

## Analysis of Factors Affecting the Quality of Traditional Chinese Medicine Preparation and Its Control Measures

Zhang Cunlao<sup>1</sup>, Guo Jin<sup>2</sup>, Zhao Mengli<sup>1</sup>

<sup>1</sup>Xi'an Medical University, 710021, China

<sup>2</sup>Xi'an Traditional Medicine Hospital, 710021, China

**Keywords:** Traditional Chinese Medicine; Preparation; Quality; Factor; Control

**Abstract:** In order to analyze the related factors affecting the quality of traditional Chinese medicine preparation in hospital, and take effective control measures actively, so as to improve the curative effect of traditional Chinese medicine preparation products and better provide high quality traditional Chinese medicine preparation for clinic. The preparation of traditional Chinese medicine preparation and the important factors affecting the quality of traditional Chinese medicine preparation in our hospital were analyzed by retrospective analysis, and the best quality control scheme of traditional Chinese medicine preparation was sought by searching the relevant literature to ensure the quality of traditional Chinese medicine preparation. Through the analysis, it is found that the main factors affecting the quality of traditional Chinese medicine preparations are prescription and preparation technology, warehouse and storage conditions, and so on. Through strict review, and strengthen the management of all links of the preparation It can effectively improve the quality of traditional Chinese medicine preparation and provide better quality traditional Chinese medicine preparation for clinic at the same time.

### 1. Introduction

The management of traditional Chinese medicine preparation in hospital is a very important link, and its management quality has a direct impact on the quality of clinical medical service and medical safety [1]. Hospital drug quality management is not only the basis of hospital medical service, but also the necessary link in medical service, and it is also the core of clinical medical service [2]. The primary task of hospital management is to provide quality and quantity drugs for clinical medical services to ensure the effectiveness and safety of clinical disease treatment [3]. The hospital internal traditional Chinese medicine preparation also includes many kinds, in the preparation process quality question has been concerned by everyone.

### 2. Diagnoses

There are many kinds of traditional Chinese medicine preparations. This study can be divided into the following categories: liquid dosage form, semi-solid dosage form and gas dosage form according to the classification of morphology. According to the dispersion characteristics in the dosage form, they are classified as true solution, colloidal solution, emulsion, suspension, gas dispersion, solid dispersion and so on. According to the route and method of administration, it can be divided into gastrointestinal administration and non-gastrointestinal administration. According to the classification method, the preparation agents are classified as five categories by the same method. This paper mainly analyzes the factors that can affect the preparation of traditional Chinese medicine in our hospital, and then summarizes the influence of various factors in the preparation of traditional Chinese medicine. The proportion of quality, and then take targeted control measures. The actual investigation shows that the main factors affecting the quality of the drug are prescription, manufacturing process, raw materials, dosage and personnel quality [5].

Table 1 Survey and classification table affecting the quality of important preparations

factor	Preparation prescription	Preparation degree	Preparation raw material	Preparation dose	Personnel quality
Proportion of importance	35%	35%	10%	10%	10%
Importance degree	critical factor	critical factor	important factor	important factor	important factor

### 3. Analysis of Related Factors Affecting the Quality of Important Preparations

#### 3.1. Preparation prescription

In the whole process of making traditional Chinese medicine preparation, the preparation prescription plays a guiding role and belongs to the key influencing factors. Scientific and effective prescription of traditional Chinese medicine preparation is the key to ensure the quality of traditional Chinese medicine preparation, which is usually summarized from ancient prescription, tested prescription and secret prescription. The ancient prescription accords with the theory of traditional Chinese medicine in our country, has a long history, the compatibility is relatively rigorous, and can be used directly. The prescription is summed up by clinicians through their own experience in a certain range of use, which is also in line with the theory of traditional Chinese medicine, but attention should be paid to the stability of effective components of drugs in the process of practical use [6]. The secret recipe is handed down from the family of traditional Chinese medicine, and its main characteristics are The effect of medication is obvious, but this kind of prescription should be adjusted as appropriate before it can be used.

