Study on Quality Standards of Jianjin Zhuanggu Paste

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Abstract [**Objectives**] Some Chinese medicinal materials of Jianjin Zhuanggu Paste were microscopically identified, and several active ingredients were studied by thin-layer identification, which provides reference for further improving the quality standards of hospital preparations. [**Methods**] The effective components of Jianjin Zhuanggu Paste were qualitatively identified by thin-layer chromatography (TLC). [**Results**] The microscopic identification of the three Chinese medicinal materials in Jianjin Zhuanggu Paste showed the microscopic characteristics of Radix Codonopsis, Radix Astragali and Radix Notoginseng. TLC identification showed that there were characteristic spots of Radix Codonopsis, Radix Astragali, Radix Rehmanniae Preparata and Radix Notoginseng in Jianjin Zhuanggu Paste. [**Conclusions**] This study established the quality standard research method of Jianjin Zhuanggu Paste, which further strengthens the safety standards of hospital preparations, and improves the clinical efficacy of drugs, as well as the quality standards of hospital preparations to a certain extent.

Key words Jianjin Zhuanggu Paste; Microscopic identification; Production technique; Thin layer chromatography; Quality standard

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Jianjin Zhuanggu Paste is prepared from Radix Codonopsis, Radix Rehmanniae Preparata, Radix Astragali, Radix Notoginseng, Colla Plastrum Testudinis, Colla Cornus Cervi, *etc.* It has the functions of nourishing yin and invigorating qi and blood, and is used to treat injuries and deficiency of qi and blood. According to the prescription analysis, both Radix Astragali and Radix Codonopsis can greatly tonify qi of the spleen and lungs, and strong qi can strengthen the bones and muscles, so they are both monarch medicines. Radix Rehmanniae Preparata, nourishing blood and tendons, is a minister medicine. Radix Notoginseng, promoting blood circulation, removing blood stasis and relieving pain, is an adjuvant medicine. It is recorded in *Bencao Fenjing*[1] and *Thoroughly Revised Materia Medica*[2] that Radix Codonopsis is "sweet and neutral" and attributive to spleen and lung meridians, and it has the effects of "invigorating the middle energizer, harmonizing the spleen and stomach and relieving polydipsia" and is often used as a tonic[3]; Radix Rehmanniae Preparata is sweet in nature and slightly warm, and has the effects of enriching yin and nourishing kidney, nourishing blood and replenishing blood, and cooling blood; Radix Notoginseng is sweet, slightly bitter and warm, and has the effects of promoting blood circulation, removing blood stasis, stopping bleeding and relieving pain[4-5]; Colla Plastrum Testudinis has the effects of nourishing yin, enriching blood and stopping bleeding; and Colla Cornus Cervi is sweet and salty in taste and warm in nature, attributive to the liver and kidney meridians[6], and often used to treat kidney deficiency, deficiency of essence and blood, and infertility due to cold[7]. Traditional Chinese herbs and some auxiliary materials in the prescription are made into decoction paste to further enhance the functions of nourishing yin and tonifying qi and blood. Therefore, an in-depth study was conducted on Jianjin Zhuanggu Paste to establish the research method for its quality standards, and improve the clinical efficacy and bioavailability of the preparation.

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Materials and Methods

Experimental materials

Medicinal materials: Radix Codonopsis (production batch number: 210307, manufacturer: Guangxi Zhongsen Traditional Chinese Medicine Pharmaceutical Co., Ltd.); Radix Astragali (production batch number: 20210802, manufacturer: Guangxi Xianzhu Chinese Medicine Science and Technology Co., Ltd.); Radix Rehmanniae Preparata (processed product of *Rehmannia glutinosa*, production batch number: 201027, manufacturers: Guangxi Zhongsen Traditional Chinese Medicine Pharmaceutical Co., Ltd.); Radix Notoginseng (production batch number: M200701, manufacturer: Guangdong Lianfeng Traditional Chinese Medicine Pieces Co., Ltd.); Colla Plastrum Testudinis (production batch number: 2020102, manufacturer: Henan Furentang Pharmaceutical Co., Ltd.); and Colla Cornus Cervi (production batch number: 2010252029, manufacturer: Hubei Kangyuan Pharmaceutical Co., Ltd.). All the above medicinal materials met the quality requirements of Chinese Pharmacopoeia (2020 edition, Part I).

