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# Study of Process of Zhuang Medicine Wuzhi Maotao Buxu Granule

**Dongmei HUANG△, Sun SUN△, Bing QING, Xiumei MA, Wen ZHONG, Zujie QIN*, Jiangcun WEI***

Guangxi International Zhuang Medicine Hospital, Nanning 530201, China

**Abstract** [**Objectives**] To study the process of Zhuang medicine Wuzhi Maotao Buxu Granule. [**Methods**] The orthogonal design method was used to optimize the best water extraction process with the amount of water, extraction time and extraction times as factors and the dry extraction yield of granules as the indicators. The concentration process was screened and molding process and the pilot production were studied. [**Results**] The optimal water extraction process was as follows: soaked in water for 30 min, decocted twice-first with 10 times the amount of water for 1 h, then with 8 times the amount of water for 1 h. The extract was concentrated using a two-step method: initial concentration under reduced pressure, followed by secondary concentration at atmospheric pressure. Ethanol concentration was 85%, with dextrin as the filler. The product yield of three batches of Wuzhi Maotao Buxu Granule all exceeded 80%. [**Conclusions**] Wuzhi Maotao Buxu Granule was extracted using the water extraction method. Through the selection of concentration processes, research on granulation techniques, and pilot-scale production studies, the granules formed well with high yield, good fluidity, high efficiency, and suitability for large-scale production.

**Key words** Wuzhi Maotao Buxu Granule, Extraction process, Preparation process, Molding process, Concentration process

## 1 Introduction

Wuzhi Maotao Buxu Granule is an empirical formula developed over years by Professor Qin Zujie, a famous TCM expert in Guangxi and an instructor in the seventh batch of the national program for inheriting the academic experience of veteran TCM experts at the International Zhuang Medical Hospital Affiliated to Guangxi University of Chinese Medicine. The formula comprises 12 medicinal components, including Radix Fici Hirtae (Wuzhi Maotao), Codonopsis Radix (Dangshen), and Atractylodis Macrocephalae Rhizoma (Baizhu). It functions to benefit qi and fortify the spleen, regulate and tonify the liver and kidney, and supplement the middle energizer to uplift yang. It is primarily indicated for patients with spleen-stomach qi deficiency and liver-kidney insufficiency manifesting as constitutional weakness, shortness of breath, fatigue, exertion-induced panting, fever with sweating, dull complexion, headache with aversion to cold, soreness and weakness in the lower back and knees, as well as chronic fatigue syndrome presenting with the above symptoms. Zhuang medicine believes that human health depends on the unobstructed state of the "three passages and two routes" and the equilibrium of qi and blood. This prescription originates from the integration of traditional Zhuang and Yao medical theories with modern medical practice, reflecting the hospital's innovative capacity and research strength in the fields of Chinese medicine and Zhuang-Yao ethnomedicine. It has significant clinical value and extensive application potential.

Oral traditional Chinese medicine preparations are mainly solution, granules and tablets. Compared with solution, granules retain the advantages of fast absorption, better stability, less dosage, less mildew and other phenomena. In the preparation process of granules, appropriate fillers should be selected according to the hygroscopicity of traditional Chinese medicine extracts, and a small amount of flavoring agent should be added to improve the taste of the preparation. Compare with tablets and capsule, that preparation process of granules is less, the operation is convenient, and the packaging is simple. In addition, the granules are easy to carry, convenient to take and suitable for a wide range of people. Therefore, the dosage form of this product is granules.

## 2 Materials

**2.1 Instruments and equipment** The instruments and equipment used in the experiment are listed in Table 1.

**2.2 Raw and auxiliary materials and reagents** Radix Fici Hirtae (Wuzhi Maotao), *Codonopsis pilosula* (Dangshen), *Atractylodes macrocephala* (Baizhu), *Angelica sinensis* (Danggui), *Citrus reticulata* peel (Chenpi), *Bupleurum chinense* (Beichaihu), *Cimicifuga foetida* (Shengma), *Lycium barbarum* (Gouqizi), salted *Cuscuta* seeds (Yantusizi), salted *Psoralea corylifolia* (Yanbuguzhi), *Epimedium brevicornu* (Yinyanghuo), and honey-fried *Glycyrrhiza uralensis* (Zhigancao) were all purchased from Guangxi Immortal Zhu Chinese Medicine Technology Co., Ltd. Dextrin was of medicinal-grade, 95% ethanol was of food-grade, and purified water was produced in-house by our hospital's Zhuang-Yao Medicine Preparation Center. All other reagents used in the experiment were of analytical grade.