#### 3.2. Manufacturing process

The final quality of traditional Chinese medicine preparation is determined by the technological process of making traditional Chinese medicine preparation, and different preparation technology will obtain different drug preparation. The feeder is not familiar with or does not strictly operate according to the technological process, which will change the feeding ratio, the degree of comminuted medicinal materials, the uniformity of mixing and so on, which will inevitably affect the quality of the final preparation. Time, concentration, temperature and steam pressure in the preparation process will also affect the quality of the final preparation [7].

#### 3.3. Raw and processed material

The quality of raw materials used in traditional Chinese medicine preparation is directly related to the quality of the final preparation. The type and source of Chinese medicinal materials are different, and there are not a few Chinese medicinal materials in the market, which will greatly reduce the quality of the final preparation. Other Chinese medicinal materials that are restricted by the state will have to be replaced by other medicinal materials because of their small amount, and the quality of the preparations will also be reduced.

#### 3.4. Preservation and use of finished products of traditional Chinese medicine preparations

The main problems in the quality management of traditional Chinese medicine preparations are more prominent. Different manufacturers, different dosage forms and different types of traditional Chinese medicine preparations are mixed, which not only increases the difficulty of drug collection, delays the time of drug collection, but also may lead to adverse events. The hidden dangers of safety are very obvious. There are also some traditional Chinese medicine preparations valid period, batch number and so on printed on the outer package, after entering the pharmacy, it is difficult to distinguish the accurate validity period of the drug after entering the pharmacy, which is likely to lead to the expired traditional Chinese medicine preparation being used in clinical treatment [8]. Even if some traditional Chinese medicine preparations have a clear period of validity, the managers of pharmacies have not placed and taken them according to the order in which they are

valid. Use, ignore the first-in, first-out principle, will also make some traditional Chinese medicine preparations expire. Unreasonable storage of traditional Chinese medicine preparations is also a major criticism in drug management. Traditional Chinese medicine preparation will change its body quality because of inappropriate light, temperature and humidity, and will also cause clinical drug use accidents.

### **3.5. Preparation dose**

In the process of producing traditional Chinese medicine preparation, the content of medicine is too high and too low will reduce the quality of the whole preparation. The dose of the preparation has an effect on the quality of the preparation, and the dose of the preparation is a key factor to determine the whole clinical treatment effect. Therefore, the dose of active components in the preparation directly affects the quality of the whole drug. Generally, it is difficult to achieve the purpose of actual drug use, and excessive content can lead to toxic and side effects.

### **3.6. Human factor**

The professional level of traditional Chinese medicine preparation production personnel, work responsibility, operation rigour and so on, quality awareness and so on will affect the quality of the preparation. The quality of the staff of the preparation has obvious influence on the quality of the whole traditional Chinese medicine preparation, which is generally manifested in the technical level and quality consciousness of the personnel [10].

## **4. Quality Control measures of traditional Chinese Medicine preparation**

### **4.1. Quality control of traditional Chinese medicine preparation before production**

Before production, we should do a good job of pre-work inspection, strict production process control in production, timely clearance after production, carry over materials, collate relevant records and file. Before production, the basic records of the production site (equipment operation, maintenance records, clearance records, central control records, environmental temperature and humidity records, etc.) inspection, can be informed of the relevant production sites, equipment, facilities information, especially equipment, The maintenance information of the facility, such as the lubrication of the transmission equipment, the use time of the integrated equipment of light, electricity and gas, etc., plays the role of grinding the knife and cutting the firewood without mistake. The materials used are in accordance with the batch production instructions, and there is a qualified inspection of the quality department. The report, the quantity of each material, should meet the quantity required for this batch of production, emphasizing that "no one should be less." Check the object before work. Such as material name, code name, entry number, production batch number, accompanied by certificate or inspection report (inspection report number, conclusion), visual appearance characteristics. The material is required to be "traced back to the source" within the validity period, and the outer packing of the material is required to be in good condition, clean and weighed and checked.

