世界中医药学会联合会国际组织标准

道地药材通则

编制说明

一、工作简况

主要起草单位：成都中医药大学、中国中医科学院中药研究所。

参与起草单位：湖北中医药大学、中国医学科学院药用植物研究所、澳门大学、香港浸会大学、中国-法国中医药中心（CFCMC）、荷兰国家生物多样性研究中心、澳洲元一中医药有限公司、塞梅尔维斯大学、美国国际中医药研究院。

主要起草人：陈士林、董林林。

参与起草人（按姓氏拼音排序）：

中　　国：刘娅、吕爱平、石礼平、王一涛、张照宇。

法　　国：吴宛霖；

荷　　兰：王梅；

澳大利亚：刘炽京；

匈牙利：　于富年；

美　　国：王守东。

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情况等）

《道地药材通则》起草主要过程如下：

2023.08 召集各起草单位并分配工作；

2023.08—2023.10 收集资料与数据：收集海内外中药材与道地药材相关文献、指南、科研成果、质量标准，并进行分类整理，深入了解道地药材的特性、检测方法、限量指标等；

2023.10 召开标准起草研讨会：邀请专家介绍标准的制订要求和关键环节，起草标准大纲；

2023.10—2023.11 收集材料并进行实验室研究：采集各道地产区中药材，并对其进行详细的分析和研究，通过分析其基原、成分、理化性质、限量指标等进行检测和分析，确定道地药材质量的关键指标和限度；

2023.11—2023.12 起草标准初稿；

2023.12 召开标准初稿研讨会：针对标准初稿，邀请海内外行内专家针对初稿内容进行评审和修订。专家们结合自身的研究和实践经验，对初稿进行认真讨论和修改；

2024.01—2024.08 二审三审：针对初稿研讨会所征求的专家意见，对标准内容进行修改完善，并对标准研究内容进行二审、二轮修改、三审。三审结束后，与会专家对标准研究内容进行投票，最终 10 票同意、0 票反对、0 票弃权，《道地药材通则》草案通过。

2024.09 开展《道地药材通则》国际组织标准草案工作讨论会。针对标准草案，邀请海内外行业专家对草案内容进行评审和修订。专家们结合自身的研究和实践经验，对草案进行认真讨论。

2024.10-2025.12　针对标准草案工作讨论会中专家的意见手机资料，修改标准草案。

三、主要技术内容介绍

（如：技术指标、参数、公式、性能要求、实验方法、检验规则等）的论据（包括试验、统计数据），修订标准时，应增加新、旧标准的对比。

本标准为新制定标准，标准编制时主要依据：本标准草案的编写格式严格按照 GB/T 1.1-2009《标准化工作导则 第 1 部分：标准的结构和编写》、GB 3095-2012 环境空气质量标准、GB 5084-2021 农田灌溉水质标准、GB 5749-2022 生活饮用水卫生标准、、GB 15618-2018 土壤环境质量 农用地土壤污染风险管控标准、GB 18596-2001 畜禽养殖业污染物排放标准、ISO 9001: 2015 Quality management systems — Requirements 、ISO 18662-1: 2017 Traditional Chinese medicine—Vocabulary—Part 1: Chinese Materia Medica、ISO 21371:2018 Traditional Chinese Medicine -Labelling requirements of products intended for oral or topical use 、 ISO 18662-2: 2020 Traditional Chinese medicine—Vocabulary—Part 2: Processing of Chinese Materia Medica 、 ISO 18664: 2015 Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine 、 ISO 19617: 2018 Traditional Chinese medicine-General requirements for the manufacturing process of natural products 、 ISO/TS 21310: 2020 Traditional Chinese medicine—Microscopic examination of medicinal herbs 、 ISO 22258: 2020 Traditional Chinese medicine Determination of pesticide residues in natural products by gas chromatography 、 ISO 22283:2020 Traditional Chinese medicine—Determination ofaflatoxins in natural product by LC-FLD 、 ISO 22590: 2020 Traditional Chinese medicine-Determination of sulfur dioxide in natural products by titration、ISO 19609-1:2021 Traditional Chinese Medicine—Quality and safety of raw materials and finished products made with raw materials —Part 1: General requirements 、 ISO 19609-1:2021 Traditional Chinese Medicine—Quality and safety of raw materials and finished products made with raw materials — Part 2: Identity testing of constituents of herbal origin 、 GB/T20014 Good Agricultural Practice for Chinese Crude Drugs (GAP)等标准，具体选择标准如下。