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△ These authors contributed equally to this work.

Dongmei HUANG, bachelor's degree, pharmacist in charge; Sun SUN, bachelor's degree; Bing QING, bachelor's degree, engineer. * Corresponding author. Zujie QIN, master's degree, professor; Jiangcun WEI, master's degree, assistant researcher.

**Table 1 instruments and equipment used in the experiment**

| Name | Model | Manufacturer |
|---|---|---|
| Electric heat jacket with electronic temperature regulation | 98-I-B | Tianjin Taisite Instrument Co. , Ltd. |
| Extraction and concentration unit | TQNS-1500 | Shen Tai Zhejiang Special Equipment Limited Company |
| Jacket pot | JCG200 | Shen Tai Zhejiang Special Equipment Limited Company |
| Trough shaped mixer | CH-200 | Jiangyin Zhouyuan Pharmaceutical Machinery Manufacturing Co. , Ltd. |
| Oscillating granulator | YK-160 | Jiangyin Zhouyuan Pharmaceutical Machinery Manufacturing Co. , Ltd. |
| Hot air circulation oven | CT-C-1 | Jiangyin Zhouyuan Pharmaceutical Machinery Manufacturing Co. , Ltd. |
| Full-servo high-speed particle packaging machine (with bags) | DXDK-40VII | Tianjin Hondon Ruibao Packaging Machinery Co. ,Ltd |
| Analytical balance | ME204 | Mettler-Toledo Instruments (China) Co. , Ltd. |
| Electronic platform scale | TCS-100 | Shanghai Yaoxin Electronic Technology Co. , Ltd. |

## 3 Methods and results

**3.1 Dry extraction yield determination** We measured the volume of the extracted liquid medicine, then precisely sucked 50 mL, put it into an evaporating dish dried to constant weight, evaporated it in water bath, dried it in an electric heating constant temperature drying oven at 105 ℃ for 5 h, transferred it to a dryer, cooled it for 30 min, precisely weighed it, dried it at the above temperature for 1 h, cooled it, and weighed it until the difference between two consecutive weighing was not more than 5 mg. Then, we calculated the dry paste rate according to Formula (1).

Dry extraction yield (%) = (Dry extract weight × Total volume of medicinal liquid)/(Total weight of raw herbs × Sampled volume) × 100% (1)

**3.2 Water absorption test** To account for the inherent water absorption of dried herbal materials, which could otherwise interfere with subsequent water addition volumes, a water absorption rate determination was first conducted. This provided the basis for adding an equivalent volume of compensatory water during the initial hydration step, thereby minimizing errors caused by herbal material absorption. For this procedure, a single-day prescription quantity of herbs was weighed and immersed in 10 times its weight of water. Rhizome-type herbs were checked every 2 h for complete saturation. Upon achieving full saturation, the mixture was filtered until dripping ceased, after which the saturated herbal weight was weighed. The water absorption rate was then calculated using Formula (2), with results indicated in Table 2.

Water absorption rate (%) = (Weight of moist medicinal material − Weight of dry medicinal material)/Weight of dry medicinal material × 100% (2)

**Table 2 Results of water absorption rate test**

| Test No. | Weight of dry medicinal material // g | Weight of moist medicinal material // g | Water absorption rate // % | Average water absorption rate // % |
|---|---|---|---|---|
| 1 | 76.45 | 191.34 | 150.28 | 157.76 |
| 2 | 76.30 | 205.61 | 169.48 | |
| 3 | 77.34 | 196.07 | 153.52 | |

The results showed that the water absorption rate of the medicinal materials after soaking was 157.76%, which was about twice the weight of the medicinal materials, so it was necessary to add twice the amount of water when adding water for the first time.

**3.3 Single factor experiment** Common factors influencing the traditional Chinese medicine water extraction process include soaking time, extraction time, water volume, and decoction times. Since the decoction times is typically chosen as once, twice, or three times, the single-factor experiment therefore focused on examining the effects of soaking time, extraction time, and water volume on the evaluation indicators[1-2].

**3.3.1** Soaking time test. Took six portions of medicinal materials equivalent to a single daily prescription dosage. Added 10 times the amount of water to each portion, soak for 0, 0.5, 1.0, 1.5, 2.0, and 2.5 h, respectively, then performed heated extraction for 1.0 h. After filtration, measured the volume of the filtrate, and calculated the dry extraction yield under each condition according to the method described in Section **3.1**. The results are shown in Fig. 1.

