Journal of Clinical and Nursing Research, 2026, Volume 10, Issue 5
http://ojs.bbwpublisher.com/index.php/JCNR
Online ISSN: 2208-3693
Print ISSN: 2208-3685

Research on Process Optimization and Quality Control of Oral Tablets

Chao Zhou, Jin Yang, Qihong Chen, Jun Qi, Yu Wang

Hunan Qianjin Xieli Pharmaceutical Co., Ltd., Zhuzhou 412000, Hunan, China

Copyright: © 2026 Author(s). This is an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY 4.0), permitting distribution and reproduction in any medium, provided the original work is cited.

Abstract: Oral tablets are the most widely used solid dosage form in clinical practice with the highest patient compliance. Their preparation process and quality control directly affect the safety and efficacy of medicines. This paper conducts an in-depth study on the process optimization and quality control of oral tablets, analyzes the key problems in quality control, and proposes practical optimization and control strategies. It aims to provide a reference for improving the production quality of oral tablets.

Keywords: Oral tablets; Process optimization; Quality control

Online publication: May 31, 2026

1. Introduction

With the advantages of low production cost, accurate dosage and convenient administration, oral tablets have become the most widely used dosage form in the global pharmaceutical industry. With the continuous improvement of China's drug regulatory system and the upgrading of GMP standardization, higher requirements have been put forward for the production process, mass uniformity and in vitro release consistency of oral tablets [1]. In actual production, oral tablets are easily affected by many factors such as coating process, ambient temperature and powder properties, which further influence the hardness, appearance, stability and dissolution of tablets [2]. Without effective control, problems such as delayed disintegration, unstable dissolution and uneven content are likely to occur, which not only affect the production efficiency and economic benefits of oral tablets, but also directly affect clinical efficacy and medication safety. Therefore, based on the production requirements of oral tablets, this paper systematically sorts out the existing problems in production and explores scientific and complete process optimization and quality control strategies, which is of great practical significance for promoting the healthy development of pharmaceutical enterprises and ensuring drug quality and safety.

2. Main problems in the preparation and quality control of oral tablets

A series of problems exist in the preparation and quality control of oral tablets, as follows:

2.1. Unreasonable formulation design and unscientific excipient selection and proportion

Formulation is an important prerequisite for tablet forming and efficacy [3]. At present, unreasonable formulation design is common. First, improper selection of excipients: poor compressibility of fillers, too strong or too weak adhesion of binders, unscientific type and dosage of disintegrants, excessive lubricants, etc. Second, insufficient research on the compatibility of some drugs and excipients leads to compatibility reactions, resulting in discoloration, increased impurities and decreased content of tablets. Third, lack of evaluation of micromeritic properties. Inadequate investigation of raw material properties causes difficulties in granulation and tableting. Fourth, insufficient uniformity design leads to uneven content of tablets. All these affect the forming and efficacy of tablets.

2.2. Extensive granulation process and large fluctuation of granule quality

Granulation is one of the key links in tablet production, with prominent problems [4]. First, in wet granulation, the concentration, dosage and stirring speed of binders are not strictly controlled, resulting in uneven tightness of granules. Second, environmental factors such as drying and high temperature affect the granulation process, leading to decomposition of active ingredients or excessive moisture content. Third, in dry granulation, unstable pressure results in uneven particle size distribution and variable compressibility. Lack of effective control of granule bulk density, moisture content and fluidity will cause fluctuations in the tableting process.

2.3. Improper tableting process control and common forming defects

Tableting is the process most prone to appearance and internal quality problems in tablet production [5]. Low tableting pressure may cause loose tablets and insufficient hardness. Excessive tableting pressure may cause capping, delayed disintegration and splitting. Excessively high tableting speed may prevent the air in the granules from being discharged in time, aggravating splitting. In addition, mismatched structure and speed of feeder will cause uneven filling of granules and weight difference beyond production standards.

2.4. Non-standard coating process control and substandard appearance and function

Coating is also one of the key processes in tablet production, with main problems focusing on process and formulation [6]. In terms of formulation, unreasonable coating solution design and unscientific proportion of pigments and plasticizers may cause spots and film brittleness. Inaccurate control of coating weight gain leads to too thick or too thin coating, affecting the production quality of tablets.

2.5. Imperfect quality control system and insufficient monitoring of key indicators

There are some problems in tablet quality control [7]. First, imperfect quality standards: only meeting the minimum requirements of pharmacopoeia, lack of in-depth research on dissolution curve and content uniformity. Second, inaccurate detection methods with low sensitivity affect the authenticity and accuracy of results, making it difficult to accurately reflect product quality. Third, insufficient process management and lack of online detection mechanism prevent early warning.

Poor batch-to-batch consistency and no evaluation and verification of process changes.

2.6. Insufficient research on dissolution and *in vitro-in vivo* correlation

Some tablets lack systematic dissolution research and only meet disintegration time limit inspection. Single dissolution medium and unscientific rotating speed cannot fully reflect the *in vivo* release behavior. Without dissolution curve comparison, bioequivalence is difficult to guarantee. Obvious fluctuation of dissolution data and insufficient process stability are inconsistent with clinical efficacy.

