

世界中联国际组织标准《中医方剂剂型与中药制剂术语》 编制说明

一、工作简况

主要起草单位：中国中医科学院中国医史文献研究所、安徽中医药大学、北京中医药大学、河南中医药大学、浙江中医药研究院、浙江中医药大学。

参与起草单位：

主要起草人：朱建平、洪梅、高新颜、许霞、赵黎、谢鸣、蔡永敏、庄爱文、崔昶旭。

参与起草人：

中国：方廷钰、王奎、单宝枝、王丽丽、杨丽雯、苏祥飞；

法国：朱勉生；

意大利：何嘉琅；

加拿大：吴滨江；

西班牙：陈春信；

澳大利亚：林子强；

美国：杨观虎、秦济成

埃及：塔里克；

沙特阿拉伯：茉莉；

摩洛哥：阿里

二、标准起草过程简介

（如：何时启动，如何开展调研，如何征求各利益相关方的意见，召开了哪些审稿会，标准审定委员会讨论或投票会）

1、本项目为国家科技部 2012 年度科技基础性工作专项重点项目“中医药基础学科名词术语规范研究”成果《中医药学名词》第二版中“方剂剂型”“中药制剂”转化而来，包括中医方剂传统剂型和中药制剂剂型两部分，术语名称、定义在转化之前已经经过多轮专家讨论，对相关术语的命名与定义，已经在领域内达成共识。

2、2023 年 7 月 21 日，世界中医药学会联合会批准《剂型术语》（SCM NP 2023-0160）立项。当月，成立项目组，由中国中医科学院中国医史文献研究所、安徽中医药大学、北京中医药大学、河南中医药大学、浙江中医药研究院、浙江中医药大学等单位共同起草。

中、意、美、法、加拿大、埃及、摩洛哥、沙特阿拉伯等国家的 10 多位代表性专家参与，所有成员均长期致力于中医临床与科研工作。

3、2024 年 9 月 根据 ISO《术语工作 原则与方法》和专家建议将《剂型术语》更

名为《中医方剂传统剂型和中药制剂剂型》，遵照世界中联相关要求转化为世界中国际组织标准。

3、2025年9月再次开展广泛的文献调研，涵盖WHO、WFCMS、中医药团体和行业标准以及工具书方剂术语英译相关内容，将中文标准翻译为英文。

4、2025年12月开展标准函审。专家提出增加“超微粉”等新剂型，并对标准结构进行微调，删除部分相关性较低的术语如“输液”等。

5、2026年2月由世界中国际标准部组织开展草案审定工作。

对标准格式、结构、标准英译等提出了修改意见。项目组在会后进行了相应修改，并确定将详细的概念树放在附录中。修改后形成征求意见稿。

三、主要技术内容介绍

中医学是中华民族的伟大瑰宝，是中华优秀传统文化的重要组成部分。中医方剂作为中医临床防治疾病的主要工具，其剂型是承载和实现疗效的重要载体。从汤、丸、散、膏、丹等传统方剂剂型，到片剂、胶囊、注射液等现代中药制剂，是中医药学术与实践演进史的体现，是古今用药智慧与技术的融合。

为适应中医药事业传承创新发展的需要，推进中医药产业化、现代化和走向世界，实现方剂剂型与中药制剂领域的学术交流、科研生产、临床使用、市场监管及国际贸易的规范化与标准化，其术语的统一与规范是必不可少的基础性工作。当前，在中医方剂剂型与中药制剂的命名、分类及定义上，仍存在概念交叉、界定不清或古今称谓混用等现象，现有标准中相关术语涵盖不全，因此，亟需建立一个更全面、系统的中医方剂剂型与中药制剂术语标准体系。

本文件的研制遵循《国际中医药术语标准编译通则》，旨在为构建统一的中医方剂剂型与中药制剂语言环境、保障中药产品质量与临床疗效、促进中医药学术进步与产业健康发展提供坚实的技术支撑，具有重要的意义。

