Research Status, Applications, Improvements, and Prospects of Compound Honeysuckle Film Coating Process

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Abstract [**Objectives**] To address the issues of rapid deterioration and unfavorable taste in compound honeysuckle preparations, as well as the challenges of high viscosity, low efficiency, and elevated water absorption rates associated with the current film coating process, optimize the process and offer a reference framework for industrial enhancement. [**Methods**] Utilizing a literature review approach, the current research status of process is systematically examined. The challenges associated with the application and industrialization of multi-dosage forms are analyzed, and improvement strategies are proposed across five domains: materials, parameters, equipment, quality control, and fundamental research. [**Results**] This process can improve the stability of preparations, mask odors, and be adapted for the production of various dosage forms. However, it presents challenges including fluctuation in the quality of plain tablets, uneven coating application, and inadequate standardization. Systematic optimization can effectively address these process deficiencies. [**Conclusions**] Following enhancements in greenness, intelligence, and standardization, the compound honeysuckle film coating process demonstrates extensive application potential and offers valuable insights for advancing coating technologies and promoting the industrial upgrading of solid preparations in traditional Chinese medicine.

Key words Compound honeysuckle, Film coating, Coating process, Quality control

1 Introduction

Compound Honeysuckle Granules consist of three traditional Chinese medicinal herbs: *Lonicera japonica*, *Forsythia suspensa*, and *Scutellaria baicalensis*. The granule is commonly utilized in the treatment of wind-heat common cold, pharyngitis, tonsillitis, eye pain, toothache, carbuncles, furuncles and sores due to its properties of clearing heat, detoxifying, cooling the blood, and reducing swelling[1]. As a widely utilized heat-clearing and detoxifying agent, this drug experiences substantial market demand. However, existing commercial products exhibit notable deficiencies, including susceptibility to deterioration caused by moisture and light exposure during storage, which compromises their efficacy and therapeutic outcomes. Additionally, the product possesses a pronounced medicinal odor, resulting in low acceptance among certain consumers. Traditional preparations employ sucrose as an excipient, thereby restricting use among individuals with "hypertension, hyperglycemia, and hyperlipidemia"[2-3]. To address these issues comprehensively, it is imperative to optimize the preparation process.

Film coating technology is an effective approach to addressing the aforementioned challenges. Common film coating agents typically consist of film-forming agents, plasticizers, colorants, and other components. When applied to the surface of solid dosage forms through spraying and coating, these agents can improve taste, prevent moisture ingress, and enhance stability. This technology serves as a novel alternative to the traditional sugar coating process[4]. The present article provides a systematic review of the current research status, practical applications, existing challenges, and potential improvement paths related to the compound honeysuckle film coating process. Furthermore, it offers insights into future development prospects, aiming to offer insights for process optimization and industrial advancement of this preparation.

2 Research status of compound honeysuckle film coating process

Film coating, a pivotal technology in the domain of solid dosage forms, has progressively supplanted the conventional sugar coating method[5]. Owing to its superior film-forming capabilities, material efficiency, and effective moisture resistance[6], it has assumed a leading role in the manufacture of traditional Chinese medicine tablets. Research efforts have consistently focused on process optimization, equipment innovation, and technological enhancement.

Currently, the research system concerning this process has become increasingly comprehensive. Regarding the mechanism influencing the process, it is well established that the hardness of plain tablets serves as the primary indicator for regulating the coating's cracking rate, with a significant negative correlation observed between the two. Furthermore, through cluster analysis, a four-tier quality classification system, comprising excellent, good, qualified, and unqualified categories, has been developed, offering a foundation for the implementation of differentiated process adaptations[7]. Regarding equipment, three primary types have been established: mechanical coating machines, air flow coating equipment, and fluidized bed coating equipment. Among these, air flow coating equipment has emerged as a focal point of development due to its advantage of enabling continuous production. Significant advancements have been achieved in numerical simulation

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technologies, with methods such as CFD-DEM and DDM providing accurate predictions of particle movement and coating outcomes. Nevertheless, there exists an imbalance in development between domestic and international contexts. Internationally, continuous production technology and high-precision simulation are at the forefront, whereas in China, efforts are primarily concentrated on the localization and optimization of processes as well as the implementation of applications.

