

Quality Status Analysis of Chinese Patent Medicines in National Drug Sampling Inspection: A Five-Year Retrospective Study (2020–2024)

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Abstract

Background: Chinese patent medicines are widely used in clinical practice, and their quality directly affects medication safety and therapeutic efficacy. The National Drug Sampling Inspection program serves as a critical quality surveillance mechanism. However, previous assessments have not systematically differentiated the risk levels of different non-conforming items, leading to potential risk misjudgment.

Methods: This retrospective study analyzed inspection data of Chinese patent medicines from the National Drug Sampling Inspection conducted between 2020 and 2024. All inspection items were classified into appearance/description items and intrinsic quality test items. Risk stratification was performed across safety, efficacy, and stability dimensions.

Results: Over five years, a total of 30,791 batches were inspected, with non-conforming rates of 0.54% (2020), 0.31% (2021), 0.65% (2022), 0.52% (2023), and 0.13% (2024). Identification, assay, related substances, dissolution, and microbial limits represented substantive high-risk defects. Description non-conformities, accounting for a minor proportion, predominantly

involved minor appearance deviations that did not alter the intrinsic material basis. Risk stratification demonstrated clear differentiation between high-risk substantive defects and low-risk appearance deviations.

Conclusions: Different inspection items correspond to markedly different quality risk levels. A risk-stratified regulatory approach is warranted to optimize regulatory resource allocation and improve the scientific basis of quality supervision for Chinese patent medicines.

Keywords: Chinese patent medicine; national drug sampling inspection; quality risk assessment; risk stratification

1 Introduction

A complete quality standard for Chinese patent medicines consists of four major components: description, identification, examination, and assay. Among these, the description (character) serves as the fundamental visual inspection item, encompassing sensory indicators such as color, form, odor, and texture, used to preliminarily evaluate the batch-to-batch consistency in physical appearance. Identification verifies the authenticity of the herbal ingredients in the formulation; the assay monitors the actual levels of active or marker components; and examination represents the largest category of tests, covering multiple sub-items including related substances, dissolution, weight variation, disintegration time, and microbial limits—each controlling distinct risks such as impurities, in-vitro release characteristics, dosage form processing, and microbial contamination. In previous rounds of national drug sampling inspections, the non-conformance rate for description has been relatively high, drawing regulatory attention. However, in practice, there is a tendency to overemphasize description results while overlooking intrinsic test data,

treating minor appearance flaws as equivalent to substantive quality deterioration. Without risk differentiation among different non-conforming items, this approach may lead to risk misjudgment and homogenized disposal measures.

To further refine quality risk classification for Chinese patent medicines, this study conducted a systematic analysis based on national sampling big data from 2020 to 2024, integrating the results of description, identification, assay, related substances, dissolution, microbial limits, and other test items, comparing the differing consequences of non-conformity across inspection categories, and providing data support for differentiated regulation and scientific risk assessment of Chinese patent medicines.

2 Materials and Methods

This retrospective study used inspection data of Chinese patent medicines from the National Drug Sampling Inspection program between 2020 and 2024, compiled by the National Institutes for Food and Drug Control (NIFDC), Beijing, China. Data sources included the annual National Drug Sampling Inspection Reports (2020–2024) and the Drug Supervision and Statistics Annual Reports published by the National Medical Products Administration (NMPA). All inspection items were classified into appearance/description items (color, form, odor, texture) and intrinsic quality test items (identification, assay, and examination sub-items including related substances, dissolution, and microbial limits).

Non-conforming samples were divided into two major categories: those with intrinsic quality non-conformity and those with appearance/description non-conformity only. Risk stratification was performed across three dimensions: safety, efficacy, and stability. Descriptive statistics were

used to summarize the distribution of non-conforming items by category, dosage form, and year.

Table 1. Annual national sampling inspection results for Chinese patent medicines (2020–2024)

Year	No. of varieties	Batches inspected	Non-conforming batches	Non-conforming rate (%)
2020	48	6,338	34	0.54
2021	46	6,380	20	0.31
2022	47	5,805	38	0.65
2023	43	5,584	29	0.52
2024	48	6,684	9	0.13
Total	232	30,791	130	0.42

Data source: NMPA Drug Supervision and Statistics Annual Reports (2020–2024).

3 Results

3.1 Overall Quality Status

National sampling data from 2020 to 2024 demonstrated that the overall quality of Chinese patent medicines in China has continued to improve. A total of 30,791 batches were inspected across 232 varieties over the five-year period, with an overall non-conforming rate of 0.42% (Table 1). The vast majority of sampled products met pharmacopoeial requirements, and no systemic or large-scale quality safety incidents were identified. Notably, the non-conforming rate declined from 0.54% in 2020 to 0.13% in 2024, representing the lowest rate in the study period (Figure 1).

