filling process. Conversely, a low relative density suggests high water content, resulting in a diluted extract that is unsuitable for molding[8]. The extraction was performed in accordance with the procedure outlined in Section **3.1**. The drug solution was filtered and subsequently concentrated to the extract with a specific relative density. The extract was then weighed, its properties were observed, and it was formulated into a single dose administered twice daily. Finally, the appropriate relative density was established. The paste exhibiting a relative density ranging from 1.23 to 1.31 demonstrated favorable properties, facilitating ease of filling and possessing an appropriate single dosage (Table 5). In conjunction with actual production practices, the concentration for the process was established as follows: the filtrate was concentrated into a thick paste with a relative density between 1.25 and 1.30 at a temperature of 60 ℃.

Table 5 Comparative results of extracts with different relative densities

No.	Relative density (60 ℃)	Extract weight//g	Property	Single dosage//g
1	1.12	98.68	Relatively thin, good fluidity, ease of filling, absence of ointment	49.34
2	1.23	70.34	Slightly viscous, good fluidity, ease of filling	35.17
3	1.31	58.75	Viscous, good fluidity, capable of filling	29.38
4	1.38	45.42	Highly viscous, poor fluidity, difficult for filling	22.71

3.3 Validation of the preparation process Through the investigation of the extraction and concentration processes, the following preparation process was established: the specified quantity of medicinal materials should be combined with eight times the volume of water for two extraction phases. The first extraction was conducted for 1.5 h, followed by a second extraction lasting 1.0 h. Subsequently, the liquid was filtered, and the resulting filtrate was concentrated into a thick paste with a relative density ranging from 1.25 to 1.30 at 60 ℃. This paste was then filled and sterilized, resulting in the final product. According to the outlined preparation process, the production of three batches (batch No.: 230901, 230902, and 230903) was scaled up for the purpose of conducting a quality standard study. The yield rates of the pilot samples from these three batches exceeded 90% (Table 6), which suggests that the aforementioned production process is both reasonable and feasible for the preparation of Rougan Huaxian ointment.

Table 6 Pilot test results of three batches of Rougan Huaxian ointment

Batch No.	Total feeding volume//kg	Amount of thick paste//kg	Theoretical amount//kg	Theoretical yield//bag	Actual yield//bag	Yield rate//%
230901	123.12	36.45 (Relative density 1.30, 60 ℃)	36.00	1 200	1 115	92.92
230902	123.12	37.28 (Relative density 1.26, 60 ℃)	36.00	1 200	1 127	93.92
230903	123.12	37.06 (Relative density 1.27, 60 ℃)	36.00	1 200	1 135	94.58

3.4 Quality standards research

3.4.1 Thin-layer chromatographic identification. (i) Preparation of test solution. 5.0 g of the product was accurately weighed and subsequently dissolved in 50 mL of heated water. Following the dissolution, the solution was allowed to cool, after which 30 mL of petroleum ether (60 – 90 ℃) was added for the purpose of extraction. The petroleum ether layer was then discarded, and the aqueous layer underwent a two-step extraction process with ethyl acetate, utilizing 25 mL of ethyl acetate for each extraction. The ethyl acetate layers were combined and evaporated to dryness. The resulting residue was dissolved in 1 mL of methanol to prepare the test solution.

(ii) Preparation of reference medicinal material solution. Accurately 1 g of reference medicinal material, specifically Radix Astragali, Lycii Fructus, and Rhizoma Polygoni Cuspidati, was each combined with 50 mL of water. Reflux extraction was performed for 30 min, after which the mixture was allowed to cool and subsequently filtered. The filtrate underwent treatment using the same method as previously described. The resulting residue was then dissolved in 1 mL of methanol to prepare the reference medicinal material solution.

(iii) Preparation of reference solution. 0.2 mg of dendrophenol reference was accurately weighed and subsequently dissolved in 1 mL of methanol to prepare the reference solution.