Current research priorities are focused on four principal areas: the precise alignment of quality grading of plain tablets and the coating process, alongside enhancing the homogeneity of plain tablets through optimization of the granulation and tabletting processes[7]; optimization of critical parameters in air flow coating equipment[8]; advanced application of multi-field coupled numerical simulations, notably the innovative CFD-DEM-DDM coupling algorithm, which offers theoretical support for process optimization; and the development of environmentally friendly functional coating materials aimed at reducing the use of organic solvents while expanding functionalities such as sustained and controlled release.

3 Application practice of compound honeysuckle film coating process

3.1 Application in different dosage forms

3.1.1 Tablet. Tablet is the primary dosage form utilized in the film coating process, encompassing traditional Chinese medicine extract tablets, conventional Western medicine tablets, enteric-coated tablets, as well as sustained-release and controlled-release tablets[9]. To mitigate challenges such as high hygroscopicity, discoloration, and caking commonly observed in traditional Chinese medicine extract tablets, coating materials like hydroxypropyl methylcellulose (HPMC) and Opadry are frequently employed. These materials substantially improve moisture resistance without adversely impacting the dissolution of active ingredients[10]. For example, following the application of Opadry coating to the Ruzengning Tablets, the disintegration time was reduced from 55 to 35 min, rendering the tablets suitable for diabetic patients[11]. Furthermore, targeted drug release can be accomplished by selecting appropriate coating materials; for instance, enteric-coated tablets prepared with polyacrylic acid resin L series prevent drug degradation in the stomach[12]. Nimodipine film-coated tablets utilize Eudragit E100, which provides moisture resistance without altering the dissolution rate[13]. Moreover, film coating can effectively mask the unpleasant odor of Western medicines and improve patient compliance.

3.1.2 Pills (including micropills). Film coating of tablets is primarily utilized to enhance stability, facilitate sustained and controlled drug release, or enable targeted delivery. Commonly employed materials, including polyacrylic acid resin and HPMC, are used to mitigate issues such as component oxidation and moisture absorption. For example, Jinchan Dingtong Micropills are coated with No. IV acrylic resin, which effectively prevents oxidation and discoloration of the active ingredients while simultaneously addressing the limitations of traditional sugar coatings, such as uneven coloration and slow disintegration[14].

3.1.3 Granules. The application of film coating to granules, including those contained within capsules, primarily serves to mitigate issues such as moisture absorption, caking, and odor masking. For example, coating the extract granules of Biantong Capsules with HPMC significantly reduces their moisture absorption rate and increases the critical relative humidity under high-humidity conditions[15]. The swallowing type of Shuanghuanglian Granules is coated with HPMC, which not only masks bitterness but also improves moisture resistance[16].

3.1.4 Capsules. Film coating is primarily employed for the pretreatment of particles contained within capsules, rather than for the capsule shells themselves. To mitigate the issue of strong hygroscopicity of the particles inside capsules, which can lead to deformation of the capsule shell, applying a film coating to the particles prior to filling effectively prevents moisture absorption. For example, coating the granules of traditional Chinese medicine extract powder capsules with No. IV acrylic resin significantly enhances their moisture resistance, thereby preventing capsule shell deformation and component degradation[17].

3.1.5 Other dosage forms. In addition to the primary dosage forms previously discussed, film coating can also be applied to drug powders, as well as to the modification of soft and hard capsule shells and targeted preparations. Specifically, coating hygroscopic drug powders can improve their storage stability. Furthermore, through specialized coating techniques, such as multilayer membranes and microporous membranes, targeted preparations, including osmotic pump type and colon-targeted type, can be developed to achieve controlled and site-specific drug release.

3.2 Application in industrialized production The compound honeysuckle film coating process emphasizes continuity, intelligence, environmental sustainability, and regulatory compliance as its core principles in industrial production. It encompasses applications in pharmaceuticals, food, and health products, facilitating large-scale manufacturing and ensuring consistent quality control.

In tablet manufacturing, fully automatic inclined coating pans are predominantly employed, particularly for medium-scale batch production. For large-scale production, continuous coating lines integrated with tablet presses are utilized. In the production of pills, granules, and granules encapsulated within capsules, fluidized bed coating is primarily applied to mitigate issues such as moisture absorption, oxidation, and flavor masking. This technique is also suitable for achieving sustained, controlled, and targeted drug release. Following the coating process, the critical relative humidity of the particles increased, leading to enhanced fluidity and consequently minimizing deformation of capsule shells. Within the food and health product sectors, film coating technolo-

gy is applied to functional candies and nutritional supplement granules to satisfy clean label requirements. Starch and calcium salts are employed as substitutes for titanium dioxide, addressing both aesthetic and safety considerations.