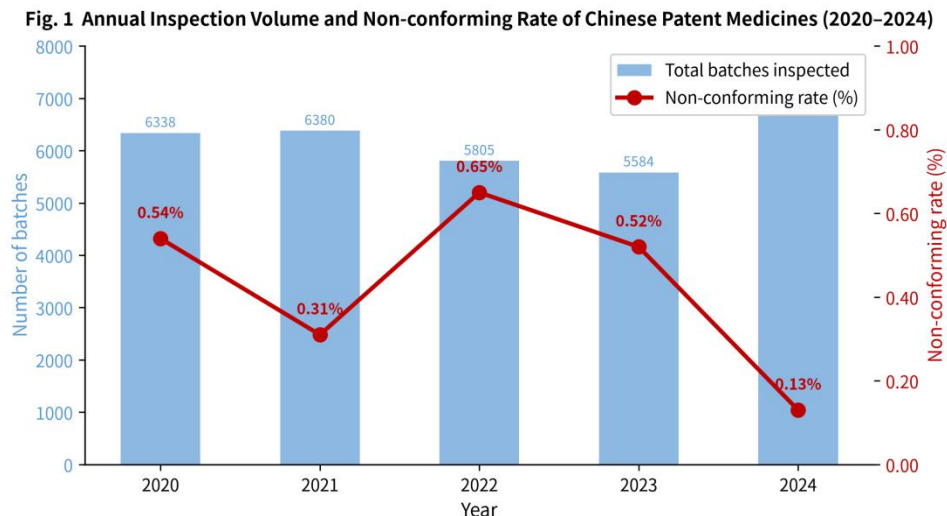


Figure 1. Annual inspection volume and non-conforming rate of Chinese patent medicines in the National Drug Sampling Inspection, 2020–2024. Blue bars represent total batches inspected; red line with markers represents the non-conforming rate.

The standardization level of the entire supply chain—including raw material control, manufacturing process control, and enterprise quality assurance systems—has been continuously enhanced. However, from the perspective of non-conforming item composition, the contributing factors and severity of harm varied considerably across inspection categories.

3.2 Distribution of Non-conforming Items

The distribution of non-conforming items by inspection category showed that examination-related defects (including related substances, dissolution, and microbial limits) constituted the largest proportion, followed by identification and assay failures (Figure 2, Table 2).

Table 2. Distribution of non-conforming items by inspection category (2020–2024)

Category	2020 (n=34)	2021 (n=20)	2022 (n=38)	2023 (n=29)	2024 (n=9)	Total
Identification	15 (44.1%)	9 (45.0%)	3 (7.9%)	10 (34.5%)	0	37
Examination	14 (41.2%)	7 (35.0%)	30 (78.9%)	19 (65.5%)	7 (77.8%)	77
Assay	2 (5.9%)	4 (20.0%)	1 (2.6%)	0	1 (11.1%)	8
Description	2 (5.9%)	0	3 (7.9%)	0	1 (11.1%)	6

Category	2020 (n=34)	2021 (n=20)	2022 (n=38)	2023 (n=29)	2024 (n=9)	Total
Supplementary	0	0	4 (10.5%)	0	0	4

Note: Some non-conforming samples had multiple item failures; percentages may not sum to 100%.

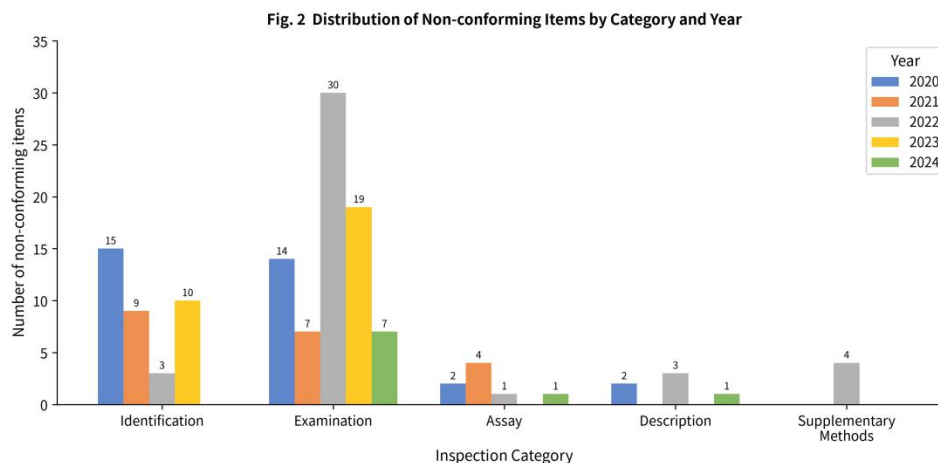


Figure 2. Distribution of non-conforming items by inspection category and year. Examination-related defects predominated across all years.

