Scientific Research Publishing

Pharmacology & Pharmacy, 2023, 14, 407-427
https://www.scirp.org/journal/pp
ISSN Online: 2157-9431
ISSN Print: 2157-9423

Design of Traditional Chinese Medicine Extraction Workshop Process and Automation System

Meisong Li[1*], Dongmei Tan[2], Qian Zhang[1]

[1]Hangzhou Dayuan Technology Co., Ltd., Hangzhou, China
[2]Ganzheng (Zhejiang) Biological Pharmaceutical Co., Ltd., Hangzhou, China
Email: *329577425@qq.com

How to cite this paper: Li, M.S., Tan, D.M. and Zhang, Q. (2023) Design of Traditional Chinese Medicine Extraction Workshop Process and Automation System. *Pharmacology & Pharmacy*, **14**, 407-427.
https://doi.org/10.4236/pp.2023.1410026

Received: September 11, 2023
Accepted: October 16, 2023
Published: October 19, 2023

Abstract

Objective: This paper takes the example of a Panax notoginseng extraction workshop and designs an automated production workshop with advanced domestic capabilities. **Methods:** 1) Based on the small-scale Panax notoginseng extraction process, the feasibility of the workshop production process is demonstrated. 2) The workshop process design for Panax Notoginseng saponin extraction is completed, including production organization plans and the selection of key equipment. 3) For the Panax notoginseng extraction workshop process, an automated production control system is designed. **Conclusion:** Through optimized design of the production process and automation system, continuous and automated production of traditional Chinese medicine extraction is achieved, leading to improvements in drug quality and production efficiency.

Keywords

Traditional Chinese Medicine Extraction, Process Validation, Panax Notoginseng Saponin, Workshop Process Design, Automation Control

1. Introduction

Traditional Chinese medicine (TCM) extraction is a crucial step in TCM production, directly impacting the quality of herbal medicines and representing a current bottleneck in quality improvement. Due to the unique and complex nature of TCM production, the process heavily relies on manual judgment, making it challenging to precisely control process parameters. The TCM industry must seize the opportunity presented by "Industry 4.0". In the design of workshop processes, modern technologies such as computer science, automation control,

communication technology, and the Internet of Things (IoT) should be leveraged. These technologies should be tailored to the characteristics of TCM extraction to create automated production workshops that enhance the pipeline, continuity, and automation of the extraction process. This approach will not only boost production efficiency but also enhance batch-to-batch consistency in pharmaceutical quality. It will propel the advancement of TCM extraction production technology and gradually achieve pharmaceutical digitization.

2. Industry Status

Currently, the integration of modern Chinese science and technology with the TCM industry is insufficient. TCM extraction processes are still at the manual or semi-automated control stage. Process parameters are difficult to precisely control. Moreover, TCM itself possesses complexity and specificity. As a result, there are numerous issues in the research and industrialization of Chinese medicine in China [1]-[6]. These issues include:

1) Low technological content, outdated production processes, and equipment.

2) Repetitive product varieties with low levels of active pharmaceutical ingredients, high impurity content, and unstable quality.

3) The dominance of small and medium-sized enterprises in the TCM production sector, coupled with a large number of manufacturers, leads to the need for improved management and low automation levels in hardware equipment.

4) Low market share and weak innovation capabilities among TCM production enterprises.

5) Lack of internationally recognized quality standards, reliance on empirical knowledge in drug use, and a failure to align with modern medicine.

These problems pose significant challenges to the development of the TCM industry. Developed countries like Germany, France, and Japan import TCM raw materials or semi-finished products from China at low prices. They utilize modern scientific and technological theories, advanced processes, and sophisticated pharmaceutical automation systems to produce high-quality and technologically advanced products. These countries not only dominate a significant portion of the international market but also aggressively penetrate the Chinese market, posing a serious threat to the development of the Chinese herbal medicine industry. Currently, the design and construction of automated control systems for TCM production have become an urgent and crucial issue in modern TCM production.

In the Chinese TCM pharmaceutical industry, the implementation of automated control for the entire TCM production process is still in its infancy and exploratory stage. Zhang Zhiwen, focused on the application of automation technology in the TCM extraction production process [6]. They utilized new, efficient, and energy-saving process equipment such as continuous countercurrent extraction, multi-effect concentration, and vacuum low-temperature drying to transform TCM extraction production equipment. This transformation enabled

the full-time online monitoring of control parameters and key quality technical parameters throughout the TCM extraction production process, ensuring product quality while reducing energy costs. Chen Yuanqi *et al.* proposed the design of an automated monitoring system for TCM extraction based on the characteristics of TCM production processes [7]. This system achieved automatic extraction and monitoring of TCM production by addressing control system mechanisms. In the context of vacuum concentration equipment, Li Hongwei *et al.* suggested the design of a fuzzy control system [8]. They recognized the unique features of vacuum concentration and proposed a design that utilized fuzzy control. Liu Qingge *et al.* conducted extensive practical work and shifted away from traditional control modes [9]. They designed a TCM extraction digital control system based on a Distributed Control System (DCS), integrating Good Manufacturing Practice (GMP), Process Analytical Technology (PAT), and automation control technologies into a unified system. This achieved product quality uniformity in TCM production. Jian Jihua explored automation control from the perspective of operations in the process of TCM extraction, covering five aspects: extraction, concentration, alcohol adjustment, alkaline precipitation [10], and reflux. Xu Xiaoqiu provided insights into the main processes and control strategies at each stage of TCM extraction [11]. They integrated process control systems with batch production management information, addressing the limitations of independently controlled processes and optimizing the TCM extraction process control system. Bai Yu introduced a self-control system for TCM extraction production, enabling automation from the extraction to the concentration process [12]. Zhang Liguo *et al.* presented theoretical models and control strategies for the TCM extraction and concentration processes, ensuring stable and controllable production process quality [13]. Tang Jiliang designed and developed computer control systems for various units in the natural drug pilot production process [14]. This allowed for the automatic monitoring and control of critical process parameters in the natural drug pilot production process. Liang Zhiguo *et al.* focused on multifunctional extraction tanks in the extraction workshop [15]. They analyzed issues and challenges in process control, identified key control parameters, and proposed integrated solutions that combine extraction processes, equipment, and control systems. Liu Cuiping *et al.* employed a Siemens process control system to automate the TCM extraction, concentration, precipitation, separation, purification, and distillation sections, achieving favorable results [16]. Other peers have also conducted research and exploration in the field of automated control for TCM extraction [17] [18] [19] [20] [21].