3.3 Advantages and existing problems in the application

3.3.1 Application advantages. (i) The product's performance has been markedly improved. The film coating material constitutes only 2% – 5% of the tablet core's weight, providing protection against moisture, light, and oxidation, thereby extending the medication's efficacy. The use of materials such as HPMC and polyacrylic acid resin enables targeted drug release, making this approach suitable for compound preparations. Compared to the sugar coating process, the production cycle is reduced by more than 60%. Additionally, the water-based technology employed is environmentally friendly and cost-effective, rendering it appropriate for large-scale manufacturing.

(ii) The process is adapted to meet the demands of industrialization and regulatory compliance. The parameters are controllable, ensuring stable batch quality that satisfies the criteria for drug consistency evaluation and GMP certification. Furthermore, the process can be integrated with equipment to establish a continuous production line, thereby enhancing utilization efficiency and reducing control costs. This method is appropriate for the coating of pharmaceuticals, food products, and health supplements.

3.3.2 Existing problems. (i) The technical threshold for this process is relatively high. The quality of the coating is highly dependent on the precise and coordinated control of various parameters. Even minor deviations in spray speed, atomization pressure, inlet air temperature and humidity, and the rotational speed of the pan can readily result in issues such as surface roughness, orange peel texture, cracked coating films, and substandard dissolution rates.

(ii) Coating materials exhibit certain limitations. Some high-performance synthetic polymer coatings are relatively costly, thereby elevating the production expenses of pharmaceutical preparations. Furthermore, the film-forming properties and stability of natural coating materials have not yet fully achieved the required standards, posing challenges in meeting the demands of advanced formulations, such as sustained-release and controlled-release preparations. Certain coating materials may interact adversely with the active pharmaceutical ingredients, and there exist potential compliance risks related to residual solvents and excessive heavy metal content.

(iii) The adaptability to industrialization remains inadequate. The high investment costs associated with continuous production equipment pose significant financial challenges for small and medium-sized pharmaceutical enterprises. Consequently, these enterprises predominantly rely on batch production, which incurs relatively high losses during batch transitions. Furthermore, for small-batch, multi-variety research transformations or the production of specialized preparations, the flexibility of existing large-scale equipment is insufficient, often leading to resource wastage.

4 Improvement path of compound honeysuckle film coating process

4.1 Optimization and innovation of coating materials The coating material is a critical component in the compound honeysuckle film coating process, and its optimization must be aligned with the characteristics of the formulation constituents. Addressing current challenges such as high viscosity and propensity for adhesion in existing coating methods necessitates prioritizing the selection of green functional excipients that do not interact with the active components of *L. japonica*, *F. suspensa*, and *S. baicalensis*. This approach aims to enhance the compatibility between materials and preparations. Furthermore, optimizing the ratio of film-forming agents to composite plasticizers can improve film-forming performance and mitigate defects including cracking, mottling, and adhesion. Concurrently, the development of natural and environmentally friendly coating materials to replace chemical raw materials, alongside the promotion of novel auxiliary materials for industrial application, can contribute to controlling production costs and fulfilling the requirements of large-scale manufacturing.

4.2 Systematic optimization of coating process parameters The parameters of the compound honeysuckle film coating process must be optimized in a coordinated manner throughout the entire procedure. The response surface methodology can be employed to systematically integrate and balance the indicators of each stage. During the raw material extraction phase, the ratio of complex enzymes, extraction temperature, and duration are regulated to maximize the retention of active ingredients. In the preparation of plain tablets, the formability and flowability of the materials are enhanced by optimizing the proportion of excipients. The preparation of the coating solution necessitates strict control of stirring speed, solution concentration, and preparation temperature to ensure system uniformity. The spray coating and drying processes involve parameter linkage, standardizing spray rate, drying temperature, and wind speed, while establishing a process defect control mechanism. By optimizing these parameters in conjunction with large-scale production conditions, production efficiency can be significantly improved without compromising the quality of the final preparations.

4.3 Upgrading and transformation of coating equipment In accordance with the requirements of the compound honeysuckle film coating process, adaptive modifications to the production equipment are essential for successful implementation. Optimizing the temperature control and airflow speed modules of the pulse airflow dryer ensures uniform drying of materials and minimizes the loss of active ingredients. Adjusting the spray and temperature control systems of the high-efficiency coating machine enhances the uniformity and smoothness of the coating film. Additionally, the installation of online monitoring devices enables real-time control of key process parameters, thereby preventing production deviations. Establishing a continuous coating production line further improves the stability and efficiency of industrial manufacturing.