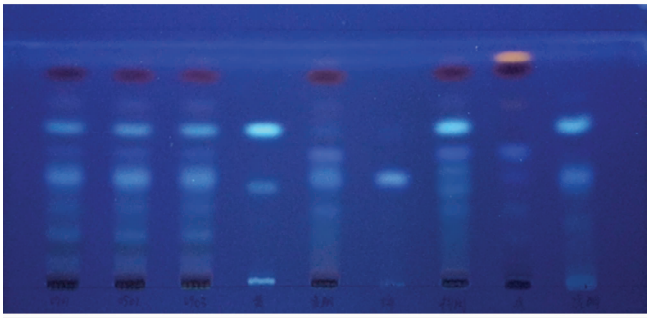
(iv) Preparation of negative sample solution. In accordance with the prescribed ratio for this product, negative samples devoid of Radix Astragali, Lycii Fructus, Herba Dendrobii, and Rhizoma Polygoni Cuspidati were prepared and subsequently weighed to formulate the negative sample solution.

(v) Identification methods. A quantitative capillary tube was utilized to draw up 3 – 5 μL of the test solution, 1 – 2 μL of each reference medicinal material solution, specifically Radix Astragali, Lycii Fructus, and Rhizoma Polygoni Cuspidati, as well as 3 – 5 μL of their negative sample solution. These samples were subse-

quently spotted onto a single silica gel G thin-layer plate and developed using a mobile phase composed of petroleum ether (60 – 90 ℃), ethyl acetate, and formic acid in a ratio of 15 ∶ 10 ∶ 1. Following development, the plate was removed, air-dried, and subjected to ammonia vapor fumigation until a color change was observed, after which it was taken out for further analysis. The identification of Radix Astragali was conducted using a UV lamp with a wavelength of 254 nm. In contrast, Lycii Fructus was identified under a UV lamp with a wavelength of 365 nm, while Rhizoma Polygoni Cuspidati was examined using a fluorescent lamp.

5 – 10 μL of the test solution, 5 – 10 μL of the Herba Dendrobii negative sample solution, and 3 – 5 μL of the dendrophenol reference solution were absorbed using a quantitative capillary and subsequently spotted onto the same silica gel G thin-layer chromatography plate. These samples were developed using a mobile phase composed of petroleum ether (60 – 90 ℃), ethyl acetate, and formic acid in a ratio of 15 ∶ 10 ∶ 1. Following the development process, the plate was removed and allowed to air dry. It was then sprayed with a 10% sulfuric acid ethanol solution and placed in a drying oven at 105 ℃ until the spot color became clear. Subsequently, the plate was removed for inspection under daylight lamp.

(vi) Identification results. The chromatographic analysis of the test material revealed a distinct color spot at the same position as observed in the chromatograms of Radix Astragali, Lycii Fructus, and Rhizoma Polygoni Cuspidati. In contrast, the chromatograms of the negative samples of Radix Astragali, Lycii Fructus, and Rhizoma Polygoni Cuspidati did not exhibit this spot, as illustrated in Figs. 1 – 3. These findings suggest that the method demonstrates a high degree of exclusivity, with no interference from negative samples, thereby confirming its suitability for the simultaneous identification of Radix Astragali, Lycii Fructus, and Rhizoma Polygoni Cuspidati.



NOTE 1. Test material (batch No. : 230901); 2. Test material (batch No. : 230902); 3. Test material (batch No. : 230903); 4. Radix Astragali reference medicinal material; 5. Radix Astragali negative sample; 6. Lycii Fructus reference medicinal material; 7. Lycii Fructus negative sample; 8. Rhizoma Polygoni Cuspidati reference medicinal material; 9. Rhizoma Polygoni Cuspidati negative sample. The same as Figs. 2 – 3.