Edible auxiliary materials: maltose (production license number: SC12345040300312, manufacturer: Guangxi Wuzhou Lehaha Food Industry Co., Ltd.).

Lobetyolin reference substance (Chengdu Must Bio-technology Co., Ltd., batch number: MUST-21061005, purity: ≥99.57%);

verbascose (Chengdu Must Bio-technology Co., Ltd., batch number: MUST-21092315, purity: ≥ 98.73%); ginsenoside R_1 (batch number: 110745-201921); ginsenoside Rg_1 (batch number: 110703202034); notoginsenoside R_1 (batch number: 110745-201921); reference material of Radix Astragali (batch number: 120974-201311). All of the materials were provided by China National Institute for Drug Control.

Reagents and instruments

Nikon E200MV biomicroscope, manufacturer: Nanjing Nikon Jiangnan Optical Instrument Co., Ltd.; electric constant temperature water bath pot, manufacturer: Bangxi Instrument Technology (Shanghai) Co., Ltd.; JP-100 ultrasonic cleaning machine, manufacturer: Jiangxi Pengchun Trading Co., Ltd.; FA2004 electronic balance, manufacturer: Shanghai Sunny Hengping Instrument Co., Ltd.; chemical reagents such as methanol, ethanol and ethyl acetate, all of which were all analytically pure, provided by Chengdu Kelong Chemical Co., Ltd.; Laboratory water is purified water; silica gel G thin plate (100 mm × 100 mm, 10 – 40 m), Qingdao Ocean Chemical Co., Ltd.; D101 macroporous adsorption resin (refined grade), Tianjin Yongxing Chemical Reagent Factory; glass capillary, Instrument Factory of West China Medical Center, Sichuan University; qualitative filter paper 15 cm, GE Biotechnology (Hangzhou) Co., Ltd.

Experimental methods

Microscopic identification and slide-preparing method of original medicinal materials

Slide-preparing method of Radix Codonopsis A proper amount of Radix Codonopsis was ground into powder, which was put on a glass slide, onto which 1 – 2 drops of glycerol acetic acid test solution or chloral hydrate test solution were dropped to coat it evenly. The glass slide was then covered by a cover glass, and observed under a microscope. According to the microscopic results in the section of medicinal materials and decoction pieces about Radix Codonopsis in *Chinese Pharmacopoeia* (2020 edition), the authenticity of Radix Codonopsis was judged.

Slide-preparing method of Radix Astragali A proper amount of Radix Astragali was ground into powder, which was put on a glass slide, onto which 1 – 2 drops of chloral hydrate test solution were dropped to coat it evenly. The glass slide was then covered by a cover glass, and observed under a microscope. According to the microscopic results in the section of medicinal materials and decoction pieces about Radix Astragali in *Chinese Pharmacopoeia* (2020 edition), the authenticity of Radix Astragali was judged.

Slide-preparing method of Radix Notoginseng A proper amount of observation part of Radix Notoginseng, a transverse (longitudinal) piece undergone softening treatment, was cut into 10 – 20 μm slices. A flat slice was selected and put on a glass slide, onto which 1 – 2 drops of chloral hydrate test solution. The glass slide was then covered by a cover glass, and observed under a microscope. According to the microscopic results in the section of medicinal materials and decoction pieces about Radix Notoginseng in *Chinese Pharmacopoeia* (2020 edition), the authenticity of Radix Notoginseng was judged.

Preparation process Chinese herbal medicines such as Radix Codonopsis, Radix Astragali, Radix Rehmanniae and Radix Notoginseng were weighed according to amounts in the prescription and added in a decocting pot. An appropriate amount of distilled water was added, and the materials were mixed evenly. The mixture was decocted for 2 times, 2 h each time, and filtration was performed to obtain filtrates, which were combined. Colla Cornus Cervi and Colla Plastrum Testudinis were added according to amounts in the prescription, and after heating and stirring uniformly, and the liquid was concentrated to a specified relative density to obtain a clear extract. After the clear extract was cooled, a proper amount of maltose was added to make a decocted extract.

