 DOI: 10.19600/j.cnki.issn2152 - 3924.2026.05.021

Bibliometric Analysis of Research Literature on Film-coated Tablets

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Abstract A bibliometric analysis of research literature on film-coated tablets from 2018 to 2025 was conducted using the CNKI and PubMed databases. The findings indicated that this field centered on pharmaceutical preparations and pharmaceutics, characterized by a notable multidisciplinary intersection. The annual number of published papers exhibited fluctuations but generally increased, reaching a peak in 2024. The literature published in English was predominant, reflecting a more integrated research chain, whereas studies published in Chinese primarily concentrated on improvements in laboratory processes. Basic research covered the screening of coating materials, formulation design, process optimization, and quality evaluation, while applied research focused on flavor masking, moisture-proofing, controlled-release enteric dissolution, and process quality control. It is recommended that future domestic research efforts should be intensified in areas such as clinical evaluation and intelligent production to further enhance the research system for film-coated tablets.

Key words Film-coated tablets, Bibliometric analysis, Formulation research

1 Introduction

Film coating agents typically consist of film-forming substances, plasticizers, colorants, and other components. These agents are applied to the surface of solid preparations through spraying, resulting in the formation of a film of a specific thickness. They are utilized in coating solid pharmaceutical preparations[1], food processing, confectionery, and crop seeds[2]. Their functions include improving taste, providing moisture protection, enhancing product stability and appearance, and they have emerged as a novel technology that replaces traditional sugar coating methods[3]. At present, film coating technology is extensively utilized in the medical field. Film-coated tablets offer several advantages, including moisture resistance, light protection, odor masking, and low water absorption, and also exhibit a reduced tendency to develop cracks, mottled spots, and mold. These properties contribute to enhanced drug stability, prolonged shelf life, and improved odor masking[4]. Furthermore, film coating demonstrates favorable processing fluidity, minimizes adhesion issues, enhances production efficiency, addresses limitations associated with existing granular formulations, and increases consumer acceptability[5].

A bibliometric analysis was conducted on the literature concerning film-coated tablets published in China over the past decade, covering various aspects such as disciplinary distribution, annual trends, journal distribution, and research institutions. The objective was to provide readers with relevant information regarding the research, development, and application of film-coated tablets by examining the current state of research in this field.

Relevant literature on film-coated tablets was retrieved through searches conducted in the China National Knowledge Infrastructure (CNKI) and the international medical database PubMed in May 2025. The search employed the subject term "film-coated tablets" and covered the period from January 1, 2018, to May 5, 2025. After removing duplicates and non-research papers, a total of 22 research literatures on film-coated tablets were included. These studies reflect the primary achievements and emerging trends in both domestic and international research on film-coated tablets. The content encompasses various aspects, including basic research, process optimization, material development, and formulation applications.

2 Literature distribution

2.1 Discipline distribution Utilizing CNKI and PubMed as data sources, original research literatures on film-coated tablets published between 2018 and 2025 were systematically screened, resulting in the identification of 22 valid studies, comprising 5 in Chinese and 17 in English. These studies were classified and subjected to statistical analysis according to disciplinary classification standards to examine the disciplinary distribution and research characteristics within this field.

In accordance with the classification standards of disciplines including pharmacy, pharmaceutical engineering, analytical chemistry, and clinical medicine, all literature was categorized into four primary groups: pharmaceutical preparations and pharmaceutics; clinical pharmacy and clinical medicine; pharmaceutical engineering and intelligent detection; and analytical chemistry and materials science. Some literature exhibited characteristics of multidisciplinary intersection, and classification was based on the core research content in statistics.

The statistical results presented in Table 1 indicated that research on film-coated tablets primarily concentrated on pharmaceutical preparations and pharmaceutics. In addition, this research integrated various fields, including clinical applications,

Received: May 6, 2026 Accepted: July 12, 2026

Supported by National Undergraduate Innovation and Entrepreneurship Training Program Project of Guangxi Zhuang Autonomous Region (202510599036S).

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intelligent manufacturing, and fundamental analysis, characterized by a notable interdisciplinary approach.