Fig. 1 Thin-layer identification chromatogram of Radix Astragali (UV lamp at 254 nm)

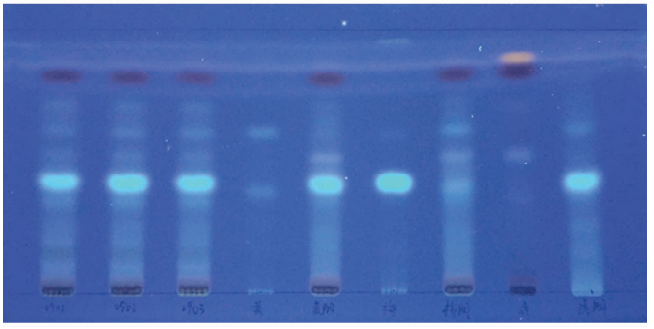


Fig. 2 Thin-layer identification chromatogram of Lycii Fructus (UV lamp at 365 nm)

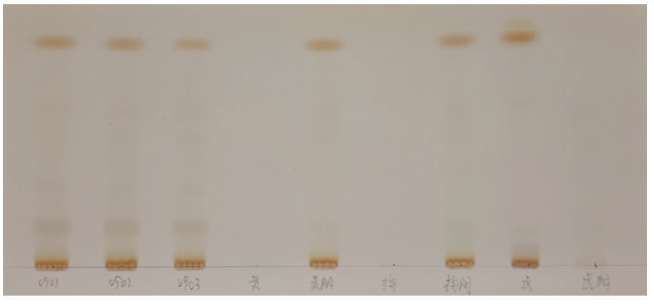
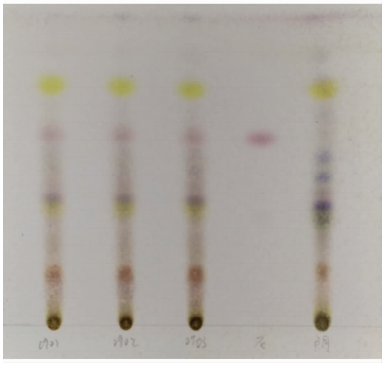


Fig. 3 Thin-layer identification chromatogram of Rhizoma Polygoni Cuspidati (daylight lamp)

The chromatogram of the test sample exhibited a color spot at the same position as that observed in the chromatogram of the dendrophenol reference. In contrast, the chromatogram of the negative sample of Herba Dendrobii did not display this spot, as illustrated in Fig. 4. These findings suggest that the method is specific, with no interference from negative samples, thereby confirming its suitability for the identification of Herba Dendrobii



NOTE 1. Test material (batch No. : 230901); 2. Test material (batch No. : 230902); 3. Test material (batch No. : 230903); 4. Dendrophenol reference; 5. Herba Dendrobii negative sample.

Fig. 4 Thin-layer identification chromatogram of Herba Dendrobii

3.4.2 Determination of extractives. Rougan Huaxian ointment was dried to a constant weight, subsequently crushed, and sieved using a No. 2 sieve. A suitable quantity of the dry paste powder was then selected to assess the content of ethanol-soluble extractives through the cold immersion method, utilizing ethanol as the solvent, in accordance with the 2020 edition of *Chinese Pharmacopoeia* (volume IV)[9]. The ethanol-soluble extractive content of

three batches of Rougan Huaxian ointment was found to range from 12.77% to 15.71% (Table 7). Given the variability in extractive content associated with the use of different batches of medicinal materials, it is imperative to implement quality control measures for mass-produced formulations. Based on the experimental data obtained from extractive determination and in consideration of the practical aspects of production, it was established that the content of ethanol-soluble extractives in Rougan Huaxian ointment should not fall below 8.0% (calculated on a dry product basis).

Table 7 Determination results of extractives from Rougan Huaxian ointment

Batch No.	Sampling amount//g	Extractive content//%	Mean//%	*RSD*//%
230901	4.015 8	12.77	12.77	1.23
	4.023 5	12.61		
	4.041 7	12.93		
230902	4.003 3	15.74	15.38	2.13
	4.021 5	15.32		
	4.015 6	15.09		
230903	4.046 4	15.85	15.71	1.83
	4.035 3	15.38		
	4.010 6	15.90		

4 Discussion

4.1 Selection of dosage form The formulation of Rougan Huaxian ointment comprises 11 traditional Chinese medicinal ingredients, resulting in a substantial prescription volume and a denser paste during extraction. The preparation of dosage forms such as pills and granules necessitates the incorporation of excipients, which can pose challenges due to the large individual dosage. It has been observed that the soft extract exhibits advantages including ease of portability, controllable quality, minimal adverse reactions, and high patient compliance[10]. Furthermore, the soft extract in single-dose packaging has transformed the conventional multi-dose containers, such as cans or bottles. This new packaging is characterized by its smaller size, resistance to extrusion, enhanced stability, and greater convenience for transport and long-term storage, thus offering improved economic and social benefits[11]. Consequently, this study opted to formulate the Rougan Huaxian ointment as a soft extract in single-dose bags.