2.7. Unsystematic stability study and unscientific shelf life and storage conditions

Stability research is unsystematic, with unreasonable condition setting, incomplete inspection items and in-depth evaluation [8]. Long-term test, accelerated test and stress test are not standardized, making it impossible to judge the influence of light, temperature and moisture on appearance, dissolution and content. In addition, unreasonable packaging materials with insufficient moisture and oxygen resistance directly affect the safety and quality of tablets.

2.8. Non-standard production management and process traceability

There are also some problems in production management and process traceability of oral tablets [9]. Some enterprises do not strictly implement GMP, with incomplete and untrue process parameter records. The range of critical process parameters is not clear, and operation mainly depends on production experience. Incomplete equipment cleaning increases the risk of pollution. Incomplete batch production records and quality traceability system make it impossible to trace problems. Inadequate personnel quality and non-standard operation lead to human accidents.

3. Systematic strategies for process optimization and quality control of oral tablets

3.1. Formulation optimization strategy: Scientific design to ensure quality from the source

To optimize the production process and improve quality control of oral tablets: First, carry out compatibility test of drugs and excipients, screen scientific and reasonable excipient combinations through appearance, content and other indicators to avoid compatibility reactions. Scientifically select fillers, lubricants, binders and other excipients [10]. Optimize excipient proportion and determine the optimal formulation through scientific design. Internal and external addition method can be used for disintegrants to improve disintegration speed. Scientifically control the dosage of lubricants to avoid affecting the compressibility and disintegration of tablets. Second, strengthen micromeritic evaluation, conduct in-depth research on angle of repose, fluidity and particle size distribution to lay a foundation for granulation and tableting. In addition, equal incremental mixing method can be used for low-dose drugs, even core granulation or solvent dispersion method to ensure uniform drug content.

3.2. Granulation process optimization strategy: Refined control to stabilize granule quality

(1) Wet granulation optimization

Clarify the concentration, dosage and adding speed of binders to ensure uniform particle size and moderate tightness.

(2) Drying process optimization

Scientifically control ambient temperature, wind speed and time to ensure optimal moisture content of granules, effectively avoiding component degradation, moisture absorption, softness or hardness.

(3) Fluidized bed granulation optimization
Scientifically control air inlet temperature, atomization pressure and spray rate to realize integration of mixing, granulation and drying, improving granule uniformity.

(4) Dry granulation optimization
Scientifically adjust roller pressure, gap, and speed to find the optimal balance range for granule density, friability, compressibility, and drug release behavior.

(5) Real-time control of granule quality
Comprehensively detect friability, bulk density and fluidity. Only qualified products can enter the tableting process to lay a foundation for improving drug production quality.

3.3. Tableting process optimization strategy: Stable forming to eliminate appearance and internal defects

First, adjust tableting pressure, speed and filling depth to ensure moderate hardness and complete appearance. Improve granule fluidity by adding appropriate glidant to reduce tablet difference.

Second, scientifically adjust granule moisture, lubricant, tableting speed and pre-pressure to reduce splitting, sticking and capping. In addition, do a good job in equipment maintenance, regularly inspect and maintain equipment to ensure good condition.

Finally, improve online monitoring mechanism by using modern technology. Digital sensors and cameras can be used to build an online monitoring mechanism, and artificial intelligence and big data can be used to realize data abnormality early warning.

3.4. Coating process optimization strategy: Improve appearance, moisture resistance and stability

First, optimize coating formulation. Select the most suitable coating materials, plasticizers and pigments to improve the uniformity and continuity of coating film. Accurately control process parameters to ensure accurate spray pressure, air outlet temperature and air inlet temperature. Second, scientifically control coating weight gain to ensure functions such as moisture protection, light shielding, and taste masking are achieved without negatively impacting disintegration and dissolution. Online monitoring technology can be used to monitor coating status in real time to avoid peeling, spots and cracking. Note that low-temperature and high-efficiency coating can be used for heat-moisture unstable drugs to improve stability.

3.5. Quality standard improvement strategy: Establish a comprehensive, scientific and controllable quality evaluation system

First, establish a complete quality standard including traits, dissolution, content uniformity and assay to ensure comprehensiveness and integrity. Second, adopt professional and accurate detection methods and complete methodological verification to ensure true and accurate test results. Third, conduct in-depth research on dissolution. A variety of pH dissolution media can be used to draw dissolution curves to evaluate intra-batch and inter-batch consistency. Meanwhile, conduct consistency evaluation of generic and original drugs. Finally, strictly control related substances and clarify the limits of single impurity and total impurity to

ensure medication safety. Uniformity inspection is also required for low-dose tablets to ensure accurate and uniform drug content.

3.6. Whole-process quality control strategy: Realize GMP standardization and traceability

First, establish a whole-process quality control system to strictly control the whole process from raw material warehousing, granulation to release. Determine Critical Process Parameters (CPP) and Critical Quality Attributes (CQA), implement process control and trend analysis. Strictly control temperature, humidity, pressure difference, cleanliness and other factors of the production environment. Complete all records in time to ensure true, accurate and complete data. A variety of methods can be used for verification to ensure stable production process without cross-contamination.