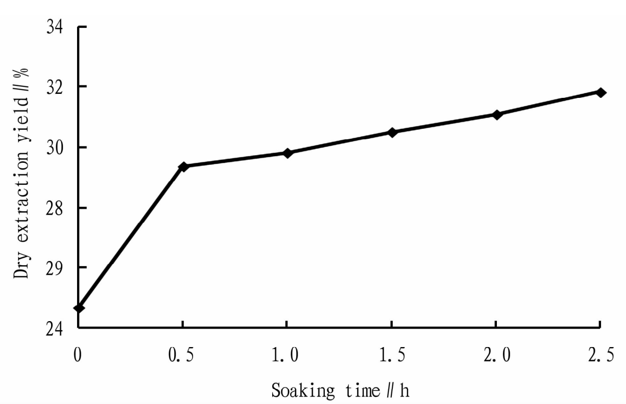


**Fig. 1 Soaking time test results** ($n = 3$)

Based on the results, the increase in soaking time has minimal impact on dry extraction yield. Therefore, soaking time was excluded as a factor for extraction process optimization. However, in actual production where large quantities of medicinal materials are processed, a pre-extraction soaking time of 0.5 h is implemented to ensure thorough hydration of the materials.

**3.3.2** Water addition volume test. Prepared six portions of medicinal materials equivalent to a single daily prescription dosage. Added 4, 6, 8, 10, 12, and 14 times the amount of water to each portion separately. After soaking for 0.5 h, perform heated extraction for 1.0 h. Following filtration, measured the volume of the filtrate and calculated the dry extraction yield under each condition according to the method described in Section **3.1**. The results are shown in Fig. 2.

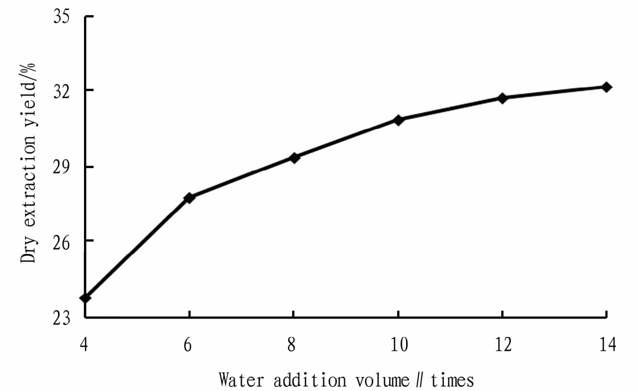


**Fig. 2 Water addition volume test results** ($n=3$)

Based on the results, variations in water addition volume significantly impact dry extraction yield. The increase in dry extraction yield becomes gentle when water volume reaches 10 times the amount. Therefore, water addition volume was selected as a key factor for extraction process optimization, with levels set at 6, 8, and 10 times the volume.

**3.3.3** Extraction time test. Prepared six portions of medicinal materials equivalent to a single daily prescription dosage. Added 10 times the water volume to each portion. After soaking for 0.5 h, performed heated extraction for 0.5, 1.0, 1.5, 2.0, 2.5, and 3.0 h, respectively. Following filtration, measured the volume of the filtrate and calculated the dry extraction yield under each condition according to the method in Section **3.1**. The results are shown in Fig. 3.

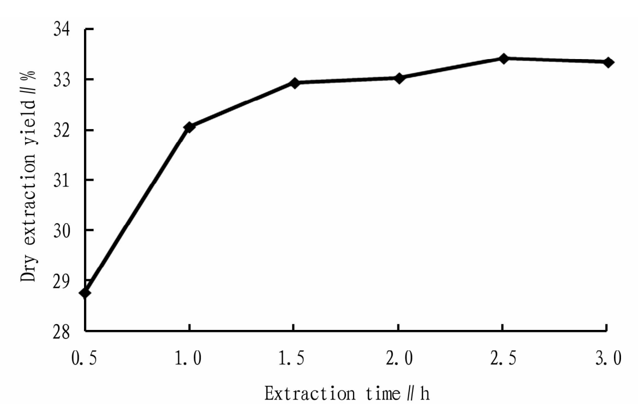


**Fig. 3 Extraction time test results** ($n=3$)

Based on the results, increasing the extraction time significantly influenced dry extraction yield. The increase in dry extraction yield becomes gentle after the extraction time reaches 1.5 h. Therefore, extraction time was selected as a key factor for process optimization, with levels set at 0.5, 1.0, and 1.5 h.