Table 1 Number and proportion of literature on film-coated tablets in various disciplines from 2018 to 2025

Discipline	Number of literature piece	Proportion of total literature//%
Pharmaceutical preparations and pharmaceutics	12	54.5
Clinical pharmacy and clinical medicine	5	22.7
Pharmaceutical engineering and intelligent detection	3	13.6
Analytical chemistry and materials science	2	9.1

Pharmaceutical preparations and pharmaceutics were the primary research areas within this field. Chinese literature mainly addressed the formulation and process optimization of film-coated tablets of traditional Chinese medicine and chemical drugs, alongside investigations into their stability[6-8]. Building upon this foundation, English-language studies had extended the scope to include enteric-coated formulations, bioequivalence assessments of generic drugs, and related topics[9]. Clinical pharmacy research was exclusively published in English and primarily focused on evaluating the safety and clinical benefits of film-coated tablets in special populations. In recent years, the application of machine vision and artificial intelligence for monitoring the coating process and identifying defects in pharmaceutical engineering has emerged as a prominent research trend. Research in analytical chemistry and materials science concentrates on developing detection methods and characterizing coating materials, thereby supporting quality control efforts for pharmaceutical preparations.

Significant differences existed between Chinese and international research. Domestic literature predominantly focused on the laboratory research and development of formulation, resulting in a relatively narrow research scope. In contrast, international research covered the entire chain from basic research and formulation development to industrial production and clinical application, demonstrating a more balanced disciplinary distribution and a higher level of integration among industry, academia, and research institutions.

Pharmaceutics has consistently been central to research within this field, with disciplinary diversification representing the primary developmental trend. Current domestic research mainly emphasizes process improvement. Future investigations may integrate clinical evaluation, intelligent manufacturing, novel coating materials, and other related areas to further enhance and expand the research framework.

2.2 Annual distribution This study utilized CNKI and PubMed as data sources to identify relevant literature on film-coated tablets published between 2018 and 2025. A total of 22 valid literatures were included, comprising 5 in Chinese and 17 in English. By conducting a statistical analysis of the publication years, the study examined trends in research interest and the developmental trajectory within this field.

The data presented in Table 2 indicated that the number of published papers in this field exhibited a fluctuating upward trend from 2018 to 2025. Notably, the years 2020, 2022, and 2024 represented peaks in publication volume, whereas no relevant literature was published in 2019 and 2023. The year 2018 corresponded to the initial phase of research, primarily focusing on the investigation of basic processes[10-11]. Between 2020 and 2022, research interest increased steadily. Domestically, studies concentrated on the preparation, dissolution rate, and stability of film-coated tablets for traditional Chinese medicine and chemical drugs[6,8,12]. In contrast, international research efforts simultaneously emphasized formulation evaluation and preliminary clinical investigations[13-14].

Table 2 Annual distribution of film-coated tablets literature from 2018 to 2025

Year of publication	Chinese literature//piece	International literature //piece	Total piece	Proportion %
2018	1	2	3	13.6
2019	0	0	0	0.0
2020	2	3	5	22.7
2021	0	1	1	4.5
2022	2	3	5	22.7
2023	0	0	0	0.0
2024	0	6	6	27.3
2025	0	2	2	9.1
Total	5	17	22	100

The number of published papers reached its peak in 2024. During this period, research directions became more diverse, with international literature constituting the absolute majority. The primary focus areas included bioequivalence, medication for special populations, intelligent detection technologies, and spectral analysis methods[9,15]. Research efforts expanded towards refinement, intelligence, and clinical application. In 2025, publication output remained high, continuing to emphasize cutting-edge technologies and clinical applications.

Significant differences were observed in the publication patterns between Chinese and international literatures. Chinese literature was predominantly concentrated between 2018 and 2022, with no related publications identified thereafter. The research cycle in China was relatively brief and primarily focused on enhancing laboratory preparation processes. International literature was consistently published throughout the entire period, particularly in the past three years, during which research outputs were more concentrated. Moreover, the pace of research iteration abroad was faster, closely aligning with technological advancements and clinical demands within the pharmaceutical industry.

Overall, research on film-coated tablets has increasingly gained prominence, with the scope of investigation gradually expanding from the optimization of individual processes to interdisciplinary applications across multiple fields. However, there remains a notable deficiency in domestic research efforts during the later stages. Future studies could benefit from incorporating international research perspectives, broadening focus areas to include

intelligent manufacturing and clinical evaluation, thereby enhancing the comprehensiveness of the research system.