Quality standards

Thin layer chromatography (TLC) identification Six parts of Jianjin Zhuanggu Paste were prepared in parallel according to the same preparation process. According to the identification methods of effective components in the section of medicinal materials in *Chinese Pharmacopoeia* (2020 edition), Radix Codonopsis, Radix Astragali, Radix Rehmanniae Preparata and Radix Notoginseng in Jianjin Zhuanggu Paste were identified by TLC. Negative samples were prepared by the same preparation process as above, while corresponding tested medicinal material was eliminated from the prescription.

Check of relative density A proper amount of Jianjin Zhuanggu Paste was weighed accurately, and added with about 2 times of water. The obtained liquid was weighed accurately and mixed evenly as the test solution. Referring to Relative Density Determination Method (General Rule 0601) in Part Four of *Chinese Pharmacopoeia* (2020 edition), the relative density of Jianjin Zhuanggu Paste should be determined according to formula 1, and it should comply relevant regulations in the section of decocted extract.

$$\text{Relative density of test sample} = \frac{W_1 - W_1 \times f}{W_2 - W_1 \times f} \quad \text{(Formula 1)}$$

In the formula, f is calculated according to f = Weight of water in the test sample added with water/(Weight of test sample + Weight of water in the test sample added with water); W_1 is the weight (g) of the test solution in the pycnometer; and W_2 is the weight (g) of water in the pycnometer.

Check of insoluble matter Six samples of Jianjin Zhuanggu Paste were weighed, 5 g each. Next, 200 ml of hot water was added to dissolve the sample by stirring evenly. After standing for 3 min, whether there were insoluble particles such as coke chips in the aqueous solution was observed.

Microbial limit test According to Microbial Counting Method (General Rule 1105), Control Microbe Examination Methods (General Rule 1106) and Microbial Limit Standards for Non-sterile Products (1107) in the section of decocted extract in Part Four of *Chinese Pharmacopoeia* (2020 edition), microbial limit tests were carried out on Jianjin Zhuanggu Paste.

A 10 ml of Jianjin Zhuanggu Paste sample was added with

100 ml of sterile sodium chloride-peptone buffer with pH 7.0 preheated to 45 ℃ to prepare a 1 ∶ 10 test solution after mixing evenly.

Total aerobic microbial count: Into a plate, 1 ml of the 1 ∶ 10 test solution was injected, and 2 – 3 plates were prepared in parallel and determined according to corresponding method.

Total yeast and mould count: Into a plate, 1 ml of the 1 ∶ 10 test solution was injected, and 2 – 3 plates were prepared in parallel and determined according to corresponding method.

Escherichia coli: Into 100 ml of tryptone liquid culture medium, 10 ml of the 1 ∶ 10 test solution was inoculated, and *E. coli* was determined according to corresponding method.

Results and Analysis

Microscopic identification

Microscopic characteristics of three kinds of Chinese herbal medicines were observed under a microscope, and compared with the literature[8-10], which showed that the three kinds of Chinese herbal medicines were identified as microscopic identification pictures of Radix Codonopsis, Radix Astragali and Radix Notoginseng. The results are shown in Fig. 1, Fig. 2 and Fig. 3.

Microscopic identification of Radix Codonopsis Radix Codonopsis powder: The powder is light yellow. Through the biological microscope, it can be observed that stone cells were square, and the wall is not very thick. The surface of cork cells is polygonal. Reticulate vessels are apparent. The microscopic results are shown in Fig. 1.