Since 2011, a few large and medium-sized domestic TCM enterprises in China have initiated the design of automation control systems in their extraction production processes. This initiative aimed to improve extraction processes, enhance energy efficiency, and elevate the quality of pharmaceutical products. However, practical operations have revealed several challenges and shortcomings in these systems.

1) Mismatch with Batch Production Characteristics: One of the significant is-

sues is that the design of the automated control system often follows a continuous flow production model, which may not align with the batch production characteristics of TCM. This incongruity can lead to operational inefficiencies and difficulties in adapting to the specific requirements of TCM production.

2) Lack of Process Understanding: In many cases, automation system designers may not possess a deep understanding of TCM extraction processes. This knowledge gap can result in incorrect instrument selection and the application of control strategies that do not suit the unique features of TCM production.

3) Validation Challenges: Validating and verifying the performance of automated systems for TCM production can be a formidable challenge. Ensuring that these systems meet their intended objectives in practice can be difficult, leading to suboptimal outcomes or even posing risks to production efficiency when designs are not adequately rationalized.

Given these issues, the design and implementation of automation control systems in TCM production have emerged as critical challenges that require immediate attention and resolution.

In this paper, we take the laboratory-scale Sanqi (Panax Notoginseng) extraction process as an example to validate the feasibility of transitioning to commercial-scale production. We conduct a comprehensive assessment of the process's viability, outline key equipment selection criteria, delve into process design considerations, and propose an automated control system design.

This case study serves as a practical illustration of the steps and considerations involved in scaling up from laboratory experiments to commercial production in the field of TCM. It highlights the importance of a systematic approach to process design and control system implementation to ensure the successful production of high-quality TCM products at a larger scale.

3. Process Scheme Validation

3.1. Extraction

For the extraction process, accurately measure 100 grams of Sanqi herbal granules into a flask. Begin by soaking them in a 2-fold volume of 85% alcohol solution for 8 to 10 hours. Then, add a 5-fold volume of 85% alcohol solution and heat it for reflux extraction for 6 hours (*Reflux extraction is a method that uses volatile organic solvents like ethanol to extract components from raw materials. The extraction mixture is heated and the volatile solvent is vaporized, then condensed and returned to the extraction vessel, repeating the process until the complete extraction of active components*). Afterward, filter the mixture. Next, add a 6-fold volume of 85% alcohol solution and heat it for reflux extraction for 6 hours, followed by another filtration step. Combine the filtrates from both extractions, yielding approximately 1200 milliliters, and set aside.

In industrial production, you may opt for a multifunctional extraction tank for reflux extraction. This extraction tank is equipped with a stirrer to ensure thorough contact between the herbal materials and the solvent during extrac-

tion. Additionally, it features a condenser for solvent heating and reflux extraction. The extraction tank's residue outlet is equipped with a 100-mesh screen and a dual-linked filter to facilitate filtration during liquid discharge. The filtered medicinal liquid is then transferred to a storage tank through a centrifugal pump. Therefore, the use of a multifunctional extraction tank fully complies with the process requirements for herbal materials extraction, demonstrating the feasibility of the extraction production process.

3.2. Concentration

The extracted medicinal liquid is subjected to vacuum concentration. During the concentration process, maintain the liquid temperature below 70˚C. Concentration continues until the specific gravity of the liquid reaches 1.1 mg/ml, yielding approximately 150 ml of concentrated liquid, which is set aside. In industrial production, an appropriate evaporative concentration method can be selected. Since the extraction liquid is an alcohol solution, a common single-effect external circulation vacuum concentrator can be employed. During the concentration process, vacuum levels can be adjusted to control the evaporation temperature of the concentrated liquid. Therefore, the use of a single-effect external circulation vacuum concentrator fully meets the process requirements for concentrating the medicinal liquid, demonstrating the feasibility of the concentration production process.

3.3. Water Precipitation

Transfer the concentrated liquid to a stoppered conical bottle and add four times the volume of purified water. Stir continuously while adding the water, and after completing the water addition, continue stirring for 10 minutes. Then, allow it to stand in a constant temperature bath at approximately 20˚C - 25˚C for 12 - 18 hours. After the precipitation period, the liquid separates into a solid-liquid layer, yielding approximately 700 ml of water precipitate, which is set aside. In industrial production, a commonly used water precipitation tank can be chosen for the water precipitation process. The water precipitation tank thoroughly mixes and settles the liquid and water, followed by low-temperature settling, after which the liquid layer is removed. Therefore, the use of a water precipitation tank fully complies with the process requirements for water precipitation, demonstrating the feasibility of the water precipitation production process.

3.4. Purification

Approximately 120 ml of macroporous adsorption resin is packed into a glass chromatography column. It is soaked in 95% alcohol for 8 - 12 hours and repeated three times. Then, rinse it with purified water until the alcohol content is ≤3%. The aqueous layer is loaded onto the column with a flow rate of 1.5 Bed Volume (BV)/h (*Bed volume refers to the total volume in a chromatography column, including the volume of the chromatography packing material itself and*

the volume of solvent between and within the packing particles). Subsequently, elution is performed with 2.5 BV of purified water at a flow rate of 2 BV/h, followed by elution using 55% alcohol at a flow rate of 2 BV/h. Collect the purified eluate, approximately 800 ml, for later use. After each elution, the resin is soaked in 95% alcohol for over 12 hours before reuse. In industrial production, a custom-designed chromatography column made of 316L stainless steel with a high diameter-to-height ratio of around 7 - 8 can be used. Compared to laboratory glass columns, it offers better process control. Therefore, the use of a custom-made chromatography column fully meets the process requirements for macroporous resin adsorption separation, demonstrating the feasibility of the purification production process.