- 基原

ISO 18662-1:2017 中列出了常用中药材品种的拉丁名、中文名、拼音名和英文名标准化术语，还提供了每个中药材术语的详细定义，包括植物学名称、动物学名称、矿物学名等信息，阐明了中药材的基原及特性；对于未列入该标准的中药材，基原依照产地国及历史文献规定。

- 生产场所大气环境质量

WHO（世界卫生组织）发布的《全球空气质量指导值（2021 年版）》（AQG 2021）提供了关于室内外环境空气质量的建议，但并不针对生产场所。

GB 3095-2012 是中国的环境空气质量标准。该标准中包括了对生产场所大气环境质量的具体要求，例如对主要污染物的浓度限制，以及监测和评估空气质量的方法。这些污染物包括但不限于可吸入颗粒物（PM10 和 PM2.5）、二氧化硫（SO_2）、二氧化氮（NO_2）、臭氧（O_3）和一氧化碳（CO）等。标准还规定了不同功能区域的空气质量要求，以确保生产活动不会对周围环境和公共健康造成不良影响。

- 土壤环境质量

在土壤环境质量标准方面，WHO，ISO 并没有发布的专门针对土壤环境质量的标准，因此我们采用 GB15618-2018 《土壤环境质量 农用地土壤污染风险管控标准（试行）》，该标准规定了土壤污染风险的筛选值和管制值，以及相关的监测、实施与监督要求。

- 农田灌溉水或环境水质量

在农田灌溉水或环境水质量方面，WHO，ISO 并没有发布的专门针对农田灌溉水或环境水质量的标准，因此我们采用 GB5084-2021《农田灌溉水质标准》。该标准规定了农田灌溉水质的要求、监测和监督管理要求，旨在加强农田灌溉水质监管，保障耕地、地下水和农产品安全。它包括基本控制项目和选择控制项目，并对一些有毒有害物质的限量进行了规定。

- 饲养用水

ISO 没有专门针对饲养用水的具体标准，WHO 发布了《饮用水水质准则》第四版，适用于所有通过饮用水可能摄入的水中病原体和化学物质。GB5749-2022 《生活饮用水卫生标准》规定了生活饮用水水质的卫生要求，适用于城乡各类集中式供水和分散式供水的生活饮用水。标准中包括了水质指标的分类，分为常规指标和扩展指标，以及对水质的具体限值要求，虽然此标准主要针对的是生活饮用水，并没有专门针对饲养用水的条款内容，但可能间接为饲养用水的水质安全提供参考。

- 畜禽养殖业污染物排放

WHO、ISO 并没有专门针对畜禽养殖业污染物排放的标准。因此我们采用 GB18596-2001《畜禽养殖业污染物排放标准》，该标准规定了畜禽养殖场和养殖区废水、废渣和恶臭的排放标准，适用于集约化、规模化的畜禽养殖场，不适用于散养户。该标准包括生化指标、卫生学指标和感观指标等，并针对不同规模的养殖场规定了排放限值，推动污染物的减量化、无害化和资源化。

- 生产过程

采用 ISO 19617: 2018 规定道地药材的生产要求。该标准通过一系列规定，为中药材的生产提供了全面的指导与要求，以确保生产过程中的规范性以及产品的质量和安全性。特定药材应参考 GAP，该标准涉及多个层级和模块，涵盖了中药材生产的种植、采收、包装等方面，为中药材生产提供了全面的指导和规范。