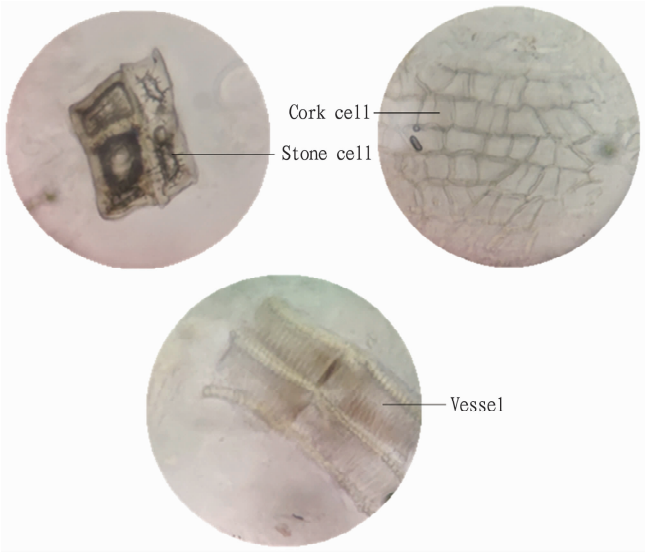


Fig. 1 Microscopic identification picture of the cross section of Radix Codonopsis

Microscopic identification of Radix Astragali Radix Astragali powder: It is yellow and white. Microscopic characteristics can be observed by a biological microscope, such as fiber bundle, thick wall, and longitudinal cracks on the surface. The primary wall is often separated from the secondary wall, and both ends are split into whiskers or relatively flat sections. Bordered pit vessels are colorless. Stone cells are rare or invisible. The microscopic results are shown in Fig. 2.

Microscopic identification of Radix Notoginseng The microscopic characteristics of the cross section of Radix Notoginseng can be observed through a biological microscope. Resin ducts are scattered in the phloem. Thin-walled cells contain a lot of starch granules and few calcium oxalate clusters. The results are shown in Fig. 3.

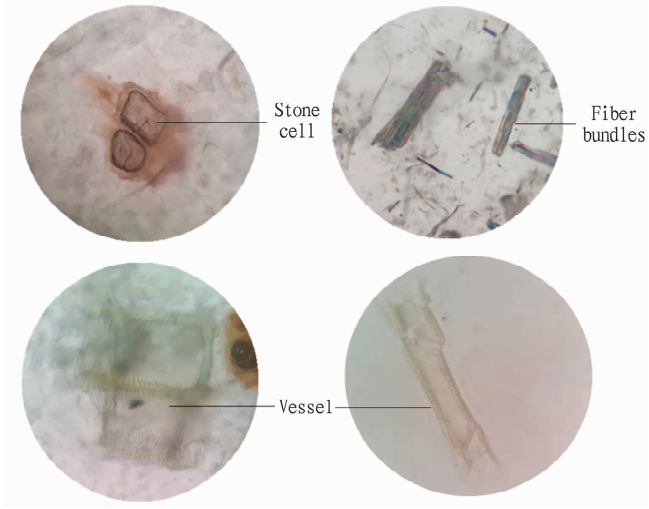


Fig. 2 Microscopic identification picture of Radix Astragali powder

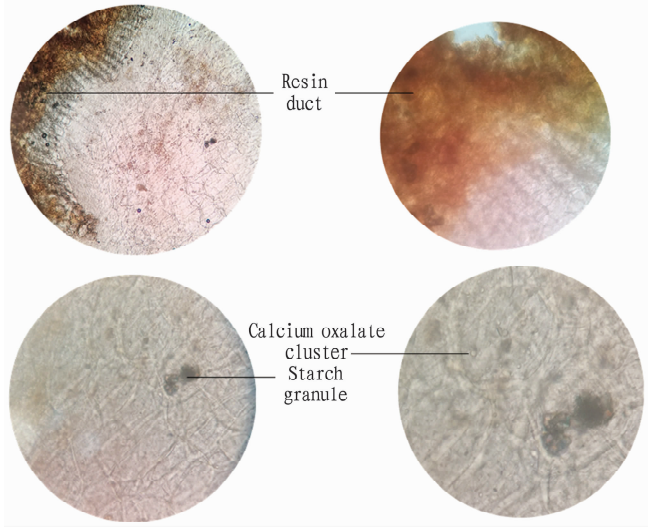


Fig. 3 Microscopic identification picture of slices of Radix Notoginseng

Quality standard results

Traits The preparation is a decocted paste, a brown thick paste, with light flavor, sweet taste and no sugar crystallization.