3.5. Decolorization

In the eluate containing alcohol, introduce it into a glass column packed with D900-type weakly basic anion exchange resin. The flow rate through the column is 2 BV/h. Collect the liquid after passing through the column, approximately 800 ml, for later use. In industrial production, a custom-designed decolorization column made of 316L stainless steel with a high diameter-to-height ratio of approximately 6 to 7 can be used. Compared to laboratory glass column operations, it offers better process control. Therefore, the use of a custom-made decolorization column fully meets the process requirements for decolorization, demonstrating the feasibility of the purification production process.

3.6. Drying

Take the liquid after passing through the decolorization column and subject it to vacuum concentration. Concentrate it until the specific gravity of the liquid is above 1.3 mg/ml. Then, transfer the concentrated liquid to a vacuum drying oven for vacuum drying until the water content is <5%. After drying, pulverize the product and package it, obtaining approximately 8 g of total saponins of Panax Notoginseng. The extraction yield from herbal materials to total saponins of Panax Notoginseng is 8%. During the vacuum concentration and drying processes, the temperature is controlled below 60˚C. In industrial production, evaporative concentration and vacuum drying methods can be employed. For concentration, start with vacuum single-effect external circulation concentrators to concentrate the liquid until the specific gravity reaches 1.1 mg/ml, then transfer it to a scraper-type vacuum concentrator to reach a specific gravity above 1.3 mg/ml. Therefore, using a combination of a vacuum single-effect external circulation concentrator, a scraper-type vacuum concentrator, and a vacuum drying oven fully meets the drying process requirements for Panax Notoginseng extract, demonstrating the feasibility of the drying production process.

Based on the above-mentioned verification of the small-scale extraction process for total saponins of Panax Notoginseng, the feasibility of transitioning from small-scale to industrial production has been confirmed. It is possible to achieve

industrial production, making the small-scale extraction process feasible.

4. Workshop Process Design

Based on the demonstrated feasibility of the Panax Notoginseng extract process, and in accordance with the "Drug Production Quality Management Specification", the workshop process design for the extraction of 2000 kg per year of Panax Notoginseng saponin extract is as follows:

Calculating based on 250 days of production per year, for the production of 2000 kg of Panax Notoginseng saponin extract, considering the previously verified extraction yield of 8%, the daily production requirement is 8 kg of extract. According to the process and material balance calculations, the production capacity and equipment selection for each production step are as follows:

1) Herbal Extraction Process:

Production time: 24 hours per day.

Daily input: 100 kg of herbal materials.

Equipment selection: 1 unit of 1 m^3 multifunctional extraction tank, equipped with a 100-mesh dual-filter, and a 1.5 m^3 extract storage tank.

2) Extract Concentration Process:

Production time: 8 hours per day.

Evaporation capacity of the concentrator: 200 L/h.

Calculated based on a typical production efficiency of 70%.

Equipment selection: Single-effect external circulation concentrator with an evaporation capacity of 300 L/h.

3) Water Precipitation Process:

Production time: 24 hours per day.

Equipment selection: 2 units of 1 m^3 water precipitation tanks, used alternately, equipped with stirring and cooling jackets. Considering the possibility of some suspended particles entering the water precipitation during the liquid-liquid separation process, include a 0.5 μm pore-size titanium rod filter and a 1 m^3 receiving filter liquid storage tank.

4) Purification Process:

Production time: 24 hours per day.

Equipment design: 2 chromatography columns, each with a diameter of 273 mm and a height of 2.6 m, used alternately. Additionally, 1 high-position tank of 1.0 m^3 and 1 liquid collection tank of 1.0 m^3.

5) Decolorization Process:

Production time: 8 hours per day.

Equipment design: 2 chromatography columns, each with a diameter of 273 mm and a height of 2.0 m, used alternately.

6) Drying Process:

Production time: 24 hours per day.

Equipment design: 1 unit of single-effect external circulation concentrator with an evaporation capacity of 300 L/h, 1 unit of scraper concentrator with an

evaporation capacity of 100 L/h, and 1 vacuum drying oven with 12 standard drying trays.

This comprehensive workshop process design ensures the efficient and continuous production of Panax Notoginseng saponin extract while meeting the necessary quality and quantity requirements.

5. Production Process Control Plan

5.1. Automated Medicinal Plant Extraction Design

Initiating the automation system, based on batch production instructions, initially, batch production information such as product name, specifications, batch number, production date, etc., is imported either manually or by the system. Upon completion, the system prompts the start of production. The control system follows the process specifications, starting from the manual loading of herbal materials, solvent addition, feeding, heating, insulation extraction time, liquid and residue extraction, cleaning, and the number of extractions, all of which are automated.

The key process control strategies are designed as follows:

1) System Self-Check: Before material loading, the production system conducts a self-check. The self-check comprises three parts: firstly, a check of the utility systems, including steam, compressed air, etc., to ensure they meet production requirements; secondly, a check of the equipment status in the extraction system, which includes verifying if the equipment is in usable condition and within its cleaning validity period; thirdly, the initialization of the equipment status in the extraction system, ensuring that all valves are in the correct positions before production. If the self-check fails, the system issues warning prompts for manual intervention. Once the self-check passes, production personnel are prompted to commence material loading.

2) Alcohol Blending: The blending tank is equipped with an alcohol concentration detector for online alcohol concentration monitoring. Upon receiving blending instructions, the system calculates the required amount of alcohol and water based on preset targets (alcohol concentration and volume). It then automatically adds the calculated amount of alcohol from the fresh alcohol storage tank to the blending tank, followed by the calculated amount of purified water. After 15 minutes of stirring, the alcohol concentration is rechecked using an alcohol concentration detector. Depending on the recheck results, if they fall within the acceptable deviation range, water or alcohol is added in small quantities as needed until the required concentration is achieved. Alcohol blending is fully automated.

