Acupuncture and Herbal Medicine

Key revisions and updates in the 2025 edition of the *Chinese Pharmacopoeia*, Volume I

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The 2025 edition of the *Chinese Pharmacopoeia* has been officially promulgated by the National Medical Products Administration (NMPA) and the National Health Commission (NHC). As the core of the traditional Chinese medicine (TCM) standards system, Volume I of the *Chinese Pharmacopoeia* further refines the standards for crude drugs and decoction pieces, strengthens the TCM safety risk prevention and control system, and actively advances the improvement of the TCM standards system. This edition will play a significant role in ensuring the quality of TCM products, safeguarding public health, and fostering high-quality development of the TCM industry.

The 2025 *Chinese Pharmacopoeia* promotes the improvement of the TCM standards system

In 1985, China's first Drug Administration Law stipulated that "drugs must comply with national drug standards or provincial, autonomous regional, or municipal drug standards." In 2001, a comprehensive revision of the Drug Administration Law specified that "drugs must comply with national drug standards," thereby establishing the legal foundation for the national drug standards system. In 2019, the newly revised Drug Administration Law, Article 28, reaffirmed that "drugs must comply with national drug standards." In July 2023, the NMPA issued the Measures for the Administration of Drug Standards, which clearly defined and standardized the formulation and revision procedures, as well as management requirements, for national drug standards, drug registration standards, and provincial TCM standards. It also explicitly distinguished drug registration standards from national drug standards in terms of nomenclature, promulgation procedures, management requirements, and responsible entities.

To further improve TCM standards management and promote the inheritance and innovative development of TCM, the NMPA issued the Special Provisions on the Administration of TCM Standards in July 2024. These provisions, taking into account the unique characteristics of TCM, further refined and clarified various requirements for TCM standards management. With the continuous enhancement of the regulatory framework for standards, and through the unremitting efforts of several generations of TCM standards workers over more than 70 years, China has preliminarily established a relatively comprehensive TCM standards system centered on the *Chinese Pharmacopoeia*. This system covers categories such as crude drugs, decoction pieces, formula granules, extracts, and finished TCM products, and is stratified into national TCM standards, TCM registration standards, and provincial TCM standards[1]. It has played a crucial role in ensuring the quality of TCM products and guaranteeing the safety and efficacy of public medication.

The new edition of the *Chinese Pharmacopoeia* strengthens technical leadership, promoting the industry's transition from quantity to quality

On October 20, 2019, the Central Committee of the Communist Party of China and the State Council issued the *Opinions on Promoting the Inheritance and Innovative Development of Traditional Chinese Medicine*, which explicitly proposed the establishment and improvement of TCM-specific methods and technical standards for evaluating TCM safety and efficacy. In terms of TCM standards, it required strict management of the use of pesticides, chemical fertilizers, plant growth regulators, and similar substances, as well as the development of geographical indication-specific and variety-specific standards for pesticide residues and heavy metal limits in crude drugs. The General Office of the State Council, in its *Opinions on Comprehensively Deepening the Reform of Drug and Medical Device Regulation to Promote High-Quality Development* of the Pharmaceutical Industry, also emphasized leveraging standards to guide innovation in drugs and medical devices. During the compilation of the 2025 edition of Volume I of the *Chinese Pharmacopoeia*, relevant measures from the NMPA to promote the inheritance and innovative development of TCM were strictly implemented. Building on drug standards improvement efforts,