Identification of Radix Codonopsis by TLC

Preparation of test samples, reference sample and negative sample Six different batches of Jianjin Zhuanggu Paste samples were weighed, 5 g each, and added into triangular bottles, respectively. Next, 50 ml of methanol was added into the samples, which were ultrasonically treated for 30 min, and filtered. Each filtrate was evaporated in an evaporating dish to dryness, and

15 ml of purified water was added to dissolve the residue. The obtained liquid was loaded to a column with D101 macroporous resin (inner diameter 1.5 cm, column height 10 cm), and eluted with 80 ml of purified water and then with 80 ml of 50% EtOH to collect an eluate, which was heated in a constant-temperature water bath to dryness. The residue was added with 2 ml of methanol to obtain a test solution. Meanwhile, 5 g of negative paste (excluding Radix Codonopsis) was weighed and prepared into a negative sample by the same method. In addition, 1 mg of lobetyolin reference substance was taken, and added with 1 ml of methanol to prepare a solution with a concentration of 1 mg/ml as the reference substance solution.

TLC identification test First, 2 μl of Radix Codonopsis reference substance, 1 μl of Jianjin Zhuanggu Paste sample and 1 μl of negative sample were transferred by capillaries, respectively, onto the same silica gel G thin-layer plate. After pre-saturation, the plate was placed in a developing tank for development, using n-butanol-glacial acetic acid-water (7∶1∶0.5) as the developing agent. Next, it was taken out and air-dried, and then sprayed with 10% ethanol sulfate solution and heated at 100 ℃ until the spots were clear. Next, inspection was conducted under sunlight and ultraviolet light (365 nm) respectively. It was observed that the test solutions and the lobetyolin reference substance showed spots with the same color and fluorescence at corresponding horizontal level (R_f = 0.630 0) of the silica gel G thin-layer plate, while the negative reference sample did not show such spot at corresponding position (Fig. 4).

Identification of Radix Astragali by TLC

Preparation of test samples, reference sample and negative sample Six different batches of Jianjin Zhuanggu Paste samples were weighed, 5 g each, and added into triangular bottles, respectively. Next, 50 ml of EtOH was added into each sample, which was heated with refluxing for 20 min. Filtration was performed to obtain filtrates, which were evaporated to dryness. Subsequently, 20 ml of 0.3% NaOH solution was added into each residue to obtain a liquid, which was filtered to give a filtrate, which was then added with dilute hydrochloric acid to adjust the pH value to 5 – 6. Next, 20 ml of ethyl acetate was added for extraction in a separating funnel. Filtration was then performed with filter paper covered with an appropriate amount of anhydrous sodium sulfate, and the filtrate was evaporated to dryness. Next, the residue was dissolved with 1 ml of ethyl acetate as the test sample. Next, 2 g of Radix Astragali reference medicinal material, 2 g of Radix Astragali decoction pieces and 5 g of negative sample were weighed in turn, and prepared into a reference material sample, a positive sample and a negative sample in the same way as above, respectively.

TLC identification test First, 10 μl of Radix Astragali reference sample, 10 μl of Radix Astragali positive sample, 5 μl of Jianjin Zhuanggu Paste sample and 5 μl of negative sample were respectively transferred by capillaries onto the same silica gel G thin-layer plate, and after pre-saturation, the plate was placed in a developing tank for development, using chloroform-methanol (10∶1) as the developing agent. Subsequently, the plate was taken out and dried, and smoked with ammonia vapor and examined under an ultraviolet lamp (365 nm). In the chromatogram of test samples, a main fluorescent spot with the same color was displayed at the position (R_f = 0.714 2) corresponding to the chromatogram of the reference medicinal material (Fig. 5).