2.3 Journal distribution This study analyzed 22 relevant literatures on film-coated tablets indexed in CNKI and PubMed. A statistical examination of the journals in which these literatures were published was conducted to identify core publication venues and the distribution characteristics of journals within this field. The results indicated that the journals could be categorized into two primary groups: Chinese journals and international professional journals. These journals exhibit a high degree of concentration and distinct professional attributes.

The data presented in Table 3 indicated that the journals publishing literature in this field can be categorized into two primary groups: Chinese journals (including those indexed in thesis and dissertation platforms) and international professional journals. Overall, these journals exhibited characteristics of low concentration and distinct professional attributes. No single journal demonstrated an exceptionally high publication volume, reflecting a decentralized publication model distributed across multiple journals.

Table 3 Statistics on the distribution of journals publishing research literature on film-coated tablets

Journal	Number of journals individual	Total number of papers published//piece	Core publication platform
Chinese journal/thesis and dissertation platform	5	5	Herald of Medicine, Process, Scientific and Technological Innovation, Thesis Database of Shanghai University of Traditional Chinese Medicine, Liaoning University Thesis Database
International professional journals	12	17	International Journal of Pharmaceutics, Pharmaceutical Development and Technology, BMC Pharmacology & Toxicology, Frontiers in Pharmacology, British Journal of Haematology, *etc.*

The Chinese literature searched included journal papers and master's theses. Specifically, five Chinese studies were published across three domestic industry journals and two university thesis databases[6-8,10,12]. The proportion of theses was relatively high, indicating that the majority of related research in China is conducted within the framework of university projects. The number of papers published in core industry journals was comparatively limited. The Chinese journals primarily focused on pharmaceutical processes and traditional Chinese medicine preparations, with their readership predominantly consisting of domestic pharmaceutical companies and researchers.

A total of 17 English-language papers were published across 12 leading SCI-indexed international pharmacy journals. These journals are highly specialized and encompass various sub-disciplines, including pharmaceutics, clinical pharmacy, and analytical chemistry[9,13,16-17]. They function as the primary platforms for disseminating advancements in the field of international film coating, exhibiting high influence and broad academic reach.

Based on the journal's positioning and the content of its papers, it is evident that domestic research primarily emphasizes the enhancement of practical processes, with research findings predominantly published in dissertations and ordinary industry journals. In contrast, international research encompasses basic theories, advanced technologies, and clinical applications. These achievements are chiefly disseminated through internationally recognized pharmaceutical journals, whose orientations closely align with the research priorities of both China and other countries.

3 Basic research

3.1 Screening and characteristic research of coating materials The selection of coating materials is the fundamental basis of film coating technology. Based on their solubility characteristics, coating materials can be categorized into three types: water-soluble, water-insoluble, and pH-dependent. Water-soluble materials, exemplified by hydroxypropyl methylcellulose (HPMC), exhibit favorable film-forming properties and dissolve rapidly in gastrointestinal fluids[18]. Water-insoluble materials, such as ethyl cellulose, are commonly employed in sustained-release and controlled-release coatings. pH-dependent materials, represented by acrylic resins (Eudragit series), enable enteric coating or colon-targeted drug release. In their study on Baoshen tablets, Wang Zhengkuan *et al.*[19] identified Opadry as the optimal coating material. The optimized coating process involved an approximate 4% increase in coating weight, a tablet bed temperature of 50 ℃, and a material concentration of 8%.

3.2 Design and compatibility of prescription systems The formulation design should prioritize the evaluation of the solvent system, solid concentration, and excipient compatibility. Water-based coatings have replaced organic solvent-based coatings due to their enhanced safety profile and environmental sustainability. Typically, the solid concentration is maintained between 8% and 15%; concentrations exceeding this range may lead to adhesion issues, whereas lower concentrations can result in uneven film formation. Compatibility assessments should be performed using techniques such as DSC and IR to ensure that the coating materials do not interact adversely with the active pharmaceutical ingredient or the tablet core excipients (*e. g.*, microcrystalline cellulose, lactose), thereby preventing drug degradation or polymorphic transformations. Ming Liangshan *et al.*[20] demonstrated that the dispersion uniformity of the coating solution significantly affected the microstructure of the coating film, which in turn influenced the dissolution behaviors.