3.7. Stability research strategy: Scientific evaluation to determine reasonable packaging and shelf life

First, strictly carry out stress test, accelerated test and long-term test in accordance with pharmacopoeia to comprehensively evaluate tablet stability. Second, conduct stability inspection, focusing on disintegration time limit, content, microbial limit and other key indicators. Select appropriate packaging materials and storage conditions. Scientifically evaluate the barrier properties of different packaging materials according to drug characteristics to effectively isolate light, oxygen, moisture and other external factors. For example, light-sensitive, moisture-sensitive or easily oxidized drugs should prefer packaging materials with excellent light avoidance, moisture resistance and oxygen isolation performance, with desiccant if necessary.

3.8. Intelligent and digital upgrading strategy: Improve quality control accuracy and production efficiency

First, introduce Process Analytical Technology (PAT). Near-infrared spectroscopy (NIRS) is used for online monitoring of moisture, content and particle size, as well as online tablet weight, hardness and thickness. Second, use orthogonal test, response surface method, neural network and other models to optimize process parameters and improve R&D and production efficiency. Finally, build a digital production management system to realize centralized data collection, trend analysis, risk early warning and continuous improvement. In this way, automated, closed and continuous production is realized, human interference is reduced, and stability and uniformity are improved.

3.9. Supporting strategy for generic drug consistency evaluation: Ensure *in vitro* and *in vivo* equivalence

First, take the original drug as the reference preparation, conduct multi-medium dissolution curve comparison to ensure that the f2 similarity factor meets the requirements. Second, optimize formulation and process to highly match dissolution behavior and improve the success rate of bioequivalence test. Finally, establish in vitro-in vivo correlation to improve the scientificity and reliability of preparation research and development.

3.10. Optimization strategy for personnel, equipment and management system

First, improve the personnel training mechanism, carry out regular training to improve professional quality and comprehensive ability, strictly implement GMP and operating procedures to reduce human error.

Second, strengthen equipment maintenance and verification to ensure high stability and accuracy. Establish and improve risk assessment, deviation handling and corrective and preventive measures system. Finally, strengthen supplier management, material management and warehouse management to ensure stable quality from the source.

4. Conclusion

In short, as the most widely used solid dosage form in clinical practice, process optimization and quality control of oral tablets are important ways to ensure drug safety, stability and effectiveness. At present, there are many problems in tablet production, such as unreasonable coating formulation, extensive granulation process, tableting and coating defects. These problems directly affect production quality, drug safety and clinical efficacy. Therefore, in the new era, we should continuously promote process innovation, quality control upgrading and management standardization, continuously improve the R&D and production level of oral tablets, provide safer, more effective and quality-controllable drugs for clinical use, and promote China from a big pharmaceutical country to a powerful pharmaceutical country.

Disclosure statement

The authors declare no conflict of interest.

References

[1] Feite Company, 2026, Safety and Closed Technology Practice in the Production of High-Active Drug Tablets. Flow Industry, 2026(02): 32–34.

[2] Li H, Zheng P, Yue Z, et al., 2026, Research on National Drug Standards of Leucogen Raw Materials and Tablets. Herald of Medicine, 1–12.

[3] Tang J, Li X, Jin S, 2025, Application Analysis of Wet Mixing Granulator in Tablet Production. Proceedings of Academic Exchange in Mechanical and Electrical Technology & Seminar on High-quality Development of Scientific and Technological Talents: 647–653.

[4] Xian W, Xu G, Zhou Y, et al., 2025, Preparation of 48% Propaneamidine · Fluazinam Water Dispersible Tablets and Its Control Effect on Gray Mold. Journal of Northwest A&F University (Natural Science Edition), 53(12): 128–136.

[5] Liao J, Wan X, Zhu W, et al., 2025, Research Progress and Countermeasures of Dissolution Behavior of Traditional Chinese Medicine Tablets Based on New Technology. Chinese Traditional and Herbal Drugs, 56(10): 3699–3711.

[6] Wu H, Zhang Z, Song Z, et al., 2025, Research on Preparation Process of Sweet Orange Flavor Vitamin A Tablets. China Fruits & Vegetables, 45(03): 23–27 + 50.

[7] Wang X, 2024, Design and Quality Research of Fluralaner Oral Tablets, thesis, Shanghai Institute of Technology.

[8] Zeng X, 2024, Co-crystal Development, Pharmacokinetic Study of Apixaban and Its Application in Oral Tablets, thesis, Chongqing University of Technology.

[9] Zhao Y, Fang Y, Wang Y, et al., 2022, Practice and Exploration of Quality Control Circle to Improve the Accuracy of Oral Tablet Dose Division for Children. Journal of Pediatric Pharmacy, 28(12): 13–16.

[10] Zeng W, Wang X, Chen J, et al., 2022, Current Situation and Countermeasure Analysis of Oral Tablet Dose Division in a Maternal and Child Health Hospital. Journal of Guangdong Pharmaceutical University, 38(06): 25–30.

Publisher's note

Bio-Byword Scientific Publishing remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.