4.2 Innovations in thin-layer chromatography Thin-layer chromatography is extensively employed in the identification of traditional Chinese medicines due to its advantages of straightforward operation, rapid analysis, and high specificity. However, the majority of thin-layer identification methods outlined in the 2020 edition of the *Chinese Pharmacopoeia* and the China National Knowledge Infrastructure (CKNI) predominantly utilize a single method for the identification of each type of medicine. This approach necessitates the development of multiple methods to achieve comprehensive thin-layer identification for a single traditional Chinese medicine compound preparation, ultimately leading to reduced detection efficiency[12-16]. Additionally, the majority of the developing agents employed in thin-layer chromatography are toxic organic solvents, which can inflict varying degrees of harm to both the human body and the environment[17]. Consequently, the development of a thin-layer identification method aimed at the simultaneous identification of multiple pharmaceuticals, with the objective of conducting a single test for various medications, has emerged as a recommended and promoted research direction in the investigation of new traditional Chinese medicines[18]. The experiment adhered to the compatibility of traditional Chinese medicine prescription, focusing on the monarch drug Radix Astragali, the ministerial drugs Lycii Fructus and Herba Dendrobii, and the adjuvant Rhizoma Polygoni Cuspidati as the primary subjects of investigation. The study analyzed the active ingredients of each medicinal component and their thin-layer chromatography by consulting relevant literature[19-27]. Furthermore, it established a thin-layer chromatography protocol for the prescription comprising Radix Astragali, Lycii Fructus, Herba Dendrobii, and Rhizoma Polygoni Cuspidati. This was achieved by employing a consistent method for test solution treatment and utilizing the same unfolding agent system, while simultaneously changing the color development and detection methods.

4.3 Selection of extractive determination methods Most traditional Chinese medicinal preparations are characterized as compound formulations, which represent a coordinated assembly of multiple components. Consequently, assessing the quality of these preparations based solely on the concentration of a single component presents certain limitations. Extractive content represents a significant class of substances within the formulation of traditional Chinese medicinal preparations. It serves as an objective measure of the quality of these preparations and is a critical indicator for quality control. Particularly for Chinese traditional patent medicines characterized by complex compositions and ambiguous active components, the determination of extractive content holds considerable practical importance[28]. This product is an aqueous extract concrete. The aqueous extract contains a higher sugar content, which makes it less amenable to drying. Therefore, ethanol was selected as the solvent, and a cold immersion method was employed to determine the content of ethanol-soluble extractives across three batches of samples. Based on the results obtained and in conjunction with actual production practices, a lower limit for the ethanol extractive content has been established and incorporated into the draft quality standard. This measure aims to ensure the overall quality control of the Rougan Huaxian ointment.

5 Conclusions

The initial phase of the experiment focused on the preparation process of Rougan Huaxian ointment, followed by an amplified production verification. The findings indicated that the preparation process was both stable and feasible. Subsequently, the study established quality standards for the preparation. It was determined that thin-layer chromatography effectively identified four medicinal components simultaneously, demonstrating strong specificity and good reproducibility. Additionally, the method for determining ethanol-soluble extractives was found to be accurate and reliable, thereby providing a foundation for the scientific control of the ointment's quality.