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relevant drug testing institutions, research institutes, and other organizations were mobilized to conduct specialized studies on pesticide residues, plant growth regulator residues, heavy metals and harmful elements, mycotoxins, and similar contaminants in TCM. Scientifically rational and practically feasible limit standards were formulated based on actual conditions, fully leveraging the guiding role of pharmacopeial standards to regulate the artificial cultivation and breeding of crude drugs and ensure their quality. Additionally, in alignment with recent NMPA regulations, such as *the Measures for Post-Marketing Changes of Drugs* and *the Measures for the Administration of Drug Standards*, the formulation of TCM standards in the 2025 edition of the *Chinese Pharmacopoeia* was developed with particular emphasis on coordination with these management provisions. In accordance with post-marketing change requirements, the "preparation method" item for finished TCM products was refined. Following *the Guiding Principles for the Expression of Specifications for Finished TCM Products,* the "specification" item for finished TCM products was standardized through a phased and batch-wise approach. In line with the requirements of *the Measures for the Administration of Drug Standards*, coordinated implementation of pharmacopeial standards and TCM registration standards was advanced.

The new edition of the *Chinese Pharmacopoeia* adopts the most rigorous standards to perfect the crude drug and decoction piece standards system

The principle of "decoction pieces for medication, with raw and processed forms having distinct therapeutic effects" is a hallmark of clinical TCM use. TCM decoction pieces can be directly used for clinical prescriptions or serve as raw materials for finished TCM production; their quality directly impacts the clinical efficacy of TCM. The quality of crude drugs and decoction pieces constitutes a critical foundation for the scientific development of the TCM industry.

During the compilation of the 2025 edition of the *Chinese Pharmacopoeia*, improving the crude drug and decoction piece standards system was designated as a key task[2]. First, coordination between crude drug standards and decoction piece standards was strengthened. Under the current pharmacopeial format, most decoction piece standards are listed under crude drug standards, with decoction piece standard items often referencing relevant methods from crude drug standards and adopting their limits. In previous standards research, due to insufficient representativeness in sample collection, lack of systematicity in studies, and other factors, some decoction piece standards had limited testing items, and inconsistencies existed between certain crude drug and decoction piece standards. During the compilation of the 2025 edition of the *Chinese Pharmacopoeia*, 68 drug testing institutions, research institutes, universities, and production enterprises collaborated on specialized research to revise 122 decoction piece standards. This included adding and refining quality control items such as morphology, moisture content, ash content, and extractives, while simultaneously enhancing coordination and unification between decoction pieces and crude drug standards. For example, the 2020 edition of the *Chinese Pharmacopoeia* established quality control items for total ash and extractives in the crude drug standard for *Sarinda glabra* (jiuxiangchong), but the corresponding testing items were absent for the processed decoction piece of fried *Sarinda glabra*. The 2025 edition added these testing items for the fried *Sarinda glabra* decoction piece. Second, the rigor of crude drug and decoction piece standards was emphasized. Items such as origin, morphology, and microscopic identification are unique to crude drug and decoction piece standards and play a vital role in ensuring authenticity. The compilation work for the 2025 edition of the *Chinese Pharmacopoeia* strictly implemented the "most rigorous standards" requirement, systematically reviewing and standardizing crude drug and decoction piece standards to enhance the standardization and rigor of TCM standards. For instance, regarding the Chinese and Latin names of originating plants/animals, based on widely accepted taxonomic research in botany and zoology, the Chinese and Latin names for origins of varieties such as pine pollen, *Ophiopogon japonicus* (maidong), cicada slough, and seahorse were standardized[3]. In terms of morphology and microscopic identification standards, through two consecutive years of dedicated validation and research, the microscopic identification features for 107 varieties, such as *Melia toosendan* fruit (chuanzhuzi), were revised to improve scientific validity[4]. Third, limits were adjusted pragmatically. Incorporating feedback from stakeholders collected during the implementation of the previous edition, and following thorough surveys and experimental verification, reasonable adjustments were made to limits for items such as total ash, moisture, extractives, and content determination for multiple crude drugs or decoction pieces, including fried perilla seed, *Lycium barbarum* bark (dubeipi), *Belamcanda chinensis* rhizome (chuanshegan), *Atractylodes lancea* rhizome (cangzhu), and *Fritillaria cirrhosa* bulb (chuangbeimu). For example, for fried perilla seed, the 2020 edition stipulated a moisture limit of not to exceed 2.0%, which proved challenging in practice; the new edition adjusted this to 4.0%, ensuring product quality while better aligning with actual conditions. Fourth, the rationality of testing indicators was evaluated, leading to the elimination of a batch of quality control items with quality control items with insufficient scientific validity or applicability. For instance, the 2020 edition of the *Chinese Pharmacopoeia* specified a total ash limit of not more than 7.0% for *Belamcanda chinensis* rhizome crude drug, but not more than 2.0% for the sliced decoction piece. Systematic research determined that *Belamcanda chinensis* contains abundant calcium oxalate prismatic crystals, with cleaning having minimal impact on total ash; thus, the 2025 edition revised the total ash limit for the *Belamcanda chinensis* decoction piece to align with the crude drug at not more than 7.0%. Additionally, the 2025 edition temporarily excludes content determination items for rosmarinic acid in *Perilla frutescens* stem (zisugeng), polygalaxanthone III in *Polygala tenuifolia* (yuanzhi), toosendanin in *Melia toosendan* fruit (chuanzhuzi), and polysaccharides in steamed *Polygonatum sibiricum* (huangjing). Fifth, coordination between pharmacopeial standards for TCM decoction pieces and *the National Specifications*