- 性状特征

采用 ISO19609-1:2021 和 ISO/TS 21310:2020 规定道地药材的性状特征。ISO19609-1:2021 中规定了中药材的外观、颜色、气味、味道、质地等性状特征的鉴别和描述；ISO/TS 21310:2020 规定了中药材显微鉴别的技术规范，为中药材显微特征的鉴别提供了科学、准确的技术手段。

- 内源性质量控制指标

选择 ISO 19609-2:2021 规定道地药材内源性质量控制指标方法，该标准涉及化学分析、分子生物学技术手段等多种方法，规定了中药原材料及成品中草药的质量控制指标方法。考虑到部分中药材的种类和特性，部分药材应参考产地国具体品种项下方法，以确保测试的准确性和可靠性。

- 外源性质量控制指标

ISO 18664:2015 规定了中药材重金属及有害物质的具体规定及检测方法；ISO 22258: 2020 为减少农药残留对中药材药效和人体健康的影响，对中药材的农药残留检测提供了详细指导和方法；ISO 22283: 2020 聚焦于中药材中外源性污染物真菌毒素的安全控制问题规定了黄曲霉等毒素的检测方法；ISO 22590: 2020 为有效减少二氧化硫残留对中药材质量的影响，规定了中药材中二氧化硫含量的检测方法。因此，本标准分别选择 ISO 18664:2015、ISO 22258: 2020、ISO 22283: 2020、ISO 22590: 2020 作为外源性质量控制指标的检测方法。考虑到中药材的种类和特性，部分药材应参考产地国具体品种项下方法，以确保测试的准确性和可靠性。

- 加工方法

ISO 18662-2: 2020 中聚焦于中药材加工领域的术语、方法、目的以及炮制品的分类与命名，为中药材加工行业提供了标准化的指导。因此本研究选择 ISO 18662-2:2020 作为道

地药材的生产加工方法。考虑到中药材的种类和特性，部分药材应参考古代文献记载以及产地国对生产和加工规定的方法，以确保测试的准确性和可靠性。

➢ 中药材标签、包装、贮藏及运输过程

我们选择 ISO 21371:2018，此标准规定了中药材及其制成品的标签要求，确保产品标签清晰、准确，提供必要的安全和使用信息，避免误用或误解。选择 ISO 19609-1:2021 涵盖了中药材原材料及其制成品的质量和安全性要求，包括包装、贮藏和运输等方面，确保药材不会因包装、贮藏及运输不当受到损坏或降解，防止药材受到外部环境的不利影响。

本标准的规定了道地药材的要求、检验方法、检验规则、判定规则、标签 包装 贮藏 运输、文件管理及产品可追溯性，包含了完整的评价技术环节及方法，具有实用性、可操作性及创新性。

本标准主要技术内容框架包括以下部分：

章编号	章标题	节编号	节标题	主要技术内容
1	范围	/	/	本文件规定了道地药材要求、检验方法、检验规则、判定规则、标签、包装、贮藏、运输、文件管理及产品可追溯性。 本文件适用于道地药材的判定。
2	规范性引用文件	/	/	无
3	术语和定义	/	/	本标准术语包括中药材、道地药材、道地产区、中药基原鉴定、可追溯性。
4	要求	4.1	本草考证	规定了道地药材的本草考证、道地产区、基原、生产管理、性状特征、内源性质量控制指标、外源性质量控制指标、加工方法的基本要求。
		4.2	道地产区	
		4.3	基原	
		4.4	生产管理	
		4.5	性状特征	
		4.6	内源性质量控制指标	
		4.7	外源性质量控制指标	
		4.8	加工方法	
5	检验方法	5.1	本草考证	规定了道地药材的本草考证、道地产区、基原、生产管理、性状特征、内源性质量控制指标、外源性质量控制指标、加工方法的检验方法。
		5.2	道地产区	
		5.3	基原鉴定	
		5.4	生产管理	
		5.5	性状特征	
		5.6	内源性质量控制指标	
		5.7	外源性质量控制指标	
		5.8	加工方法	
6	生产管理	6.1	生产环境	规定了生产过程中生产环境、采收及加工方法的要求。
		6.2	采收	
		6.3	加工方法	
7	检验规则	7.1	抽样方法	规定了批次、抽样方法、检验项目的主要内容。
		7.2	检验项目	
8	判定规则	/	/	对道地药材的判定进行