Identification of Radix Rehmanniae Preparata by TLC

Preparation of test solutions, reference solution and negative sample Six different batches of Jianjin Zhuanggu Paste samples were weighed, 5 g each, and added into triangular bottles, respectively. The weighed samples were ultrasonically treated for 30 min, and filtered to obtain filtrates, which were evaporated to dryness. Next, 10 ml of water was added to dissolve each residue, and the obtained solution was shaken and extracted with water-saturated n-butanol for 4 times, 10 ml each time. The n-butanol solutions were combined and evaporated to dryness, and the residue was dissolved with 2 ml of methanol as the test solution. Meanwhile, 5 g of negative sample was prepared by the same method as above into a negative sample. In addition, 1 mg of verbascoside reference substance was added with methanol to prepare a solution of 1 mg/ml as the reference substance solution.

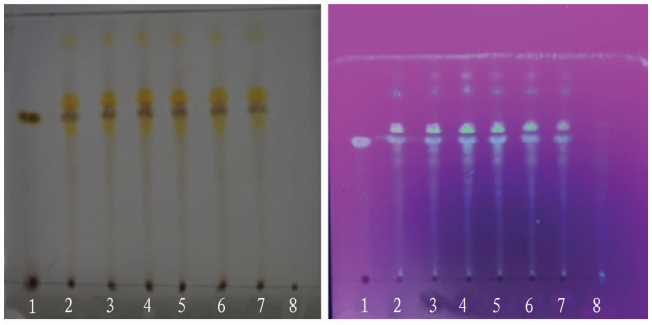
TLC identification test First, Radix Rehmanniae Preparata reference sample, Radix Rehmanniae Preparata decoction piece, six batches of Jianjin Zhuanggu Paste samples and negative sample were respectively transferred onto the same silica gel G thin-layer plate, and after pre-saturation, the plate was placed in a developing tank for development, using ethyl acetate-methanol-formic acid (16∶0.5∶2) as the developing agent. Subsequently, the plate was taken out and air-dried. After color development with 0.1% 2,2-diphenyl-1-picrylhydrazyl anhydrous ethanol solution, it was observed that the test solutions showed the same color and fluorescent spots at the horizontal level corresponding to the verbascoside reference substance and the Radix Rehmanniae Preparata reference substance (R_f = 0.528 5) on the silica gel G thin-layer plate, while the negative reference substance did not show such spot at the corresponding position (Fig. 6).

Identification of Radix Notoginseng by TLC

Preparation of test solutions, negative sample and reference solutions Six different batches of Jianjin Zhuanggu Paste samples were weighed, 5 g each, and added into triangular bottles, respectively. The weighed samples were added with an appropriate amount of water and stirred evenly, and then with 15 ml of water-saturated n-butanol. Each triangular bottle was tightly plugged and shaken for 10 min. After standing for 2 h, each liquid was centrifuged to collect a supernatant, which was added with 3 times of water-saturated n-butanol and shaken to mix well. After standing for layering, the n-butanol layer was collected and evaporated to dryness, and the residue was dissolved with 1 ml of methanol as the test solution. Meanwhile, 5 g of negative sample was prepared by the same method as above into a negative sample. In addition, 1 mg of ginsenoside Rb_1, ginsenoside Rg_1 and notoginsenoside R_1 were taken, respectively, and methanol was added in turn to make 1 mg/ml solutions as reference substance solutions.

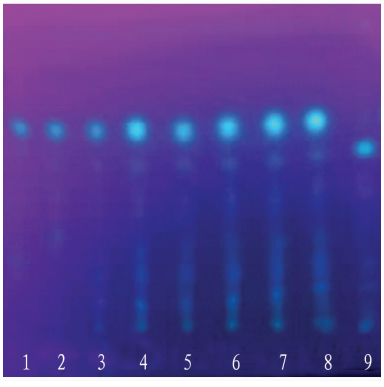
TLC identification test First, Radix Notoginseng reference samples, Radix Rehmanniae Preparata decoction pieces six batches

of Jianjin Zhuanggu Paste samples and negative sample were respectively transferred onto the same silica gel G thin-layer plate, and after pre-saturation, the plate was placed in a developing tank for development, using the solution at the lower layer of chloroform-ethyl acetate-methanol-water (15 ∶ 40 ∶ 22 ∶ 10) stood at 10 ℃ as the developing agent. Next, the plate was taken out and air-dried, sprayed with 10% sulfuric acid ethanol for color development, and then observed under an ultraviolet lamp at 365 nm. It was observed that the test solutions showed the same color and fluorescent spots on the silica gel G thin-layer plate at the horizontal level corresponding to ginsenoside Rb_1, ginsenoside Rg_1 and notoginsenoside R_1 (R_f = 0.300 0, 0.500 0, 0.400 0), but the negative control sample showed no spot at the corresponding position (Fig. 7).