3.3 Risk Stratification of Non-conforming Items

Risk stratification analysis revealed clear differentiation between high-risk substantive defects and low-risk appearance deviations (Figure 3).

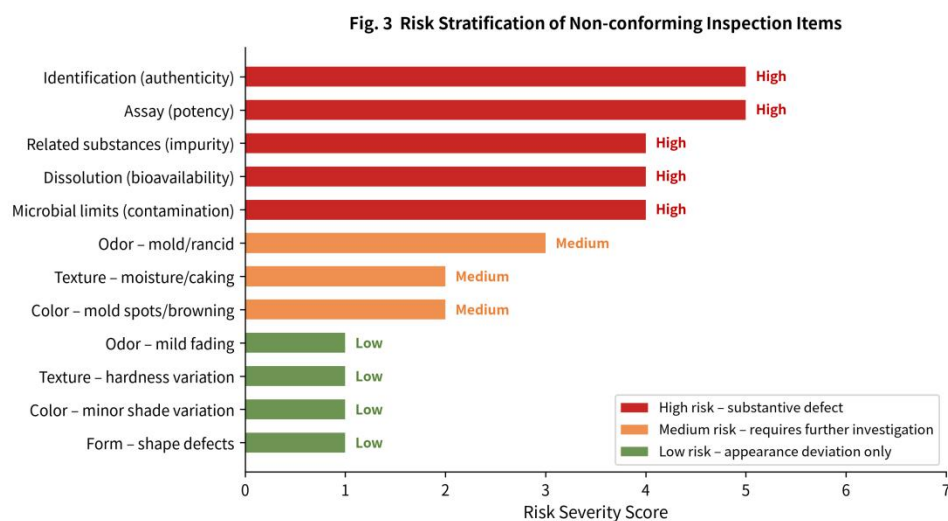


Figure 3. Risk stratification of non-conforming inspection items. Red: high-risk substantive defects; orange: medium-risk items requiring further investigation; green: low-risk appearance deviations.

Identification non-conformity represents the highest risk, indicating uncertainty in the authenticity of ingredient sourcing. Non-conformity in the assay directly compromises clinical efficacy; non-conformity in related substances presents an impurity toxicity hazard; non-conformity in dissolution reduces drug bioavailability; and non-conformity in microbial limits presents an infection risk. All of the above constitute high-risk substantive defects.

Description non-conformities, by contrast, were predominantly low-risk. Among the four description sub-items, odor non-conformity with mold or rancidity represented the highest risk within the description category, followed by texture abnormalities involving moisture-induced softening. Simple color variation and physical form defects represented the lowest risk level.

3.4 Contributing Factors

Non-conformity in high-risk intrinsic items generally stems from systemic control deficiencies throughout the entire chain of raw materials, manufacturing, and storage. Chinese herbal medicines originate from diverse sources and production areas; some enterprises exercise insufficient scrutiny during procurement, acquiring adulterated or deteriorated materials, directly causing identification non-conformity. During manufacturing, unreasonable extraction process parameters, inadequate impurity removal, or material degradation due to heat or light exposure can directly cause related substance exceedance. Non-conforming cleanroom classification, irregular operator practices, insufficient material sterilization, and packaging seal defects can allow moisture and microbial ingress.

Description non-conformity, by contrast, is predominantly caused by minor fluctuations in drying temperature and duration, subtle differences in coating powder composition, or small environmental temperature and humidity variations during storage. The intrinsic material basis of

the medicine remains unchanged, and such defects carry virtually no risk to safety or efficacy.