本文件规定了中医方剂剂型与中药制剂的基础术语和通用术语的中文名、英文名、中文定义、英文定义。

本文件适用于各国家与地区中医方剂剂型与中药制剂的生产、管理、销售、经营、新闻出版、教育教学及学术交流等。

四、重大分歧意见的处理经过和依据

关于标准的概念树结构，项目认为应该在标准正文中体现，有专家认为术语标准不宜分级过多，概念上下级关系可以通过“种差+属”概念表述，可以避免悬置段的出现导致

引用不精确的问题。针对此问题，2026年2月3日在世界中联进行了专门的讨论。国家标准委专家张敬娟建议概念层级不宜太多，上下位概念关系通过“种差+属”的定义模式来体现，并将详细概念树画图放在附录中。项目组采纳了此项建议。

五、其他应说明的事项

无

六、附件

立项通知书

世界中医药学会联合会

世界中医药学会联合会国际组织标准

立项通知

World Federation of Chinese Medicine Societies

Announcement for International Standard

世界中医药学会联合会批准《剂型术语》（SCM NP 2023-0160）

立项，现予通知。

The SCM standard of *Terms of preparation form* (SCM NP 2023-0160) was initiated by World Federation of Chinese Medicine Societies and was now effective.

世界中医药学会联合会

World Federation of Chinese Medicine Societies

二〇二三年七月二十一日

July 21, 2023

World Federation of Chinese Medicine Societies (WFCMS)
International Standard

Vocabulary for dose forms of Chinese medicine prescriptions and Chinese
medicine preparations
FORMULATION EXPLANATION

I. Project Overview

Leading Drafting Institutions: Institute of Chinese Medical History and Literature, China Academy of Chinese Medical Sciences; Anhui University of Chinese Medicine; Beijing University of Chinese Medicine; Henan University of Chinese Medicine; Zhejiang Academy of Chinese Medical Sciences; Zhejiang University of Chinese Medicine

Participating Drafting Institutions: None

Leading Drafting Experts: Zhu Jianping, Hong Mei, Gao Xinyan, Xu Xia, Zhao Li, Xie Ming, Cai Yongmin, Zhuang Aiwen, Cui Changxu

Participating Drafting Experts:

- China: Fang Tingyu, Wang Kui, Shan Baozhi, Wang Lili, Yang Liwen, Su Xiangfei
- France: Zhu Miansheng
- Italy: He Jialang
- Canada: Wu Binjiang
- Spain: Chen Chunxin
- Australia: Lin Ziqiang
- USA: Yang Guanhu, Qin Jicheng
- Egypt: Tariq
- Saudi Arabia: Molly
- Morocco: Ali

II. Brief Introduction to the Standard Drafting Process

(Including initiation time, research and investigation methods, solicitation of opinions from all stakeholders, review meetings held, discussions or voting sessions of the Standard Examination Committee, etc.)

1. This project is adapted from the chapters of *Prescription Dosage Forms* and *Chinese Materia Medica Preparations* in *Nomenclature of Chinese Medicine (2nd Edition)*, a research achievement of the Key Project of the National Science and Technology Basic Work Program of China in 2012 – *Standardization Research on Nomenclature of Basic Disciplines of Chinese Medicine*. It covers two parts: traditional TCM prescription dosage forms and Chinese materia medica preparation dosage forms. The names and definitions of the relevant terms have undergone multiple rounds of expert discussions and reached a consensus in the field prior to the adaptation.
2. On July 21, 2023, the World Federation of Chinese Medicine Societies approved the project initiation of *Terminology of Dosage Forms* (SCM NP 2023-0160). A project team was established in the same month, jointly responsible for the drafting work with the participation of the Institute of Chinese Medical History and Literature of China Academy of Chinese Medical Sciences, Anhui University of Chinese Medicine, Beijing University of Chinese Medicine, Henan University of Chinese Medicine, Zhejiang Academy of Chinese Medical Sciences, Zhejiang

University of Chinese Medicine and other institutions. More than 10 representative experts from China, Italy, the United States, France, Canada, Egypt, Morocco, Saudi Arabia and other countries participated in the project, all of whom have long been committed to the clinical practice and scientific research of TCM.