for Processing TCM Decoction Pieces was strengthened to improve the TCM decoction piece standards system. In accordance with unified deployment by the NMPA, specifications for 69 decoction pieces under the National Specifications for Processing TCM Decoction Pieces were formulated, complementing the TCM decoction piece standards in the *Chinese Pharmacopoeia* and rendering the system more comprehensive.

The new edition of the *Chinese Pharmacopoeia* focuses on safety risks, reconstructing the TCM industry ecosystem

TCM serves as a special commodity for disease prevention and treatment, requiring not only efficacy but also safety. In recent years, societal attention to drug safety has intensified. Addressing the intrinsic toxic and harmful chemical components in TCM, as well as contamination by extrinsic toxic and harmful substances during cultivation, processing, production, transportation, and storage, the compilation of the *Chinese Pharmacopoeia* incorporated risk control concepts to further strengthen the quality control system for TCM safety. First, substitution studies were conducted on extracts of aconite diester-type alkaloids and total strychnine alkaloids. In compliance with requirements from the Ministry of Public Security, aconitine and strychnine, as highly toxic components, cannot be distributed as single reference standards, making limit checks or content determinations for aconitine and strychnine in over 60 finished TCM products containing ingredients such as *Aconitum carmichaelii* (chuwu), *Aconitum kusnezoffii* (caowu), *Aconitum carmichaelii* prepared root (fuzi), and *Strychnos nux-vomica* (maqianzi) infeasible within the standards of the *Chinese Pharmacopoeia* and posing potential safety risks to clinical use. During the compilation of the 2025 edition, specialized research was organized to substitute the aforementioned monomeric toxic reference standards with aconite diester-type alkaloid reference extracts and total strychnine alkaloid reference extracts. Dedicated substitution guiding principles were developed through research, and standards for 57 varieties were revised to ensure controllability of intrinsic toxic components in relevant preparations. Second, control of pesticide residues was further strengthened, increasing the number of prohibited pesticides in crude drugs and decoction pieces from 33 to 47[5]. Corresponding pesticide residue limit standards were established for 10 crude drug varieties, including *Panax ginseng* (renshen), *Panax notoginseng* (sanqi), *Lycium barbarum* fruit (gouqizi), *Chrysanthemum morifolium* (juhua), *Lilium brownii* bulb (baihe), *Dendrobium officinale* (tiepi shihu), *Corydalis yanhusuo* tuber (yanhusuo), *Lonicera japonica* flower (jinyinhua), *Fritillaria* bulb (beimu), and *Atractylodes macrocephala* rhizome (baizhu). Additionally, methods for pesticide residue determination were revised and refined. Third, requirements for heavy metals and harmful elements' limits were steadily advanced[6]. Based on risk levels, unified limit standards for heavy metals and harmful elements in 52 crude drugs and decoction pieces were specified in the general notices for crude drug and decoction piece testing. The "heavy metals and harmful elements" test item was incorporated into the main text of standards for seven varieties: *Ligusticum chuanxiong* rhizome (chuanxiong), *Coptis chinensis* rhizome (huanglian), *Panax ginseng* (renshen), *Cornus officinalis* fruit (shanzhuyu), *Gardenia jasminoides* fruit (zhizi), *Pueraria lobata* root (gegen), and *Lonicera japonica* flower (jinyinhua), with specific limit requirements defined. Fourth, plant growth regulators were included for the first time in the scope of extrinsic pollutant control, with a limit standard for uniconazole in *Ophiopogon japonicus* (maidong) established. Fifth, general testing methods and guiding principles for safety detection were further refined. In terms of general notices, revisions to the crude drug and decoction piece testing general notices systematically specified limit requirements for residual pesticides, heavy metals and harmful elements, plant growth regulators, and similar contaminants. For general testing methods, a new method for plant growth regulator residue determination was added, the pesticide residue determination method was revised, and the determination method for lead, cadmium, arsenic, mercury, and copper was also revised. For guiding principles, a new guiding principle for photostimulated luminescence detection of irradiated TCM was added, and the guiding principle for mycotoxin determination in TCM was revised[7].