3) Material Loading (Herbal Materials): After a successful self-check, the system prompts for the manual loading of 100 kg of Sanqi herbal materials. Upon confirmation by the operators in the control room, control permissions are transferred to the on-site button. Simultaneously, site indicator lights start flashing. On-site personnel perform an on-site inspection and confirm com-

pliance before pressing the on-site button to initiate material loading. Once material loading is complete, they press the on-site button again, transferring control authority back to the control room operation station.

4) Alcohol Addition: Following the completion of material loading, the system automatically initiates the precise addition of 200 liters of alcohol from the blending tank to the extraction tank in accordance with the process requirements. The alcohol flow rate is controlled through flow meters and valves. When the predetermined value is reached, the system automatically closes the valves.

5) Soaking: After the initial addition of alcohol, the herbal materials enter the soaking phase. The system automatically starts a timer, and when the soaking duration reaches 8 hours, the system provides a prompt indicating the completion of the soaking phase, initiating the first extraction operation.

6) Heating: Upon completion of the soaking phase, the system, following a predefined heating curve, automatically adjusts the steam pressure by modulating the valves for heating. During the heating process, intermittent opening of bypass valves is carried out for automatic purging of excess water. Simultaneously, stirring is initiated to ensure uniform temperature within the tank. Temperature sensors inside the tank continuously monitor the liquid temperature. When the temperature reaches the reflux extraction temperature, the system proceeds to the insulation extraction phase.

7) Temperature Maintenance Extraction: When the system reaches the reflux state during heating, the timer for temperature maintenance extraction begins with a timing error of ±60 seconds. When the timer reaches 6 hours, the system signals the completion of extraction. Throughout the temperature maintenance extraction process, the system automatically adjusts steam pressure by modulating the valve to maintain a gentle boiling state inside the tank.

8) Liquid Extraction and Anti-Clogging Measures: After the extraction process is completed, the system activates the corresponding valves and equipment to transfer the medicinal liquid to the extraction liquid storage tank. The liquid extraction pipe is equipped with a flow meter and a liquid level switch for measuring the liquid extraction. When the set liquid extraction quantity is reached, and there is no liquid flow detected in the pipeline, the system automatically determines that the liquid extraction is complete. If the liquid extraction falls short of the set quantity, the system identifies it as a blockage and initiates an automatic compressed air backflush process. This process involves three consecutive cycles of 10 seconds each before resuming liquid extraction. Additionally, the extraction liquid storage tank is equipped with a liquid level sensor that, when reaching a high level, automatically stops the inflow and issues a warning to prevent spillage.

9) Second Extraction: After adding an additional 600 liters of alcohol according to the predetermined quantity, the system follows the procedures outlined in items 5) to 7) to perform heating, maintaining extraction, and liquid extraction.

10) Residue Removal: Upon completion of the second extraction, the system

prompts for the preparation of residue removal, and the on-site indicator lights flash. The control room operator confirms the residue removal by clicking a button, and control is transferred to the on-site personnel. On-site personnel inspect and confirm the conditions for residue removal, and upon their confirmation through an on-site button press, the system opens the bottom cover of the extraction tank to remove the residue. To prevent safety incidents, the extraction tank's bottom lock and bottom opening mechanism have interlocking safety measures. The system strictly adheres to a safety procedure (at least two-level verification) for residue removal. If there is no confirmation within 30 seconds after the system prompts for residue removal, it issues a warning and initiates a safety verification process again. After residue removal is completed, control is returned to the control room.

11) Cleaning: Clicking the "Cleaning" button for the extraction tank triggers a sequence of actions. First, the system performs a self-check to ensure that the tank's bottom cover is closed. If the bottom cover is not closed, the system automatically initiates the process to close it until it is fully closed. Once the bottom cover is confirmed closed, the system activates the purified water cleaning system. This system is used to clean the extraction tank, filters, and pipelines in a cyclic manner for a specified duration. After the cleaning process is completed, the system automatically updates the status of the extraction tank from "Cleaning in Progress" to "Cleaned" and initiates a countdown for the next scheduled cleaning.

12) Safety Interlock Procedure: The extraction tank's jacket is equipped with pressure sensors. If the pressure in the jacket exceeds the maximum working pressure, the system will automatically close the steam inlet valve and simultaneously open a bypass valve for pressure relief. The system issues a warning and synchronously eliminates the safety hazard. Once the safety concern is resolved, the system will re-activate the steam system. Pressure sensors are also installed inside the extraction tank, and if the internal pressure reaches a preset value, the system will issue an alarm and prompt on-site personnel to address the issue.

The extraction production process, starting from the addition of herbal materials, automatically follows the predetermined extraction process, including alcohol preparation, measured alcohol addition, heating, maintaining extraction, liquid extraction, residue removal, and cleaning. This entire process is automated. Compared to traditional manual operations, it offers advantages such as uniform temperature during extraction, automatic foam control, prevention of liquid blockages, safety interlocks, and energy-saving steam control. These advantages ensure safety, increase extraction efficiency, and reduce production costs.

5.2. Concentration Automation Design

The automation system is initiated based on the extraction batch production instructions, automatically updating production information such as drug name,

specifications, batch number, production date, etc. Once completed, the system prompts the start of production. The control system follows the process specifications and initiates automated control of the entire process, including vacuum extraction from the concentrator, feeding, concentration, liquid extraction, and cleaning. The key control strategies for the process are designed as follows:

1) System Self-Check: Prior to formal initiation, the system's production system performs a self-check. This includes a self-check of the common systems and an equipment status self-check for the concentration system, as well as the initialization of equipment status within the concentration system. The aim is to ensure that all valves are in the correct state before production. If the self-check fails, the system issues a warning prompt, and manual intervention is required. Upon successful self-check, the system proceeds to automatic feeding.

2) Vacuum Feeding: After passing the self-check, the system automatically opens the vacuum valve (in automatic mode, the vacuum valve is linked to the vacuum pump). When the vacuum level reaches −0.06 MPa, the bottom liquid valve of the storage tank and the fully open feed control valve are opened, initiating the feeding process. Feeding stops once the set liquid level is reached.

3) Heating: Open the drain bypass valve, and through the adjustment of valves, automatically regulate the steam pressure. After a certain time for draining, close the bypass valve, and begin the heating process, with the vacuum level controlled at −0.08 MPa through valve adjustments.