1. Lobetyolin reference substance; 2 – 7. Jianjin Zhuanggu Paste samples; 8. negative paste excluding Radix Codonopsis. (The left picture shows color development with 10% sulfuric acid ethanol solution, and the right picture shows the observation result under ultraviolet at 365 nm).

Fig. 4 Thin layer chromatogram of Radix Codonopsis in Jianjin Zhuanggu Paste



1. Radix Astragali reference medicinal material; 2. Radix Astragali decoction pieces; 3 – 8. Jianjin Zhuanggu Paste samples; 9. negative paste excluding Radix Astragali.

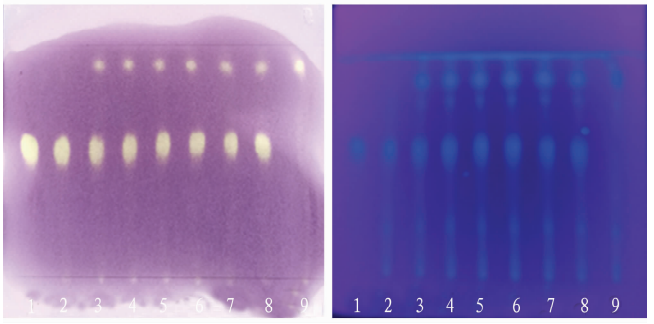
Fig. 5 Thin layer chromatogram of Radix Astragali of Jianjin Zhuanggu Paste

Relative density, insoluble matter and microbial limit test

Relative density The relative densities of six batches of samples were determined according to Relative Density Determination Method (General Rule 0601) in Part Four of *Chinese Pharmacopoeia* (2020 edition). The calculated relative densities of the decoctions were between 1.32 and 1.34, and the viscosity was moderate and the fluidity was good. The results are shown in Table 1.

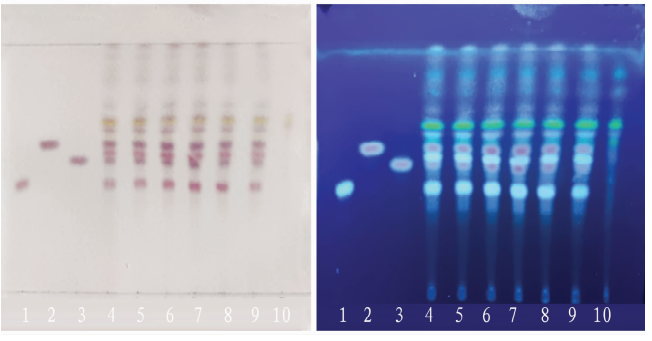
Insoluble matter Insoluble particles were not found in the samples of Jianjin Zhuanggu Paste, which met the pharmacopoeia standards.

Microbial limit test In the microbial limit test, it met the requirements. The results are shown in Table 1.



1. Verbascoside reference substance; 2. Radix Rehmanniae Preparata decoction pieces; 3 – 8. Jianjin Zhuanggu Paste samples; 9. negative paste excluding Radix Rehmanniae Preparata. (The left picture shows color development with 0.1% 2,2-diphenyl-1-picrylhydrazyl anhydrous ethanol solution, and the right picture shows the observation result under ultraviolet at 365 nm).

Fig. 6 Thin layer chromatogram of Radix Rehmanniae Preparata of Jianjin Zhuanggu Paste



1. Ginsenoside Rb1; 2. ginsenoside Rg_1; 3. notoginsenoside R_1; 4 – 9. samples of Jianjin Zhuanggu Paste; 10. negative sample of the paste containing no Radix Notoginseng. (The left picture shows color development with 10% sulfuric acid ethanol solution, and the right picture shows the observation result under ultraviolet at 365 nm).