The new edition of the *Chinese Pharmacopoeia* adheres to a clinical orientation, enhances standards applicability, and supports high-quality development of traditional medicine

As drugs used under the guidance of TCM theory, the formulation of TCM standards must be based on TCM theory. During the compilation of TCM standards for the 2025 edition of the *Chinese Pharmacopoeia*, adherence to a clinical orientation was upheld as a fundamental principle. First, the "[dosage and administration]" item was clarified. In recent years, some opinions within the TCM clinical community have suggested that the "[dosage and administration]" in the *Chinese Pharmacopoeia* crude drug and decoction piece standards restricts the clinical use of decoction pieces. This discourages physicians from exceeding the maximum specified dosage. To address this, a dedicated explanation of "[dosage and administration]" was added to the preface of Volume I, evolving from the previous edition's "the dosage of decoction pieces refers to the adult daily dose, which may be adjusted as per physicians' instruction if necessary" to "the [dosage and administration] of decoction pieces serves as guidance for clinical use, with actual clinical application following physicians' instruction." This revision clarifies its recommendatory positioning and facilitates clinical application. Second, variety additions and removals adhered to a clinical orientation. Varieties newly included in this edition of the *Chinese Pharmacopoeia* were selected based on the principles of "commonly used in clinical practice, proven efficacy, safe use, mature processing techniques, and controllable quality." This approach fully considered clinical safety and efficacy. Conversely, varieties that are infrequently used clinically or have not been produced for many years were excluded from this edition. Third, decoction piece standards were formulated in accordance with actual clinical use. For example, *Panax notoginseng* (sanqi) is a commonly used TCM with a hard texture that

is difficult to pulverize; previous editions of the pharmacopeia included only the "sanqi powder" decoction piece. However, with advancing pulverization technology and increasing usage volume, the whole herb *Panax notoginseng* decoction piece was added to meet clinical needs. The standard specifies an extemporaneous processing requirement of "crush or grind into fine powder at the time of use." Similarly, for sophora flower (*Styphnolobium japonicum*, huaihua), the 2020 edition described sophora flower and seed (*Styphnolobium japonicum* seed, huaimi) separately only under the morphology item for the crude drug, with decoction pieces limited to sophora flower, fried sophora flower, and carbonized sophora flower. The 2025 edition, based on actual clinical use, listed fried sophora flower and fried sophora seed in parallel under decoction pieces, as well as carbonized sophora flower and carbonized sophora seed, with distinct content limits specified for certain testing items.