3.3 Optimization of preparation process and film-forming mechanism High-efficiency coating machines are widely em-

ployed for film coating applications. Key process parameters include inlet air temperature (ranging from 40 to 60 ℃), spray rate, pan rotation speed, and coating weight gain (2% – 5%). Adhering to the quality by design (QbD) principle, the quantitative relationships between these parameters and quality attributes can be established through experimental design to minimize batch-to-batch variability. The film formation process can be delineated into three stages: droplet adhesion, solvent evaporation, and polymer fusion. Terahertz pulse imaging technology enables real-time monitoring of the hydration and dissolution kinetics of the coating film, demonstrating that film density exerts a more significant influence on drug release rate than coating weight gain.

3.4 Construction of quality evaluation system Quality assessment includes the evaluation of appearance, physical properties, microstructure, and dissolution behavior. Appearance criteria include uniform coloration without cracking or adhesion. The mechanical properties of the membrane focus on tensile strength and elongation at break. SEM and AFM are employed to analyze the morphology and surface roughness of the membrane. The acid resistance of enteric coatings must be assessed, the release rates of sustained-release coatings at various time points should be determined, and the photostability and hydration kinetics of TiO_2-free coatings require evaluation.

4 Application research

4.1 Odor masking and moisture-proofing applications For pharmaceuticals characterized by a bitter taste or unpleasant odor, film coating is the most frequently employed technique to mask these sensory attributes. Coating systems utilizing water-soluble film-forming polymers, such as HPMC and polyvinyl alcohol, rapidly establish a barrier layer within the oral cavity, effectively preventing direct contact between the drug and the taste buds. Research has demonstrated that the application of Opadry coating materials to compound licorice tablets addresses issues related to moisture absorption and volatilization, resulting in complete taste masking of bitterness and significantly enhancing patient medication adherence[21].

Regarding moisture resistance, film coating effectively prevents environmental moisture from penetrating the tablet core, thereby inhibiting the degradation of hydrolysis-sensitive drugs. For example, the application of film coating technology combined with the incorporation of calcium hydrogen phosphate into the formulation to maintain tablet dryness resulted in a 20% improvement in the moisture resistance of tea polyphenol film-coated tablets following process optimization, and all quality parameters satisfied the required standards[22].

4.2 Controlled-release and enteric-coated applications Controlled-release film coating is an important technology for achieving sustained and regulated drug release. Enteric-coated formulations are specifically engineered to prevent drug degradation by gastric acid or to minimize gastric irritation. Tablets coated with pH-sensitive materials, such as Eudragit L100-55, exhibit minimal drug release in gastric fluid. After reaching the intestine, the coating rapidly dissolves, resulting in immediate drug release[23]. Recent research has focused on developing colon-targeted coating systems that exploit the unique pH environment or microbial enzymatic activity in the colon, offering novel therapeutic strategies for managing refractory bowel diseases.

4.3 Process optimization and quality control The quality of film coating depends on the coordinated regulation of multiple process parameters, including spray rate, atomization pressure, bed temperature, and air intake volume. Research indicates that excessively high temperatures within the tablet bed may result in rough coatings and even tablet cracking. Conversely, temperatures that are too low can lead to insufficient water evaporation, which often causes tablets to adhere to one another. The application of the QbD concept[24], coupled with the determination of the design space for critical process parameters through DEM[25], can effectively ensure batch-to-batch consistency and maintain product quality stability.

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nasty. The term Zibeitiankui was originally used interchangeably with Tukui. During the Qing Dynasty, works such as *Zhiwu Mingshi Tukao* and *Bencao Gangmu Buyi* sought to address this confusion by distinguishing Tukui from Tiankui, thereby clarifying both the nomenclature and the actual identity of Tiankui. Taoism frequently employs Tiankui in the preparation of external elixirs. Due to the purple coloration on the underside of its leaves, it is referred to as Zibeitiankui. In the *Diannan Bencao*, Zibeitiankui corresponds to *G. bicolor* (Roxb. ex Willd.) DC., a species within the Compositae family, whereas in botanical taxonomy, Zibeitiankui denotes *B. fimbristipula* Hance of the Begoniaceae family. Although both plants share the name Zibeitiankui as used in *Leigong Paozhilun*, they represent distinct species.

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