(To page 28)

macology and molecular docking[J]. Hunan Journal of Traditional Chinese Medicine, 2024, 40(6): 191 - 198. (in Chinese).
[16] YANG XL, YUAN ZF, XU HJ. Studies on the flavonoid compounds of Rhododendrom micranthum [J]. Chinese Journal of Pharmaceutical Analysis, 2010, 30(9): 1750 - 1752. (in Chinese).
[17] YAN HM. Study on chemical constituents and preliminary screening of pharmacological activities of *Rhododendron micranthum* [D]. Shijiazhuang: Hebei Medical University, 2017. (in Chinese).
[18] LI R, LI J. Advances in pharmacological research and structure-activity relationship of flavonoids[J]. Anhui Medical and Pharmaceutical Journal, 2005, 9(7): 481 - 483. (in Chinese).
[19] HAO L, XIA YQ, LIU J. Research of prescription rules of professor Xia Yuqing for lung cancer based on data Mining and network pharmacology [J]. Traditional Chinese Medicinal Research, 2024, 37(7): 59 - 64. (in Chinese).
[20] CHEN Y, WANG Z, FU HD, *et al*. Research progress of Src protein kinase[J]. Journal of Liaoning University: Natural Sciences Edition, 2023, 50(4): 359 - 365. (in Chinese).
[21] MA WP, LI X, LIU M, *et al*. Exploring the mechanism of Haimufang Decoction in the treatment of non-small cell lung cancer based on network pharmacology and serum pharmacology[J]. Chinese Journal of Modern Applied Pharmacy, 2024, 41(13): 1781 - 1789. (in Chinese).

(From page 22)