4) Concentration: Once the temperature has been raised to the point where the liquid in the concentrator exhibits a spray-like state, the system enters the liquid concentration phase. During concentration, the system automatically controls the liquid based on the set vacuum level and temperature to maintain the liquid in the optimal evaporation state. Temperature control during concentration remains below 70˚C, with a temperature error of ±2˚C, and an alert is triggered if the temperature exceeds these limits. The feeding rate is adjusted by the feed control valve to maintain a stable liquid level within the concentrator. A level switch indicates the status of liquid output from the storage tank. After liquid output is completed, the feed control valve is closed and a signal is provided to indicate the end of the replenishment process. Real-time monitoring of liquid level is carried out during concentration. When the high-level threshold is reached, automatic liquid discharge is initiated, and it is closed when the liquid level is low.

5) Defoaming Control: The foam electrode conducts online checks and interlocks with the vacuum system of the concentrator. When foam reaches a certain height, it is automatically eliminated by breaking the vacuum.

6) Concentration Endpoint Control: Concentration is halted when the liquid reaches a specific gravity of 1.10 mg/ml. The volume of concentrated liquid is simultaneously measured.

7) Discharge: After reaching the concentration endpoint, the steam system is automatically closed and depressurized, and a signal is provided for discharge. Once the discharge is confirmed, the concentrated liquid is automatically trans-

ferred to a settling tank.

8) Cleaning: After production is completed, the cleaning valve and drainage valve of the concentrator are opened. The cleaning timer runs according to the set parameter <cleaning time>. The cleaning valve is automatically closed when the timer reaches its set time. After a delay to allow drainage to complete, the drainage valve is closed. Status detection confirms that the drainage valve is in the closed position, and the equipment status is automatically changed from "awaiting cleaning" to "cleaned," with the clean status countdown timer initiated.

9) Safety Interlock: The concentrator's jacket is equipped with pressure detection points. If the pressure in the jacket exceeds the maximum working pressure, the system automatically closes the steam inlet valve and simultaneously opens the bypass valve for pressure relief. The system issues a synchronous warning. Once the safety hazard is resolved, the steam system is reactivated. All operational components return to their safe positions after completion of concentration.

The concentration production process encompasses the entire automated production operation, including vacuum extraction, feeding, heating, concentration, intermediate supplementation, solvent removal, concentration endpoint determination, discharge of concentrated solution, and cleaning. Compared to traditional manual methods, it offers distinct advantages such as high concentration efficiency, automatic foam control, anti-surge capabilities, precise concentration endpoint detection, accurate temperature control, and steam energy conservation.

5.3. Water Settling Automation Design

In the water settling production process, the system automatically imports batch information for pharmaceutical production from the previous step, including drug name, specifications, batch number, and production date. Once the concentrated solution enters the settling tank, the system prompts the start of water settling production. Following the process specifications, the system controls various aspects of the operation, including the amount of pure water added, addition rate, motor stirring, cooling water temperature reduction, refrigeration settling, settling time, upper clear liquid extraction, cleaning of the settling tank and filter, and storage tank for filtrate. The entire process is automated, but manual intervention is required for the separation step. The main control strategies for the process are as follows:

1) System Self-Check: Before introducing the concentrated solution, the production system conducts a self-check. The self-check consists of three parts: first, a check of the utility systems, including the compliance of cooling water and compressed air with production requirements; second, a check of the equipment status in the water settling system, including whether the equipment is in working condition and within the cleaning validity period; and third, the initialization of equipment status in the water settling system to ensure that all valves are in the correct state before production. In case of a failed self-check, the system is-

sues a warning message, and manual troubleshooting is required. After passing the self-check, the operator is prompted to begin the water settling operation.

2) Water Addition Control: When introducing the concentrated solution, the water settling tank automatically opens the vacuum, and when it reaches the set value of −0.06 MPa, the feed valve is opened to draw the concentrated medicinal solution into the tank. The system calculates the amount of water to be added (four times the volume) based on the amount of medicinal solution added and automatically starts stirring. It then opens the pure water valve and adds water at a pre-set feed rate until the calculated amount of water is reached, at which point the pure water valve is closed.

3) Stirring and Cooling: After adding water, the system automatically opens the cooling water inlet valve and starts stirring and cooling. The cooling follows a pre-set cooling curve, and the temperature of the material inside the tank is monitored. When the temperature of the medicinal solution reaches the required process temperature of 20˚C - 25˚C, the system automatically stops the stirring motor, activates the settling time function, and begins isothermal refrigeration settling.

4) Alcohol Settling and Storage: During the refrigerated settling phase, the system automatically times the duration with a timing error of ±1 minute. The cooling water is adaptively adjusted based on the set temperature value inside the tank to ensure that the medicinal solution temperature is maintained between 20˚C to 25˚C. When the settling period ends, the system prompts for manual liquid extraction.

5) Separation Control: After the water settling period is complete, the system prompts for manual liquid extraction. Upon manual confirmation, the system activates the relevant equipment.

6) Safety Interlock Control: Pressure detection points are installed inside the alcohol settling tank. When the pressure inside the tank reaches the set value, the system automatically activates pressure relief and eliminates the risk, while issuing an alarm. The upper layer storage tank is equipped with a high-level alarm for liquid level. When the liquid level reaches the warning line inside the tank, the system automatically closes the current inlet valve and issues an alarm.

7) Online Cleaning: By clicking the "Cleaning" button on the water settling tank, a purified water cleaning process is initiated. The spray parameters are set with a specified "equipment cleaning time." After the stirring motor is activated for the designated time, drainage begins. Once the drainage is complete, the valves are automatically closed. After confirming that the drainage valve is in the closed position, the equipment status is automatically changed from "waiting cleaning" to "cleaned," and the cleaning validity period countdown begins.

The water settling production process, including material inflow, water addition, flow rate control, stirring and cooling, settling, liquid extraction, and cleaning, is entirely automated. Compared to traditional manual methods, this process provides precise control over water addition and flow rate, accurate temperature control for cooling and maintaining a stable settling effect, resulting

in consistent batch quality control.