3. In September 2024, in accordance with ISO *Terminology Work - Principles and Methods* and expert suggestions, *Terminology of Dosage Forms* was renamed *Terminology of Traditional Chinese Medicine Prescription Dosage Forms and Chinese Materia Medica Preparation Dosage Forms*, and converted into an international organizational standard of WFCMS in compliance with the relevant requirements of WFCMS.
4. In September 2025, an extensive literature research was conducted again, covering the English translations of prescription terminology in WHO, WFCMS, TCM association and industry standards as well as reference books, and the Chinese version of the standard was translated into English.
5. In December 2025, a correspondence review of the standard was carried out. Experts proposed adding new dosage forms such as *ultramicronized powder* and fine-tuning the structure of the standard, with the deletion of some less relevant terms such as *infusion solution*.
6. In February 2026, the International Standard Department of WFCMS organized the examination of the standard draft, and put forward revision suggestions on the standard format, structure, English translation and other aspects. The project team made corresponding revisions after the meeting, and decided to place the detailed concept tree in the appendix. The exposure draft was formed after the revision.

III. Introduction to Main Technical Contents

Traditional Chinese Medicine is a great treasure of the Chinese nation and an important part of China's excellent traditional culture. As the primary tool for the clinical prevention and treatment of diseases in TCM, prescription dosage forms serve as a crucial carrier for undertaking and realizing therapeutic effects. The evolution from traditional prescription dosage forms such as decoctions, pills, powders, plasters and pellets to modern Chinese materia medica preparations including tablets, capsules and injections reflects the academic and practical evolution of TCM, and represents the integration of the wisdom and techniques of medication in ancient and modern times.

To meet the needs of the inheritance, innovation and development of the TCM cause, advance the industrialization, modernization and global dissemination of TCM, and realize the standardization of academic exchanges, scientific research and production, clinical application, market supervision and international trade in the field of prescription dosage forms and Chinese materia medica preparations, the unification and standardization of the relevant terminology is an indispensable basic work. At present, problems such as overlapping concepts, unclear definition and mixed use of ancient and modern denominations still exist in the naming, classification and definition of TCM prescription dosage forms and Chinese materia medica preparations, and the relevant terms in the existing standards are not fully covered. Therefore, it is urgent to establish a

more comprehensive and systematic standard system for the terminology of TCM prescription dosage forms and Chinese materia medica preparations.

The development of this document abides by the *General Principles for the Compilation and Translation of International TCM Terminology Standards*, aiming to provide solid technical support for building a unified linguistic environment for TCM prescription dosage forms and Chinese materia medica preparations, ensuring the quality of Chinese materia medica products and their clinical efficacy, and promoting the academic progress and healthy development of the TCM industry, which is of great significance.

This document specifies the Chinese and English names, as well as the Chinese and English definitions, of the basic and general terms of TCM prescription dosage forms and Chinese materia medica preparations.

This document is applicable to the production, management, sales, operation, journalism and publishing, education and teaching, academic exchanges and other related activities of TCM prescription dosage forms and Chinese materia medica preparations in all countries and regions.

IV. Handling Process and Basis for Major Divergent Opinions

Regarding the structure of the concept tree of the standard, the project team initially proposed to present it in the main text of the standard, while some experts held the view that a terminology standard should not have an excessive number of hierarchical levels. They suggested that the superior-subordinate relationship of concepts could be expressed through the conceptual expression of "specific difference + genus", which could avoid the problem of inaccurate citation caused by the appearance of floating paragraphs. A special discussion on this issue was held at WFCMS on February 3, 2026. Zhang Jingjuan, an expert from the Standardization Administration of China, suggested that the number of conceptual levels should not be too many, the superior-subordinate relationship of concepts should be reflected through the definition mode of "specific difference + genus", and the detailed concept tree should be drawn and placed in the annex. The project team adopted this suggestion.

V. Other Explanatory Matters

None

VI. Annexes

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