References

[1] WU SS, WANG ZC, LU YH, *et al*. Clinical efficacy observation of Rougan Huaxian Jiedu Formula in treating primary hepatic carcinoma syndrome after TACE[J]. China Journal of Traditional Chinese Medicine and Pharmacy, 2021, 36(5): 3038 - 3041. (in Chinese).
[2] JIANG JE, WANG ZC, CHEN DD, *et al*. Brief analysis of WANG Zhenchang's experience in treatment of cirrhosis[J]. Liaoning Journal of Traditional Chinese Medicine, 2021, 48(8): 36 - 38. (in Chinese).
[3] TIAN MX, NI CR, ZHOU HL, *et al*. Optimization of the extraction process of Kunkuai Baoshen Granules[J]. Chinese Traditional Patent Medicine, 2023, 45(12): 4066 - 4070. (in Chinese).
[4] ZHANG WX, CHEN SH, ZHU TM, *et al*. Preparation technology for Wenyang Tongbian granules[J/OL]. Central South Pharmacy, 2024, 22(10): 2623 - 2627. (in Chinese).
[5] SHEN L, WU JJ, YI HZ, *et al*. Optimization of the extraction process of Jian'gao of Sijunzi Decoction by multi-index orthogonal test method[J]. Zhejiang Journal of Traditional Chinese Medicine, 2014, 49(11): 852 - 854. (in Chinese).
[6] LI XJ, WU L, TANG N, *et al*. Study on extraction technology and taste of Wuzang Wenyang Huayu Decoction agent by orthogonal test[J]. Inner Mongolia Journal of Traditional Chinese Medicine, 2018, 37(12): 95 - 97. (in Chinese).
[7] NIU JE, WU GT, DU LD, *et al*. Preparation technology and quality standard of Dangguirunchang paste[J]. Science and Technology of Food Industry, 2019, 40(13): 107 - 112, 140. (in Chinese).
[8] YUAN JC, GAO XJ, ZHOU QM. Investigation of indexes in quality control of decocted extract[J]. Chinese Journal of Experimental Traditional Medical Formulae, 2013, 19(1): 51 - 53. (in Chinese).
[9] The Pharmacopoeia Commission of the People's Republic of China. Pharmacopoeia of the People's Republic of China: Volume IV[S]. Beijing: China Medical Science Press, 2020: 232. (in Chinese).
[10] LI ZY, GUO DL, LIU Y, *et al*. Research progress on traditional Chinese herbal paste[J]. Journal of Pharmaceutical Research, 2020, 39(10): 597 - 600. (in Chinese).
[11] JIANG XY. Investigation on some stability indicators of small package Chinese medicine decocted paste[J]. Guiding Journal of Traditional Chinese Medicine and Pharmacy, 2015, 21(11): 51 - 52. (in Chinese).
[12] The Pharmacopoeia Commission of the People's Republic of China. Pharmacopoeia of the People's Republic of China: Volume I[S]. Beijing: China Medical Science Press, 2020. (in Chinese).
[13] WU Y, HUANG CY, LEI C, *et al*. Establishment of preparation process and quality standard for Ruanjian Sanjie Granules[J]. Chinese Traditional Patent Medicine, 2024, 46(4): 1118 - 1125. (in Chinese).
[14] LIU SY, JIA YX, WANG YJ, *et al*. Studies on preparation technology and quality standards research of Anshen granules[J]. Lishizhen Medicine and Materia Medica Research, 2023, 34(5): 1122 - 1125. (in Chinese).
[15] LIU M, ZHANG MY, WU YX, *et al*. Preparation and quality standard for Shenhuo Wuwei Granules[J]. Chinese Traditional Patent Medicine, 2022, 44(7): 2107 - 2114. (in Chinese).
[16] YANG YJ, ZOU JB, ZHANG XF, *et al*. Research on the preparation process and TLC of Xuanyunfang granules[J]. West China Journal of Pharmaceutical Sciences, 2021, 36(2): 163 - 168. (in Chinese).
[17] DENG Z, JING WG, LIU A. Discussion about application of thin layer chromatography in current quality standard control[J]. Chinese Journal of Experimental Traditional Medical Formulae, 2019, 25(7): 201 - 206. (in Chinese).
[18] GAO YJ, TANG CH, LIN BS, *et al*. A thin layer chromatography based "One-test with Multi-drugs" identification method for benchmark material of Juanbi Decoction[J]. Modern Chinese Medicine, 2023, 25(8): 1776 - 1781. (in Chinese).
[19] WANG JJ, XIANG SX, XIE ZS, *et al*. Research progress on antifibrotic effect and molecular mechanisms of chemical components from Astragali Radix[J]. Traditional Chinese Drug Research and Clinical Pharmacology, 34(12): 1799 - 1805. (in Chinese).
[20] HOU XY, LI JT, WAN LJ, *et al*. Study on extraction process optimization and quality control method of Guiqi Yiyuan Decoction[J]. Chinese Journal of Modern Applied Pharmacy, 2023, 40(21): 2978 - 2983. (in Chinese).
[21] ZHANG M, YUE K, JIANG JH, *et al*. Research progress on pharmacological effects of Lycii Fructus and its active ingredients[J]. Drug Evaluation Research, 46(7): 1611 - 1619. (in Chinese).
[22] The Pharmacopoeia Commission of the People's Republic of China. Pharmacopoeia of the People's Republic of China: Volume I[S]. Beijing: China Medical Science Press, 2020: 260 - 261. (in Chinese).
[23] LI ZQ, ZHOU HQ, OUYANG Z, *et al*. Comparison of active ingredients and protective effects of *Dendrobium huoshanense* of different growth years on acute liver injury[J]. China Journal of Chinese Materia Medica, 46(2): 298 - 305. (in Chinese).
[24] XU L, WU JR, GUO L, *et al*. Chemical constituents from *Dendrobium nobile*[J]. Chinese Traditional Patent Medicine, 40(5): 1110 - 1112.
[25] The Pharmacopoeia Commission of the People's Republic of China. Pharmacopoeia of the People's Republic of China: Volume I[S]. Beijing: China Medical Science Press, 2020: 94 - 95. (in Chinese).
[26] HOU QY, ZHANG LL, HAO YQ, *et al*. Research progress and q-marker prediction analysis of traditional Chinese medicine *Polygonum cuspidatum*[J]. Modern Chinese Medicine, 26(5): 912 - 926. (in Chinese).
[27] GUO MH, HUANG LF, QIU L, *et al*. Identification of Ruanjian Hugan tablets and determination of its emodin[J]. West China Journal of Pharmaceutical Sciences, 30(2): 222 - 225. (in Chinese).
[28] WU Y, WU YM, WEI YJ, *et al*. Study on determination method of extract from Gushuning tablets[J]. Guangzhou Chemical Industry, 50(1): 84 - 86. (in Chinese).