The new edition of the *Chinese Pharmacopoeia* explores diverse quality evaluation technologies, promoting the improvement of a standards system aligned with TCM characteristics

Given the diversity of TCM components and the complexity of their mechanisms of action, the *Chinese Pharmacopoeia* has long been committed to refining quality control and evaluation methods for TCM. On one hand, it emphasizes the universality of analytical methods while adhering to holistic evaluation of TCM quality. TCM fingerprint chromatograms and characteristic chromatograms are based on the holistic control concept for TCM, typically employing conventional analytical techniques such as high-performance liquid chromatography (HPLC) or gas chromatography (GC) to analyze samples, fully characterizing their chemical components with integrity and specificity. The 2010 edition of the *Chinese Pharmacopoeia* introduced fingerprint chromatograms for the first time, and this technology has seen increasingly widespread application in TCM quality control. The new edition further expanded the use of fingerprint chromatogram or characteristic chromatogram technologies, adding fingerprint chromatograms for five varieties and characteristic chromatograms for 11 varieties, bringing the total number of varieties using these for quality control to nearly 90. The "one-measurement-multi-evaluation" technique generally uses a single reference substance as a benchmark, establishing correction factors between the reference and various analytes, thereby enabling the analysis of multiple structurally similar index components with one reference. This technique is increasingly applied in the *Chinese Pharmacopoeia*; for instance, methods for determining multiple alkaloid components in *Coptis chinensis* (huanglian) or multiple saponin components in *Panax ginseng* (renshen) are now highly mature, a development that carries significant implications for holistic TCM quality evaluation. Meanwhile, exploration and application of new technologies are strengthened to address key challenges in TCM quality control. For example, HPLC-mass spectrometry (MS) was employed to determine the content of characteristic peptides in donkey-hide gelatin (ejiao) and to authenticate its origin, effectively controlling adulteration issues. Polymerase chain reaction-restriction fragment length polymorphism (PCR-RFLP) was used to authenticate *Fritillaria cirrhosa* (chuangbeimu) and *Dendrobium officinale* Huoshan Dendrobium officinale (huoshan shihu), ensuring origin accuracy. HPLC-MS was applied to control intrinsic toxic components such as aristolochic acid—known for severe nephrotoxicity—in herbs like *Asarum sieboldii* (xixin), thereby safeguarding public medication safety. Guiding principles for photostimulated luminescence testing of irradiated TCM were formulated, establishing methods for irradiation residue determination to gradually guide and standardize the application of irradiation sterilization in TCM[8].

The new edition also revised and added methods for process analytical technologies such as infrared spectroscopy and near-infrared spectroscopy, and incorporated guiding principles for multivariate statistical process control—a commonly used model in process analytical method development—as well as common data processing methods in model establishment, further promoting the application of process analytical technologies in China's pharmaceutical industry and aligning with the concept of full-process quality control for TCM.

The compilation of the 2025 edition of the *Chinese Pharmacopoeia* adhered to principles of scientificity, advancement, practicality, and standardization, integrating the realities of China's pharmaceutical industry development. It balanced safeguarding the baseline of drug safety with promoting high-level industry advancement, incorporating international drug quality control management concepts to render drug quality more controllable. The promulgation and implementation of the new edition will play a pivotal role in ensuring drug quality, protecting public medication safety, bolstering technical support for drug regulation, and driving high-quality development of the TCM industry.

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Author contributions

The sole author was responsible for all aspects of this article including conceptualization, literature collation, manuscript drafting, and critical revision.

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All data generated or analyzed during this study are included in this published article.

Declaration of generative AI in scientific writing

The conception and writing of this article were carried out collaboratively by all authors. Artificial intelligence was utilized exclusively for refining sentence coherence and amending punctuation. All citations in this manuscript were manually searched for and incorporated. After utilizing the aforementioned tools/services, the authors thoroughly reviewed and revised the content and take full responsibility for the entirety of this publication.

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