				科学地描述、分析和判断。
9	标签 包装 贮藏 运输	9.1	标签	规定了道地药材的标签、包装、贮藏、运输的基本要求。
		9.2	包装	
		9.3	贮藏	
		9.4	运输	
10	文件管理及产品可追溯性	10.1	文件管理	规定了道地药材文件管理及产品可追溯性的基本要求。
		10.2	产品可追溯性	

经检索，目前尚没有任何国际组织或机构制定道地药材 通用质量标准，本标准草案是国际独有的、能够契合道地药材市场需求和发展的标准。

四、重大分歧意见的处理经过和依据

通过会议讨论，邮件等方式，向企业、科研机构征询意见，并针对意见进行回复，收到19条意见，采纳11条，具体如下：

序号 No.	标准条文号 Standard Clause	意 见 内 容 Comment	提出单位/个人 Proposed Unit/ Individuals	处理意见（由起草单位填写） Proposed Comments (Filled by Draft Unit)	备注 Notes
1	(一)申请	“国家成员体”表述不清，需要修改	王梅（荷兰）	采纳，修改为ISO 国家成员体。	
2	(一)申请	应该为“3. 申报提案的项目负责人和联合体案负责人应来自至不同的国家。”	王梅（荷兰）	未采纳，项目负责人和联合体案负责人为不同人员。	
3	(一)申请	应该为“4. 同一项目负责人本年度申报提案不能超过两项。”	王梅（荷兰）	未采纳，应明确包含两项。	
4	（三）评审结论及反馈	1. 如果评审结论为推荐项目 2. 如果评审结论为不推荐项目	王梅（荷兰）	未采纳，原文已能表述明白含义。	
5	英文部分	等中文订稿后，翻译成为英文， 我再检查一次。	王梅（荷兰）	采纳。	
6	第三段	“全球最大的标准制定者——国际标准化组织”，“世界中联申报的《中医药——脉博波格式》”双破	天士力医药集团股份有限公司 何毅	未采纳，原文符合中文标点的使用要求。	

		折号建议调整为单破折号。			
7	（一）申请	“提交申请材料” 建议明确是否要求提交纸质版、盖章原件等材料	天士力医药集团股份有限公司 何毅	未采纳，形式审查后，文件会有一定的修改，目前仅收集电子扫描文件。	
8	（一）申请	“1.申报的提案中必须有一名项目负责人（PL）以世界中联身份注册”建议调整为“项目提案人（PL）必须以世界中联身份注册”。	天士力医药集团股份有限公司 何毅	未采纳，并非所有项目负责人都从世界中联注册身份，可联合其他国家专家共同制定标准。	
9	（一）申请	“2.提案可以有多位联合项目负责人（Co-PL），但每一个国家成员体仅能选派一位项目负责人”建议修订为“提案可以有多位联合提案人（Co-PL），但每一个国家成员体仅能选派一位联合提案人。	天士力医药集团股份有限公司 何毅	采纳，已修改。	
10	（一）申请	“3.申报提案的项目负责人应来自至少两个以上国家”建议调整为“3.申报提案的项目负责人应来自至少 2 个以上国家”。	天士力医药集团股份有限公司 何毅	采纳，已统一修改数字表述方式。	
11	（一）申请	“4.同一项目负责人本年度申报提案不能超过两项（含两项）” 建议调整为“4.同一提案人本年度申报提案不应超过 2 项(含 2 项)”	天士力医药集团股份有限公司 何毅	采纳，已统一修改数字表述方式。	
12	（一）申请	“5.A 级联络组织不接受已在本年度提交至 ISO/TC249 中方对口单位的提案，请勿一项提案多处投递”建议调整为“5.A 级联络组织不接受已在本年度提交至 ISO/TC249 国内技术对口	天士力医药集团股份有限公司 何毅	未采纳，世界中联作为国际组织，没有“国内外”之分。	