Fig. 4 Dosage Form Analysis of Non-conforming Chinese Patent Medicines

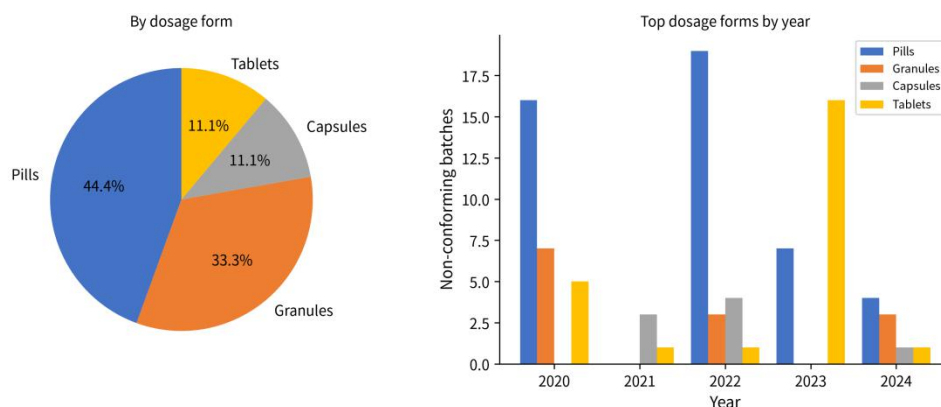


Figure 4. Dosage form analysis of non-conforming Chinese patent medicines. Left panel: proportion by dosage form in 2024. Right panel: trends for the top four dosage forms across years.

4 Discussion

Description is merely a preliminary sensory screening indicator with inherent subjective limitations and cannot be used to infer the authenticity of identification, the level of active ingredients, the extent of impurity levels, the dissolution performance of the preparation, or the degree of microbial contamination. In practice, cases exist where samples appear normal in description but have related substance exceedance, dissolution non-conformity, or microbial contamination; conversely, samples with minor appearance flaws may have all intrinsic test items fully compliant with pharmacopoeial standards.

In current regulatory practice, some disposal approaches treat all non-conforming items equally, applying identical measures to minor description non-conformity and to issues such as related substance exceedance or identification fraud. When a Chinese patent medicine exhibits only minor description non-conformity while all intrinsic quality indicators meet pharmacopoeial requirements, no substantive harm to clinical safety or efficacy is expected. Such defects are

low-risk appearance deficiencies and fundamentally distinct from overall product quality deterioration. These findings support the adoption of a risk-stratified regulatory approach (Figure 5).

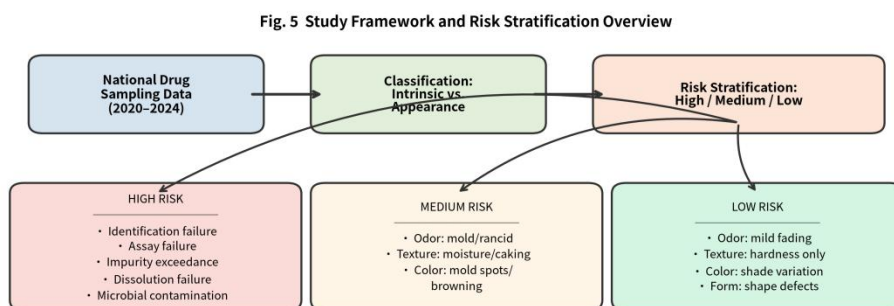


Figure 5. Study framework and risk stratification overview. The analytical workflow proceeds from data collection through classification and risk stratification, resulting in three risk tiers that inform differentiated regulatory responses.

5 Conclusions and Recommendations

Different inspection items for Chinese patent medicines correspond to markedly different quality risk levels. Non-conformity in identification indicates uncertainty regarding the authenticity of ingredient sourcing; non-conformity in the assay directly compromises clinical efficacy; non-conformity in related substances presents an impurity toxicity hazard; non-conformity in dissolution reduces drug bioavailability; and non-conformity in microbial limits presents an infection risk. All of the above constitute high-risk substantive defects. In contrast, samples exhibiting only minor description deviations while all intrinsic indicators meet specifications have only appearance flaws with no substantive adverse impact on safety or efficacy. Quality evaluation of Chinese patent medicines must integrate the full set of pharmacopoeial test items for comprehensive risk assessment, and regulatory approaches should differentiate between substantive defects and minor appearance deviations.

5.1 Recommendations

Enterprises should be urged to strictly enforce incoming quality acceptance of Chinese herbal medicine raw materials and strengthen identification screening of incoming materials. Key process parameters for extraction, purification, and final product formation should be optimized to maintain consistent control over content levels and related substance impurity profiles. In-process controls for dissolution of solid preparations should be improved. Cleanroom management during production should be reinforced to ensure controllable microbial limits. On the basis of ensuring that core indicators remain consistently within specifications, efforts should simultaneously be made to improve batch-to-batch consistency of product appearance, thereby comprehensively elevating the quality of Chinese patent medicine products.

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