The production site is clean, hygienic, in accordance with the hygiene requirements of the area, there are cleaning (cleaning) records or certificates, the temperature, humidity, pressure difference, ventilation times and other corresponding measures of the production environment within the validity period of the clearance certificate should meet the requirements or have corresponding measures. All surfaces in contact with drugs are sterilized and sterilized. Equipment, console, walls, ceilings, etc., all have a surface. Because of the humidity of the air, there is a layer of water-bearing film on all surfaces, which is soaked with dust, particles and microorganisms because of its electrostatic attraction. Therefore, it is necessary to be sterilized and sterilized effectively before production. Whether the dust prevention and dust capture measures in the production site are available or not, the effect should be achieved. Evaluation Dust is a means of transportation for microbes. Traditional Chinese medicine oral solid preparation dust production process, such as traditional Chinese medicine pretreatment, crushing, batching, preparation molding workers,

separate loading must be the corresponding facilities, such as direct exhaust fan, relative negative pressure, buffer corridor and so on. The purpose is to prevent pollution and cross-pollution.

The health examination of the production operators meets the requirements, and the personnel with infectious diseases or wounds on the body surface are prevented from engaging in the post adaptability inspection of the production operators who are in direct contact with drugs or have adverse effects on the quality of drugs: whether they have been trained to take up their posts, Operator technical level, work experience, industry basic knowledge level understanding (safety education, microbial knowledge, the corresponding standard operating procedures for the post).

#### **4.2. Quality control in the production of traditional Chinese medicine preparations**

The process control in production follows: safety, quality, schedule, specification, cost requirements; timely corrosion information, in the form of field analysis to solve the deviation in the production process. Weighing, checking measurement should be accurate, high titer, small dosage of expensive and fine, toxic medicinal materials and other toxic materials need to be double review, monitoring and feeding, carefully fill in records and signatures; this process is often prone to errors of the process, is the source of quality control production site. Receive the wrong material, say the wrong quantity of quality accidents occur from time to time in the whole industry. The skills and responsibility of the personnel in this position should be made key requirements. Strictly implement the operating rules and regulations and shall not change the contents of the operation without authorization; cut Carry out the production operation instruction rules, strictly prevent pollution, cross pollution and confusion, correct the bad operation behavior and habit, strictly investigate the removal of posts, channeling, sliding, sleeping; Control equipment operation parameters, process technical parameters, product (intermediate) quality index, batch input and output rate of this process, strict batch management, we should have the concept of batch. Prevent the generation and flying of dust. The equipment is required to have good sealing performance and sealing cover; dust-producing equipment has partial enclosure or installation of dust collection device; local straight discharge or installation of dust removal system (such as crushing equipment); dust production operation room to maintain relative negative pressure on the corridor. Timely entry to clean up scattered materials on the ground, classification Recovery and production of the head, tail material. The operator shall not do a large amount of exercise unrelated to the operation. The upper and lower materials should be carried out lightly and according to their strength.

Pharmaceutical water should be selected according to the requirements of process rules, purified water, water for injection, storage should be standardized requirements, if there is no heat preservation cycle, filtration, UV sterilization, because of the absence of chloride ion sterilization, it is easier to breed bacteria than tap water. Compressed air water-bearing belt oil, aluminum foam cover machine when using compression blowing foam machine to bring water directly affect tablets, capsule in storage water absorption mold, directly on the quality of the preparation, air conditioning purification system perforation, cracks, Can not play the role of temperature regulation, humidity regulation, dust removal, sterilization, microbial control quality can not be guaranteed; The humidity of the production environment of the whole extract tablet of traditional Chinese medicine preparation can not be controlled. The production cannot be carried out by pulling and punching when pressing the sheet.