5.4. Purification Automation Design

Initiating the automation system, the production information such as drug name, specifications, batch number, and production date is automatically updated based on the batch production instructions. Once completed, the system prompts the start of production. The control system follows the process specifications, automating the entire process from adsorption on the resin column, water washing, alcohol elution, collection of alcohol eluate, to resin cleaning and regeneration. The main control strategies are designed as follows:

1) System Self-Check: Before formal initiation, the production system performs a self-check. It conducts equipment status self-check for the purification system and initializes the equipment status to ensure that all valves are in the correct state before production. If the self-check fails, the system issues a warning message for manual troubleshooting. After passing the self-check, it prompts for production.

2) High-Level Tank Control: When vacuum reaches −0.06 MPa, it pumps the aqueous drug solution to the high-level tank, and then vents it to atmospheric pressure while measuring the volume using a level gauge. After the drug solution is used up, it automatically adds water to the tank based on measurements from the inlet valve and tank level gauge. After water is used up, it conveys alcohol from the mixing tank to the high-level tank via a peristaltic pump, also measuring the volume.

3) Liquid Loading onto the Resin Column: At the top of the resin column, a micro-pressure difference level gauge is installed, linked to the high-level tank outlet valve to automatically control the column's liquid level. At the bottom of the resin column, a control valve and flow meter are installed to automatically control the flow rate of liquid leaving the column and the cumulative liquid loading onto the column. After the liquid exits the column, it flows into an intermediate transfer tank before being discharged. With this design, the liquid loading onto the column is carried out at the required flow rate and volume according to the process requirements. Based on real-time flow rates of liquid entering and exiting each column, the liquid loading is evenly distributed between two resin columns. Once the cumulative liquid loading on each column reaches the process requirement, it proceeds to the next step: water washing.

4) Water Washing: Similar to the control of liquid loading onto the column, the flow rate and flow volume of water washing are automatically controlled according to the process requirements. The liquid exiting the column flows into an intermediate transfer tank before being discharged. Once the cumulative volume of water washing reaches the process requirement, it proceeds to the next step: alcohol elution.

5) Alcohol Elution: Similar to the control of liquid loading onto the column, the flow rate and flow volume of alcohol elution are automatically controlled according to the process requirements. The liquid exiting the column is trans-

ferred to a liquid collection tank for storage. Once the cumulative volume of alcohol elution reaches the process requirement, it proceeds to the next step: resin cleaning and regeneration.

6) Liquid Collection Control: During liquid loading onto the column and water washing processes, the materials flow into the intermediate transfer tank before being discharged, while during alcohol elution, the materials flow into the liquid collection tank and are stored. The intermediate transfer tank is equipped with a level gauge linked to pumps for automatic conveying.

7) Resin Cleaning and Regeneration: 95% ethanol from the resin regeneration cleaning tank is reversed and pumped into the column through the column's bottom valve. It flows back to the cleaning tank through the top valve, and after maintaining the backwash for a certain time, the pump and bottom valve are closed, and the ethanol immersion timer begins. After 12 hours of immersion, the resin is washed with pure water, controlling the flow rate, until the effluent alcohol content is less than 2%. The resin separation reaches a certain batch number; an alkaline wash is performed in the cleaning tank, where a 2% sodium hydroxide solution is prepared. After backwashing, it is rinsed with pure water until the pH becomes neutral. After 95% ethanol backwash and 12 hours of immersion, purified water is added to the high-level tank, and the resin column is flushed positively at the set flow rate until the alcohol content in the effluent is less than 2%. Simultaneously, this process compacts the resin bed, making it ready for use.

From liquid loading onto the resin column, water washing, alcohol elution, collection of alcohol eluate, to resin cleaning and regeneration, the entire process is essentially automated. Compared to traditional manual methods, the critical process parameters such as column loading flow rate, column loading volume, and liquid collection are digitally and precisely controlled, enhancing process control stability and batch-to-batch consistency. In future research, the use of near-infrared online detection devices can be explored to achieve real-time component analysis, automatic switching of elution solutions, and automatic collection of target components. This approach eliminates the reliance on manual experience, resulting in increased efficiency and improved product quality.

5.5. Decolorization Automation Design

Initiating the automation system, the production information such as drug name, specifications, batch number, and production date is automatically updated based on the batch production instructions. Once completed, the system prompts the start of production. The control system follows the process specifications for the entire decolorization process, including liquid loading onto the column and resin cleaning, to achieve automation. The main control strategies for the process are designed as follows:

1) System Self-Check: Before formal initiation, the production system performs a self-check. It conducts equipment status self-check for the decoloriza-

tion system and initializes the equipment status to ensure that all valves are in the correct state before production. If the self-check fails, the system issues a warning message for manual troubleshooting. After passing the self-check, it prompts for production.

2) Decolorization Control: At the bottom of the column, a control valve and flow meter are installed to automatically control the flow rate of liquid leaving the column. The flow rate of liquid entering the column is controlled by a variable frequency control of the liquid inlet pump, linked to the flow meter for adaptive adjustment. This achieves automation of the liquid loading and decolorization process, automatically adjusting the liquid inlet flow rate, controlling liquid loading, and measuring the volume of liquid loaded onto the column.

3) Liquid Collection Control: The decolorized drug solution is automatically collected in an intermediate transfer tank. The transfer tank is equipped with a level gauge to measure the volume of liquid inside.

4) Resin Cleaning and Regeneration: After preparing a 3% sodium hydroxide solution in the resin regeneration cleaning tank, it is pumped into the column through a pump and bottom valve for backwashing. The liquid is then returned to the cleaning tank through the top valve. After backwashing for a certain period, the effluent is discharged through the cleaning tank and bottom valve. Purified water is added to the cleaning tank, and after multiple backwashes to achieve a neutral pH, purified water is added to the alcohol elution liquid collection tank. The resin column is positively flushed using a pump to achieve a compact resin bed arrangement. The flow rate is controlled, and after a certain period, the flushing liquid is discharged. The resin is then soaked in purified water and is ready for use.