## 3.4 Orthogonal design[3-5]

**3.4.1** Factor level design. According to the single factor test results and in combination with the actual production, water addition volume (A), extraction time (B) and extraction times (C) were selected as the investigation factors of the orthogonal test. The factor levels of the orthogonal design are shown in Table 3.

**Table 3 Factor level test**

| Level | Factor | | |
|---|---|---|---|
| | Water addition volume (A) // times | Extraction time (B) // h | Extraction times (C) // times |
| 1 | 6 | 0.5 | 1 |
| 2 | 8 | 1.0 | 2 |
| 3 | 10 | 1.5 | 3 |

**3.4.2** Orthogonal test. Using dry extraction yield as the evaluation criterion, the optimal extraction process was determined based on the evaluation results of dry extraction yield. The orthogonal experimental design and corresponding results are presented in Table 4, and the analysis of variance (ANOVA) is shown in Table 5.

**Table 4 Orthogonal test arrangement and results**

| Test No. | A Water addition volume | B Extraction time | C Extraction times | D Blank | Dry extraction yield // % |
|---|---|---|---|---|---|
| 1 | 1 | 1 | 1 | 1 | 19.88 |
| 2 | 1 | 2 | 2 | 2 | 32.04 |
| 3 | 1 | 3 | 3 | 3 | 36.35 |
| 4 | 2 | 1 | 2 | 3 | 31.64 |
| 5 | 2 | 2 | 3 | 1 | 37.92 |
| 6 | 2 | 3 | 1 | 2 | 24.44 |
| 7 | 3 | 1 | 3 | 2 | 36.26 |
| 8 | 3 | 2 | 1 | 3 | 26.52 |
| 9 | 3 | 3 | 2 | 1 | 35.83 |
| $K_1$ | 29.42 | 29.26 | 23.61 | 29.42 | |
| $K_2$ | 31.33 | 32.16 | 33.17 | 31.33 | |
| $K_3$ | 32.87 | 32.21 | 36.84 | 32.87 | |
| $R$ | 3.45 | 2.95 | 13.23 | 3.45 | |

**Table 5 Variance analysis of dry extraction yield**

| Error source | *SS* | *f* | *S* | *F* | *P* |
|---|---|---|---|---|---|
| A | 17.87 | 2 | 8.94 | 33.97 | <0.05 |
| B | 17.12 | 2 | 8.56 | 32.51 | <0.05 |
| C | 280.00 | 2 | 140.00 | 531.81 | <0.01 |
| Error | 0.53 | 2 | 0.26 | | |

Based on ANOVA results, factor C (extraction times), factor A (water addition volume), and factor B (extraction time) all significantly influenced the extraction process, with effect magnitudes ordered as C > A > B. While visual analysis indicated $A_3B_3C_3$ as the optimal combination, the $A_2B_2C_2$ protocol was ultimately adopted to conserve energy, ensure industrial scalability, and maintain consistency with traditional decoction methods, specifically involving soaking prescribed herbs for 30 min followed by two extraction cycles: first with 10 times water volume for 1 h, then with 8 times water volume for 1 h.

**3.5 Extraction process validation** The extraction process was validated based on orthogonal experimental optimization results. Specifically, the prescribed daily quantity of herbs was weighed, soaked in water for 30 min, and subjected to two extraction cycles: the first with 10 times water volume and the second with 8 times water volume, each lasting 1 h. The extracts were then filtered, and the filtrates combined. The dry extraction yield was calculated according to the method outlined in Section **3.1**. Results demonstrated a mean dry extraction yield of 34.42% under the optimized protocol, confirming the process rationality and feasibility.

**3.6 Selection of concentration process** The currently predominant concentration methods, atmospheric and reduced-pressure concentration, prioritize the latter for industrial TCM production due to its shorter duration, higher efficiency, and lower boiling points, which minimize thermal decomposition of heat-sensitive compounds and enhance active ingredient preservation. Based on production realities and preliminary trials, a dual-stage protocol was implemented: primary reduced-pressure concentration at 75 – 95 ℃ condensed the filtrate to a clear paste (relative density 1.05 – 1.15 at 60 ℃), followed by secondary atmospheric concentration yielding a thick paste (relative density 1.28 – 1.35 at 60 ℃).