		单位的提案，请勿一项提案多处投递”			
13	（二）评审	“需要项目申报负责人进行答辩”，建议调整为“根据评审需要，由项目提案人或联合提案人进行答辩”	天士力医药集团股份有限公司 何毅	采纳，已修改	
14	参考文献	参考文献中的《中国药材产地生态适宜性区划（第二版）》应为 2017 年出版	成都中医药大学 陈士林	采纳，已修改。	
15	2.规范性引用文件	在规范性引用文件中后面三个最好能明确注明日期 or 版本号(《中国药典》《GAP《GAC 指南》)需要增加版本号及相关信息。如《中华人民共和国药典》2020 版	成都中医药大学 陈士林	采纳，已标注版本号	
16	英文部分	部分英文 term 缺失。如 3.1 中药材的英文;英文的前后翻译一致,如道地药材的翻译部分英文翻译的准确把握，如道地产区、中药基原鉴定	成都中医药大学 陈士林	采纳，已斟酌并检查全文英文翻译部分。	
17	6.1 批次	6.1 批次的项下描述，是否有数量的规定?	成都中医药大学 陈士林	未采纳，批次数量的规定因每种药材名贵程度、大小不一，无法明确界定具体批次，需根据药材品种调整	
18	英文部分	部分英文翻译需要全文统一，且斟酌更为准确	成都中医药大学 陈士林	采纳，已统一全文英文翻译并斟酌用法	
19	2 规范性引用文件	文中标准强调了《中华人民共和国药典》，但是作为国际标准，如何体现这一属性？还需要加强	成都中医药大学 陈士林	采纳，已添加《中华人民共和国药典》国际属性的描述	

五、其他应说明的事项

无。

International Standard of WFCMS

General rule for genuine medicinal materials

Formulation Explanations

Ⅰ. Overview

Main drafting units: Chengdu University of TCM, Institute of Chinese Materia Medica China Academy of Chinese Medical Sciences.

Drafting units participated: Hubei University of Chinese Medicine, Institute of Medicinal Plant Development, University of Macau, Hong Kong Baptist University, Centre France Chine de la Médecine Chinoise (CFCMC), Naturalis Biodiversity Center, Australia Yuanyi Traditional Chinese Medicine Co., Ltd., Semmelweis University, American Institute of Traditional Chinese Medicine

Main Drafters: Chen Shilin, Dong Linlin.

Drafters participated (Alphabetized by surname):

China: Liu Ya, Lv Aiping, Shi Liping, Wang Yitao, Zhang Zhaoyu.

France: Wu Wanlin;

Netherlands: Wang Mei;

Australia: Liu Chijing;

Hungary: Yu Funian;

USA: Wang Shoudong.

Ⅱ. Introduction to the standard drafting process

(As for: when was the time of initiation, how the research was conducted, how stakeholders' opinions were solicited, what review meetings were held, and discussions or voting outcomes of the standard review committee, etc.)

The drafting process for the *General Rules for Daodi Medicinal Materials* was mainly as follows:

August 2023 Convened the drafting units and assigned tasks.

August 2023 – October 2023 Material and data collection: Collected and categorized relevant literature, guidelines, scientific research findings, and quality standards related to Chinese medicinal materials and Daodi Medicinal Materials from domestic and international sources. Conducted a comprehensive analysis of the characteristics, testing methods, and specification limits of Daodi Medicinal Materials.

October 2023 Convened a standard drafting seminar: Invited experts to introduce the requirements and key steps in standard development, and drafted the standard outline.