Fig. 7 Thin layer chromatogram of Radix Notoginseng of Jianjin Zhuanggu Paste

Conclusions and Discussion

In this study, the authenticity of three kinds of raw materials in Jianjin Zhuanggu Paste was determined by microscopic identification, and corresponding microscopic characteristics were observed under a microscope. The identification results of thin layer chromatography (TLC) showed that both the test solutions and the reference substances had the same color or fluorescent spots at the same horizontal level. The properties, relative density, insoluble matter and microbial limit were examined, and the test results met the requirements, indicating that the Jianjin Zhuanggu Paste was qualified. The quality standards of Jianjin Zhuanggu Paste reported in this study are scientific and reasonable, and the data is

reliable. Therefore, they are suitable for actual production and quality control of the preparation.

Table 1 Data sheet of properties, relative density, insoluble matter and microbial limit of Jianjin Zhuanggu Paste

Batch	Property	Relative density	Insoluble matter	Microbial limit
210629	Thick brown liquid	1.32	Compliant with regulations, no foreign objects such as burnt debris	Total aerobic microbial count l ≤ 10 cfu/ml, total yeast and mould count ≤ 10 cfu/ml, *Escherichia coli*: not detected
201720	Thick brown liquid	1.34	Compliant with regulations, no foreign objects such as burnt debris	Total aerobic microbial count ≤ 10cfu/ml, total yeast and mould count ≤ 10cfu/ml, *E. coli*: not detected
210812	Thick brown liquid	1.33	Compliant with regulations, no foreign objects such as burnt debris	Total aerobic microbial count ≤ 10 cfu/ml, total yeast and mould count ≤ 10 cfu/ml, *E. coli*: not detected
210903	Thick brown liquid	1.33	Compliant with regulations, no foreign objects such as burnt debris	Total aerobic microbial count ≤ 10 cfu/ml, total yeast and mould count ≤ 10 cfu/ml, *E. coli*: not detected
210928	Thick brown liquid	1.32	Compliant with regulations, no foreign objects such as burnt debris	Total aerobic microbial count ≤ 10 cfu/ml, total yeast and mould count ≤ 10 cfu/ml, *E. coli*: not detected
211026	Thick brown liquid	1.33	Compliant with regulations, no foreign objects such as burnt debris	Total aerobic microbial count ≤ 10 cfu/ml, total yeast and mould count ≤ 10 cfu/ml, *E. coli*: not detected

Decocted extract is a semi-fluid preparation made by concentrating and decocting the decoction of Chinese herbal medicines and adding refined honey or syrup, also known as oral thick paste[11]. Oral thick paste is also a traditional Chinese medicine preparation, the production process of which includes five steps: soaking, decocting, concentrating, collecting paste (forming) and cooling[12,14]. It has a nourishing effect and a soothing therapeutic effect. It has a high osmotic pressure, and is not prone to mold and spoilage. Oral thick paste is suitable for long-term use and patients with gastrointestinal dysfunction. It has become an important physical form of health food[15]. Compared with capsules, decocted extract has higher drug concentration[16], better taste, wider application range and more optimistic market prospect.

In this study, in order to ensure the safety and effectiveness of hospital preparations, and improve the therapeutic effect of drugs, the quality standards of Jianjin Zhuanggu Paste in all aspects were investigated according to the requirements of *Chinese Pharmacopoeia* (2020 edition), and quality control items and limits of the product were determined, and scientific, reasonable and feasible quality standards that can reflect product characteristics and quality changes were formulated. The microscopic identification test proves that the Chinese herbal medicines purchased by our hospital are safe, reliable and of guaranteed quality. The main effective components of the preparation were identified by TLC, and the properties, relative density, insoluble matter and microbial limit of the preparation were tested, and the test results met the requirements.

To sum up, the quality standards of Jianjin Zhuanggu Paste were established in this study. This study improves the quality control of traditional Chinese medicine preparations in our hospital to a certain extent and has certain guiding value for the development of new dosage forms in our hospital in the future.

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