From liquid loading onto the resin column, collecting decolorized liquid, to resin cleaning and regeneration, the entire decolorization process is essentially automated. Compared to traditional manual methods, critical process parameters such as column flow rate and column liquid loading are digitally and precisely controlled, improving decolorization quality and product quality. Additionally, the continuous production operation reduces production cycles and enhances production efficiency.

5.6. Concentration and Drying Automation Design

As the drying cabinet equipment comes with its own PLC control system, this production process focuses solely on concentration automation design.

Upon initiating the automation system and based on batch production instructions for extraction, the system automatically updates production information such as drug name, specifications, batch number, and production date. Once this is completed, the system prompts the start of production. The control system follows the process specifications for the entire concentration process, including vacuum extraction, feeding, concentration, liquid discharge, and cleaning, to achieve automation. The primary control strategies for the process are designed as follows:

1) System Self-Check: Before formal initiation, the production system conducts a self-check. This includes a self-check of the public utility systems and equipment status self-check for the concentration system, as well as initializing the equipment status to ensure that all valves are in the correct state before production. If the self-check fails, the system issues a warning message for manual troubleshooting. After passing the self-check, it prompts for automatic feeding.

2) Vacuum Feeding: After the system's self-check passes, the system automatically opens the vacuum valve (in automatic mode, the vacuum valve is linked with the vacuum pump), and when the vacuum level reaches −0.06 MPa, it opens the bottom valve of the storage tank and fully opens the liquid inlet control valve, commencing feeding. Feeding stops when the set liquid level is reached inside the concentrator, at which point stirring is initiated.

3) Heating: The bypass valve for draining condensate is opened, and the steam pressure is automatically adjusted by a control valve. After a specific time of draining condensate, the bypass valve is closed, and the heating process begins. The vacuum level is controlled to be −0.08 MPa by regulating the valve.

4) Concentration: Once the temperature inside the concentrator reaches a boiling state, the drug solution enters the concentration phase. During concentration, the system automatically controls the process based on the set vacuum level and temperature to maintain the drug solution in the optimal evaporation state. Temperature control during concentration is kept below 70˚C, with a temperature error of ±2˚C and temperature exceeding limits triggering a warning. Throughout the concentration process, the liquid inlet flow rate is adjusted by the feed control valve to maintain a steady liquid level inside the concentrator. A liquid level switch displays the status of liquid discharge from the storage tank, and after liquid discharge is completed, the liquid inlet control valve is closed, and a refill completion alert is issued. Liquid level in the evaporator is monitored in real-time, and when it reaches a high level, automatic liquid discharge to the alcohol recovery storage tank is initiated. When the level is low, liquid discharge is closed.

5) Defoaming Control: A foam electrode provides online detection and interlocks with the vacuum system of the concentration tank. When foam reaches a certain height, it is automatically eliminated by venting the vacuum.

6) Concentration Endpoint Control: During concentration, an external circulation pipeline is activated, and the density of the drug solution is monitored in real-time. Concentration stops when the drug solution density reaches 1.35 mg/ml.

7) Discharging: Once the concentration reaches its endpoint, the steam system is automatically shut off and vented. It prompts manual collection of the concentrate in a Class D clean area before transferring it to a vacuum drying cabinet.

8) Cleaning: After production is completed, the concentrator's cleaning valve and drain valve are opened. Cleaning is timed until the set parameter for clean-

ing time is reached, at which point the cleaning valve is automatically closed. After a delay to ensure complete drainage, the drain valve is closed. After confirming that the drain valve is in the closed position, the equipment status is automatically changed from "Pending Cleaning" to "Cleaned," and the effective cleaning period countdown begins.

9) Safety Interlock: The concentrator jacket is equipped with pressure detection points. When the jacket pressure exceeds the maximum working pressure value, the system automatically closes the steam inlet valve and opens the bypass valve for pressure relief. The system simultaneously issues a warning and, after eliminating the safety hazard, reopens the steam system. After concentration is completed, all actuating mechanisms return to a safe position.

The scraping concentrator production process, covering vacuum extraction, feeding, heating, concentration, intermediate refeeding, solvent discharge, concentration endpoint determination, and cleaning, is fully automated. Compared to traditional manual methods, it offers advantages such as high concentration efficiency, automatic defoaming, anti-surge feeding, precise density control, accurate temperature control, and energy-efficient steam utilization.

5.7. Workshop Utility Engineering Automation Design

Real-time monitoring, warning, control, energy measurement, and management are applied to the utility systems, and the control strategies are outlined as follows:

1) Steam Supply System: Pressure monitoring is performed on the steam main to ensure that the steam supply to each device on the production line meets the required range, thereby ensuring production. Simultaneously, steam usage is metered and statistically analyzed to guide rational usage and conserve energy.

2) Vacuum System: Pressure monitoring is conducted on the vacuum main to ensure that the vacuum supply to each device on the production line is within the required range, thereby ensuring production. Workshop vacuum demands are linked with vacuum pump units, and the vacuum pumps are frequency-controlled based on vacuum requirements to save energy.

3) Compressed Air System: Pressure monitoring is carried out on the compressed air main to ensure that the compressed air supply to each device on the production line falls within the required range, thereby ensuring production. Workshop compressed air demands are linked with compressed air compressor units, and the compressors are frequency-controlled to maintain stable output pressure and save energy.

4) Cooling Water System: Pressure and temperature monitoring are conducted on the cooling water main to ensure the normal operation of production equipment. The inlet water temperature of the cooling water is linked with cooling tower units, and the cooling pumps are frequency-controlled to maintain stable output pressure and temperature of the cooling water, conserving energy.

5) Drinking Water System: Pressure monitoring is carried out on the drinking water main to ensure production supply. Simultaneously, drinking water usage

is metered and statistically analyzed to guide rational usage and conserve energy.

5.8. Automation System Design

This automation control system design is based on production equipment and employs a computer network system as its framework, combining equipment device layer (including detection instruments and transmitters), process control layer, and production scheduling layer into a comprehensive system.