October 2023 – November 2023 Material collection and laboratory research: Collected Chinese medicinal materials from various Daodi production regions and conducted detailed analyses and studies. Through the tests and analysis of botanical origin, composition, physicochemical properties, and specification limits, identified key quality indicators and specifications for Daodi Medicinal Materials.

November 2023 – December 2023 Drafted the preliminary version of the standard.

December 2023 Convened a seminar on the preliminary draft: Invited domestic and international experts to review and revise the preliminary draft. Experts thoroughly discussed

and revised the preliminary draft based on their research and practical experience.

January 2024 – August 2024 Second and third review: Refined the standard based on expert feedback from the seminar on the preliminary draft. Conducted a second review, a second round of revisions, and a third review. Following the third review, the attending experts voted on the standard. The draft of the *General Rules for Daodi Medicinal Materials* was approved with 10 votes in favor, 0 against, and 0 abstentions.

September 2024 Held a working discussion on the draft of the international standard *General Rules for Daodi Medicinal Materials*. Domestic and international industry experts were invited to review and revise the draft. Experts thoroughly discussed the draft based on their research and practical experience

October 2024 – December 2025 Collected materials and revised the draft standard in response to the expert comments from the working discussion meeting.

Ⅲ. Introduction to the major technical contents

(As in: supporting basis (including tests and statistical data) for technical specification, parameters, formulas, performance requirements, test methods, inspection rules, etc. When revising the standard, a comparison between the new and old versions shall be added.

This standard is a newly developed standard, which is primarily based on the following: the drafting format strictly follows GB/T 1.1-2009 Directives for standardization—Part 1: Structure and drafting of standards, GB 3095-2012 Ambient air quality standards, GB 5084-2021 Standard for irrigation water quality, GB 5749-2022 Standards for drinking water quality, GB 15618-2018 Soil environmental quality Risk control standard for soil contamination of agricultural land, GB 18596-2001 Discharge standard of pollutants for livestock and poultry breeding, ISO 18662-1: 2017 Traditional Chinese medicine — Vocabulary — Part 1: Chinese Materia Medica, ISO 21371:2018 Traditional Chinese Medicine -Labelling requirements of products intended for oral or topical use, ISO 18662-2: 2020 Traditional Chinese medicine—Vocabulary—Part 2: Processing of Chinese Materia Medica, ISO 18664: 2015 Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine, ISO 19617: 2018 Traditional Chinese medicine-General requirements for the manufacturing process of natural products, ISO/TS 21310: 2020 Traditional Chinese medicine — Microscopic examination of medicinal herbs, ISO 22258: 2020 Traditional Chinese medicine Determination of pesticide residues in natural products by gas chromatography, ISO 22283:2020 Traditional Chinese medicine — Determination of aflatoxins in natural product by LC-FLD, ISO 22590: 2020 Traditional Chinese medicine-Determination of sulfur dioxide in natural products by titration, ISO 19609-1:2021 Traditional Chinese Medicine—Quality and safety of raw materials and finished products made with raw materials — Part 1: General requirements, ISO 19609-1:2021 Traditional Chinese Medicine—Quality and safety of raw materials and finished products made with raw materials — Part 2: Identity testing of constituents of herbal origin, GB/T20014 Good Agricultural Practice for Chinese Crude Drugs (GAP), and others. The details for referenced standards are as follows:

- Botanical origin

ISO 18662-1:2017 lists standardized terminology for commonly used Chinese medicinal materials, including their Latin, Chinese, pinyin, and English names. The standard also provides detailed definitions for each term, covering botanical, zoological, and mineralogical names, and

specifies the botanical origin and characteristics of the Chinese medicinal materials. For those not listed in this standard, their botanical origins shall be determined in accordance with the producing countries and historical literature.

- Ambient air quality at production sites

The WHO *Global Air Quality Guidelines (2021)* (AQG 2021) provides recommendations on indoor and outdoor ambient air quality, but does not address production sites.