4.4 Improvement and strengthening of quality control system Establishing a comprehensive quality control system throughout the entire production process is essential for stabilizing the quality of compound honeysuckle film-coated tablets. It is imperative to develop quality standards for raw materials and coating excipients to ensure control over material quality from the outset. Detection indicators for critical production processes should be defined to rigorously monitor core parameters, such as maintaining the relative density of the thick paste within the range of 1.10 to 1.15. The finished product evaluation system has been improved by including mandatory inspection items such as water absorption rate and mold rate. Additionally, stability tests are conducted under conditions of 60 ℃ and 75% relative humidity, and detection technologies have been upgraded to enhance the accuracy and efficiency of quality control.

4.5 Strengthening fundamental research and technological innovation Advancing fundamental research on the compound honeysuckle film coating process can offer theoretical foundations for optimizing this procedure and further elucidate the interaction mechanisms between the coating film and active ingredients, as well as the regulatory principles governing drug release. The integration of artificial intelligence and big data technologies facilitates intelligent parameter regulation and early warning of quality risks. The existing process is enhanced through interdisciplinary integration and the application of novel preparation technologies. In accordance with the demands for high-quality development of traditional Chinese medicine preparations, standardized production protocols and quality systems are established to promote the standardized and normalized advancement of this coating process.

5 Development prospects of compound honeysuckle film coating process

The compound honeysuckle film coating process has been systematically optimized, effectively addressing the limitations of traditional methods, including uneven coating, numerous defects, and poor compatibility. These improvements have enhanced the quality and stability of the preparation, reduced production energy consumption and costs, and facilitated the green, intelligent, and efficient advancement of the process, thereby providing robust support for the quality enhancement of the preparation. Moreover, the process aligns with the high-quality development trends in traditional Chinese medicine preparations and holds considerable potential for future applications. At the material level, development will focus on green degradability, functional synergy, and cost reduction. By leveraging research and development in bio-based membrane materials, simultaneous improvements in environmental sustainability and cost efficiency can be achieved[18]. Technologically, the primary trends include intelligence, precision, and efficiency. Through the intelligent upgrading of solid dosage forms, automatic parameter regulation and enhanced process controllability will be realized. Quality evaluation methods are expected to become more comprehensive, rapid, and accurate. From an industrial perspective, driven by the extension of the industrial chain and market demand, large-scale and standardized production will be promoted. This will be complemented by full-process quality traceability to strengthen industrial competitiveness.

Looking forward, it is imperative to rigorously comply with the high-quality development standards for traditional Chinese medicine preparations and to foster continuous advancements in the coating process, particularly in terms of environmental sustainability and intelligent technologies. Future research should prioritize the following areas: first, the development of novel green functional coating materials, investigation of the interaction mechanisms between these materials and active ingredients, and enhancement of material compatibility; second, an in-depth study of the process mechanisms, integrating multi-factor collaborative optimization techniques to refine intelligent process models[19]; and third, the optimization of industrial adaptability. By leveraging intelligent upgrading technologies for solid traditional Chinese medicine preparations, it is possible to facilitate the efficient transition from laboratory-scale innovations to large-scale production, thereby providing valuable guidance for subsequent process research and applications and promoting the advancement of the compound honeysuckle preparation industry.

6 Conclusions

This paper provides a comprehensive review of the compound honeysuckle film coating process. It addresses key challenges associated with this preparation method, including susceptibility to deterioration, unfavorable taste, and the high viscosity coupled with low efficiency of current coating techniques. The review systematically examines the current state of research, elucidating advancements in areas such as plain tablet control, equipment selection, and numerical simulation, while also highlighting developmental disparities between domestic and international contexts. The coating process is extensively applied across various dosage forms, including tablets, pills, and granules, enhancing formulation stability, masking odors, and fulfilling industrialization requirements. Nonetheless, the process faces significant challenges, such as high technical barriers, limited availability of suitable materials, and inadequate adaptation to industrial-scale production. To address these issues, the article proposes optimization strategies encompassing five key aspects: materials, process parameters, equipment, quality control, and foundational research. The study concludes that the future development of this process, emphasizing green, intelligent, and standardized approaches, holds considerable promise, offering valuable insights for the coating technology of solid dosage forms in traditional Chinese medicine and the industrial advancement of compound honeysuckle preparations.

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(From page 8)

tent is influenced by various factors. This article offers a foundational reference for further research on the processing techniques of the mineral medicine lapis lazuli.

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