#### **4.3. Quality control after production**

Health operation requirements are first things then ground, from top to bottom, from inside to outside, from easy to difficult. After each production stage of each batch of products, the production site, equipment, materials, status marks, documents and so on need to be cleaned and cleared. It is strictly forbidden to use water to wash the production site in a large area: washing with water is strictly prohibited by all pharmaceutical enterprises, followed by: corrosion equipment, burning electrical appliances, blocking floor drain, water in circular arc, breeding bacteria, emphasis on ventilation and dehumidification after cleaning.

After the production of the approved products, the use of the materials shall be settled; after the remaining materials have been checked by the quality supervision personnel, the remaining

materials shall be sealed, marked, and returned to the warehouse and recorded in accordance with the procedures; When the material settlement deviation occurs, execute the deviation processing procedure, analyze the cause, confirm that there is no potential quality hazard.

## 5. Conclusion

To sum up, the influencing factors of the quality of traditional Chinese medicine preparations mainly include preparation prescription, preparation technology, raw materials, preparation dosage, personnel factors and so on. It is necessary to formulate targeted control measures and strengthen quality control in drug management. In each link of drug management, we should record drug information in detail, set up professional drug quality control posts, ensure drug quality and deal with anomalies in time. In this paper, the quality control of traditional Chinese medicine preparation before, during and after production is introduced in detail, and the quality control of traditional Chinese medicine preparation is realized by controlling the quality of the whole process in the production process.

## Acknowledgement

Shaanxi International Cooperation Exchange Project: The study of synergism interaction between the combination use of herb and drug, NO.2019KW-073.

## References

- [1] Liang S, Hua W, Feng Z, et al. Qualitative analysis and quality control of Traditional Chinese Medicine preparation Tanreqing injection by LC-TOF/MS and HPLC-DAD-ELSD. *Analytical Methods*, 2013, 5(22):6431-6440.
- [2] Li J, Bai Y, Zhang P, et al. Simultaneous Determination of 5 Flavonoids and 7 Saponins for Quality Control of Traditional Chinese Medicine Preparation Xinnaoshutong Capsule Using HPLC-VWD-ELSD. *Journal of Analytical Methods in Chemistry*, 2017, 2017(23):1-8.
- [3] Li H, Wang S W, Zhang B L, et al. Simultaneous quantitative determination of 9 active components in traditional Chinese medicinal preparation ShuangDan oral liquid by RP-HPLC coupled with photodiode array detection. *Journal of Pharmaceutical & Biomedical Analysis*, 2011, 56(4):820-824.
- [4] Hong Z, Chan K, Yeung H W. Simultaneous determination of bufadienolides in the traditional Chinese medicine preparation, liu-shen-wan, by liquid chromatography. *Journal of Pharmacy & Pharmacology*, 2011, 44(12):1023-1026.
- [5] Batey R G, Bensoussan A, Fan Y Y, et al. Preliminary report of a randomized, double-blind placebo-controlled trial of a Chinese herbal medicine preparation CH-100 in the treatment of chronic hepatitis C. *Journal of Gastroenterology & Hepatology*, 2010, 13(3):244-247.
- [6] Kai S, Jingyu F, Jingyan H. Ameliorating effects of traditional Chinese medicine preparation, Chinese materia medica and active compounds on ischemia/reperfusion-induced cerebral microcirculatory disturbances and neuron damage. *Acta Pharmaceutica Sinica B*, 2015, 5(1):8-24.
- [7] Zhao X L, Yang C R, Yang K L, et al. Preparation and characterization of nanostructured lipid carriers loaded traditional Chinese medicine, zedoary turmeric oil. *Drug Development & Industrial Pharmacy*, 2010, 36(7):773-780.
- [8] Liang S, Hua W, Feng Z, et al. Qualitative analysis and quality control of Traditional Chinese Medicine preparation Tanreqing injection by LC-TOF/MS and HPLC-DAD-ELSD. *Analytical Methods*, 2013, 5(22):6431-6440.