**3.7 Molding process study**

**3.7.1** Selection of excipients. The selection of excipients should prioritize safety, efficacy, and stability of the formulation. Given the pronounced hygroscopicity of Chinese herbal extract powder, dextrin was selected as the diluent for this preparation due to its high absorption capacity, low cohesiveness, and robust chemical inertness.

**3.7.2** Selection of ethanol concentration. Ethanol functions as a binder/lubricant during granulation, with its concentration optimized to produce granules exhibiting cohesive-yet-friable characteristics, forming compact masses when squeezed while readily disintegrating under light pressure without adhesion. Based on granule formability and process yield criteria, three 1 500 g batches of fine powder were blended with process-optimized ethanol concentrations, transformed into damp masses, granulated through a 10-mesh screen using an oscillating granulator, and dried in an oven at 85 ℃ until achieving moisture content below 4.0% *w/w*, with results documented in Table 6.

**Table 6 Selection of ethanol concentration**

| Test No. | Ethanol concentration//% | Granulation |
|---|---|---|
| 1 | 80 | The overly moist damp mass caused screen adhesion issues during granulation, reducing process yield despite adequate granule formation |
| 2 | 85 | The damp mass exhibited optimal moisture content, facilitating smooth granulation with minimal resistance and yielding granules of excellent formability. |
| 3 | 95 | The damp mass displayed insufficient moisture binding, resulting in a crumbly texture, excessively fine granules, and poor formability. |

The results show that when the ethanol concentration is 85%, the granulation is good, the molding rate is high, and the fluidity is good.

**3.7.3** Pilot production study. The pilot-scale production of Wuzhimaotao Buxu Granules involved: Extraction of 45.6 kg herbal materials soaked for 30min followed by dual hot-water extraction (1st cycle: 10 times water volume; 2nd cycle: 8 times water volume; 1 h each); filtration through 100-mesh sieve with filtrate consolidation; concentration via reduced-pressure evaporation (75 – 95 ℃) to clear paste (relative density 1.05 – 1.15 at 60 ℃), then atmospheric evaporation to thick paste (relative density 1.28 – 1.35 at 60 ℃); granulation by blending thick paste with dextrin in trough mixer, oven-drying at 65 – 85 ℃, pulverization, wet massing with 85% ethanol, oscillating granulation through 10-mesh screen, and final drying to < 4.0% moisture, finishing through sizing and packaging (15 g/bag). Three consecutive batches (batch No. 230901, 230902, 230903, respectively) were produced with quality outcomes in Table 7.

**Table 7 Pilot production results of three batches**

| Batch | Total input//kg | Thick paste yield//kg | Dextrin added//kg | Theoretical output//kg | Actual granule output//kg | Granule yield//% | Theoretical units//bags | Actual units packaged//bags | Product recovery rate//% |
|---|---|---|---|---|---|---|---|---|---|
| 230901 | 45.6 | 17.27 (RD 1.29 at 60 ℃) | 14.89 | 27 | 23.08 | 85.5 | 1 800 | 1 514 | 84.1 |
| 230902 | 45.6 | 17.03 (RD 1.29 at 60 ℃) | 15.06 | 27 | 23.25 | 86.1 | 1 800 | 1 523 | 84.6 |
| 230903 | 45.6 | 16.74 (RD 1.29 at 60 ℃) | 15.10 | 27 | 23.51 | 87.1 | 1 800 | 1 542 | 85.7 |

The results of pilot production test showed that the yield of three batches of Wuzhi Maotao Buxu Granule products was more than 80%, which indicated that the extraction process and preparation process were reasonable, stable and suitable for production.

## 4 Conclusions

Through systematic single-factor screening, orthogonal optimization, and validation trials, the extraction process for Wuzhi Maotao Buxu Granules was finalized as: soaking prescribed herbs for 30 min followed by dual hot-water extraction (first cycle: 10 timeswater volume; second cycle: 8 timesd water volume; 1 h each). Clinical demand-driven process parameterization employed single-factor and orthogonal designs with dry extraction yield as the criti-

(To page 46)

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(From page 18)

cal metric to define extraction/concentration specifications. Subsequent single-factor studies targeting granule performance indicators, formation rate, hygroscopicity, flowability, and solubility, optimized the granulation protocol. Scale-up validation via three pilot batches (45.6 kg input each) confirmed the scientific robustness and operational viability of the integrated manufacturing methodology.

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