The system is divided into three layers: the equipment device layer, the process control layer, and the production scheduling management layer. The production scheduling management layer and the process control layer are primarily responsible for real-time monitoring and data collection of the entire extraction process. They issue control commands to the equipment control layer, enabling all system operators to track process activities and participate in production control through standard, user-friendly, and process-oriented interfaces.

The control layer adopts a client/server architecture, with connections between clients and servers utilizing standard industrial Ethernet. In the central control room, there are large screens and operator workstations. Operators gain detailed insights into production operations through terminal operations and can issue operational control commands. The third layer is the equipment device layer. This equipment control layer utilizes the Siemens PROFIBUS-DP fieldbus and is equipped with on-site touch screens connected to the bus. It can display real-time working statuses of unit equipment, receive instructions, and control the production process.

All control valves, solenoid valves, flow meters, liquid level gauges, level switches, temperature transmitters, pressure transmitters, as well as stirring motors and pumps, are connected to the control system via the bus, achieving the automation of the entire TCM extraction production process.

6. Conclusions

In this paper, using the example of Panax Notoginseng Saponins (PNS) extraction, workshop process design and automation solution design were carried out. The following conclusions can be summarized:

1) Feasibility analysis was conducted for the industrial production of PNS based on small-scale extraction trials. The feasibility of transitioning from small-scale trials to industrial production was established.

2) Based on capacity planning, the design of various production processes and equipment selection was performed.

3) An automated control system for the extraction workshop was designed, enabling continuous and automated production. This has enhanced the consistency of product quality and significantly improved production efficiency.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

References

[1] Halmemies, S., Grondahl, S., Arffman, M., *et al.* (2003) Vacuum Extraction Based Response Equipment for Recovery of Fresh Spills from Soil. *Journal of Hazardous Materials*, **97**, 127-143. https://doi.org/10.1016/S0304-3894(02)00249-2

[2] Cirimele, V., Kintz, P., Majdalani, R., *et al.* (1995) Supercritical Fluid Extraction of Drugs in Drug Addict Hair. *Journal of chromatography B*, **673**, 173-181. https://doi.org/10.1016/0378-4347(95)00281-7

[3] Li, L., Liu, F., *et al.* (2002) Investigation of a Liquid-Liquid Extraction System Based on Non-Ionic Surfactant-Salt-H_2O and Mechanism of Drug Extraction. *Analytica Chemical Acta*, **452**, 321-328. https://doi.org/10.1016/S0003-2670(01)01471-4

[4] Zou, L. and Ye, Y.G. (1998) Environmental and Countermeasure Discussion on the Confrontation between Traditional Chinese Medicine and Western Medicine. *China Pharmaceutical Industry*, **2**, 14-15.

[5] Chen, Y.K. (1992) Production Technology of Traditional Chinese Medicine Extraction. Shenyang Publishing House, Shenyang.

[6] Zhang, Z.W. (2013) Discussion on the Application of Automation Technology in the Field of Traditional Chinese Medicine Extraction Production. *Science and Technology Innovation and Application*, **8**, 94.

[7] Chen, Y.Q. and Li, S.Y. (2012) Design of Automatic Monitoring System for Traditional Chinese Medicine Extraction. *Mechanical and Electrical Engineering Technology*, **6**, 10-13.

[8] Li, H.W. and Li, H.L. (2007) Research on the Automation of Vacuum Concentration Equipment in Traditional Chinese Medicine Extraction. *Today's Science*, **12**, 120.

[9] Liu, Q.G., Tang, X.B., Gao, B., *et al.* (2010) Digital Control System for Traditional Chinese Medicine Extraction. *China Instrumentation*, **S1**, 183-185.

[10] Jian, J.H. (2010) Preliminary Study on Traditional Chinese Medicine Extraction Production and Automation Control. Mechatronics, **10**, 43-45.

[11] Xu, X.Q. (2009) Traditional Chinese Medicine Extraction Production Process and Automation Control. *Mechatronics*, **32**, 25-27.

[12] Bai, Y. (2007) Automation Control of Traditional Chinese Medicine Extraction Process. *Automation and Instrumentation*, **3**, 69-72.

[13] Zhang, L.G., Zhu, J. and Ni, L.J. (2007) Theoretical Model and Control Strategy of Traditional Chinese Medicine Extraction and Concentration Process. *Journal of Tianjin University*, **12**, 1490-1494.

[14] Tang, J.L. (2002) Design and Application of Computer Control System for Traditional Chinese Medicine Extraction Process. *Pharmaceutical Engineering Design Journal*, **6**, 39-44.

[15] Jiao, L.Z. (2005) Modernization of Traditional Chinese Medicine and Pharmaceutical Equipment. *Mechatronics*, **20**, 47-48.

[16] Liu, C.P., Dong, L. and Jin, L. (2004) Application of Siemens PCS 7 System in Traditional Chinese Medicine Extraction Concentration Production Process. *Chinese Traditional Medicine Research and Information*, **7**, 23-28.

[17] Liu, G.Q., Liu, C.P. and Chen, H.Q. (2006) Self-Control System of Traditional Chinese Medicine Extraction. *Shandong Pharmacy*, **12**, 761-763.

[18] Liang, Z.G. and Liu, L.K. (2015) Discussion on Several Key Instrumentation and Process Control Difficulties in Traditional Chinese Medicine Multi-Function Ex-

traction Tank. *Chemical Engineering and Pharmaceutical Engineering*, **6**, 56-60.

[19] Lu, P. and Zhan, J.L. (2007) Design and Application of Traditional Chinese Medicine Extraction Process Control System. *Microcomputer Information*, **3**, 69-71.

[20] Jia, X.W., Hao, T., Liu, S.Y., *et al.* (2020) Analysis of Key Measurement Instruments and Process Control Difficulties in the Automation of Traditional Chinese Medicine Extraction. *China Equipment Engineering*, **3**, 114-116.

[21] Fei, Y.C., Wang, G.H., Zhou, Y.H., *et al.* (2021) Application of Intelligent Manufacturing Technology in Traditional Chinese Medicine Extraction. *Mechatronics*, **30**, 66-68.