GB 3095-2012, China's ambient air quality standard, specifies requirements for atmospheric environmental quality at production sites, including concentration limits for major pollutants and methods for monitoring and assessing air quality. Pollutants covered include, but are not limited to, inhalable particulate matter (PM10 and PM2.5), sulfur dioxide (SO_2), nitrogen dioxide (NO_2), ozone (O_3), and carbon monoxide (CO). The standard also specifies air quality requirements for different functional zones to prevent adverse impacts on the surrounding environment and public health from production activities.

- Soil environmental quality

Neither WHO nor ISO has issued standards specifically addressing soil environmental quality. Therefore, *GB 15618-2018 Soil environmental quality Risk control standard for soil contamination of agricultural land (Trial)* is adopted. This standard specifies the screening values and intervention values for soil contamination risks, as well as related requirements for monitoring, implementation, and supervision.

- Farmland irrigation water quality or environmental water quality

Neither WHO nor ISO has issued standards specifically addressing farmland irrigation water quality or environmental water quality. Therefore, GB 5084-2021 Standard for irrigation water quality is adopted. This standard specifies the requirements, monitoring, and supervision and management requirements for farmland irrigation water quality, aiming to strengthen the supervision of farmland irrigation water quality and ensure the safety of cultivated land, groundwater, and agricultural products. The standard covers both basic and optional control items, and sets limits for certain toxic and hazardous substances.

- Water for breeding

ISO has not issued any specific standard for water used in animal breeding. WHO has published the *Guidelines for drinking-water quality, fourth edition*, which applies to waterborne pathogens and chemical substances that may be ingested through drinking water. *GB 5749-2022 Standards for drinking water quality* specifies the hygienic requirements for drinking water quality and applies to all types of centralized and decentralized water supplies in urban and rural areas. The standard classifies water quality indicators into routine indicators and expanded indicators, and specifies limit requirements for water quality. While the standard is primarily intended for drinking water and does not include provisions for water used in animal breeding, it may indirectly serve as a reference for the safety of water used in breeding.

- Discharge of pollutants for livestock and poultry breeding

Neither WHO nor ISO has issued standards specifically addressing the discharge of pollutants from livestock and poultry breeding. Therefore, *GB 18596-2001 Discharge standard of pollutants for livestock and poultry breeding* is adopted. This standard specifies the discharge limits for wastewater, waste residue and odor from livestock and poultry farms and breeding areas. It applies to intensive, large-scale livestock and poultry farms, but does not apply to small-scale household operations. The standard includes biochemical indicators, hygienic indicators and

sensory indicators. It sets discharge limits varying by farm scales, aiming to promote the reduction, harmless treatment, and utilization of pollutants.

- Production Process

ISO 19617:2018 is adopted to specify the production requirements for Daodi medicinal materials. This standard provides comprehensive guidance and requirements for the production of Chinese medicinal materials, aiming to ensure the standardization of production processes as well as product quality and safety. Specific medicinal materials shall comply with GAP. The standard covers multiple levels and modules, including cultivation, harvesting, and packaging, thereby providing comprehensive guidance and specifications for the production of Chinese medicinal materials.

- Characteristics

ISO 19609-1:2021 and ISO/TS 21310:2020 are adopted to specify the characteristics of Daodi medicinal materials. ISO 19609-1:2021 specifies the identification and description of characteristics such as appearance, color, odor, taste and texture of Chinese medicinal materials. ISO/TS 21310:2020 specifies technical specifications for microscopic identification, providing scientific and accurate technical means for identifying microscopic characteristics.

- Endogenous quality control indicators

ISO 19609-2:2021 is referred to specify the methods for endogenous quality control indicators of Daodi medicinal materials. The standard covers chemical analysis, molecular biology techniques, and other methods. It specifies quality control indicator methods for Chinese medicinal raw materials and finished products. Given the diversity and characteristics of certain Chinese medicinal materials, some materials should refer to the methods specified under the relevant monographs of the producing country to ensure testing accuracy and reliability.

- Exogenous quality control indicators

ISO 18664:2015 specifies the specific requirements and testing methods for heavy metals and harmful substances in Chinese medicinal materials. ISO 22258:2020 provides detailed guidance and methods for pesticide residue testing in Chinese medicinal materials to mitigate the impact of pesticide residues on the efficacy of Chinese medicinal materials and human health. ISO 22283:2020 focuses on the safety control of exogenous contaminant mycotoxins in Chinese medicinal materials and specifies testing methods for aflatoxins and other toxins. ISO 22590:2020 specifies testing methods for sulfur dioxide in Chinese medicinal materials to effectively reduce the impact of sulfur dioxide residues on the quality of Chinese medicinal materials. Accordingly, this standard adopts ISO 18664:2015, ISO 22258:2020, ISO 22283:2020 and ISO 22590:2020 as the testing methods for exogenous quality control indicators. Given the diversity and characteristics of Chinese medicinal materials, some materials should refer to the methods specified under the specific monographs of the producing country to ensure the accuracy and reliability of testing.

- Processing Methods

ISO 18662-2:2020 focuses on terminology, methods, objectives, as well as the classification and naming of processed products in Chinese medicinal material processing, providing a standardized guidance for the Chinese medicinal material processing industry. Therefore, this standard adopts ISO 18662-2:2020 as the production and processing method for Daodi Medicinal Materials. Given the diversity and characteristics of certain Chinese medicinal materials, the production and processing of certain materials should refer to methods specified in ancient

literature, and the methods prescribed by the producing countries, to ensure the accuracy and reliability of testing.

- Labeling, packaging, storage and transportation of Chinese medicinal materials

ISO 21371:2018 is adopted. The standard specifies labeling requirements for Chinese medicinal materials and their finished products, ensuring that product labels are clear and accurate, providing necessary safety and usage information to avoid misuse or misunderstanding. ISO 19609-1:2021 is adopted. This standard covers quality and safety requirements for raw materials and finished products of Chinese medicinal materials, including packaging, storage and transportation, ensuring that medicinal materials are not damaged or degraded due to improper packaging, storage or transportation, and preventing adverse effects from external environmental conditions.

This standard specifies the requirements, test methods, inspection rules, acceptance criteria, labeling, packaging, storage, transportation, documentation management, and product traceability for Daodi medicinal materials. It encompasses the complete evaluation technical process and methods, and is practical, operable, and innovative.

The main technical content framework of this standard includes:

Chapter No.	Chapter title	Section No.	Section title	Main technical content
1	Scope	/	/	This document specifies the requirements, test methods, inspection rules, acceptance criteria, labeling, packaging, storage, transportation, documentation management, and product traceability for Daodi medicinal materials. This document is applicable to the evaluation of Daodi medicinal materials.
2	Normative references	/	/	None
3	Term and definition	/	/	The terms defined in this standard include Chinese medicinal materials, Daodi medicinal materials, Daodi production regions, identification of botanical origin of Chinese medicinal materials, and traceability.
4	Requirements	4.1	Textural research	This document specifies the basic requirements for textual research, Daodi production regions, botanical origin, production management, characteristics, endogenous quality control indicators, exogenous quality control indicators, and processing
		4.2	Daodi production regions	
		4.3	Botanical origin	
		4.4	Production management	
		4.5	Characteristics	

		4.6	Endogenous quality control indicators	methods of Daodi medicinal materials.
		4.7	Exogenous quality control indicators	
		4.8	Processing methods	
5	Test methods	5.1	Textural research	This document specifies the basic requirements for textual research, Daodi production regions, botanical origin, production management, characteristics, endogenous quality control indicators, exogenous quality control indicators, and processing methods of Daodi medicinal materials.
		5.2	Daodi production regions	
		5.3	Botanical origin	
		5.4	Production management	
		5.5	Characteristics	
		5.6	Endogenous quality control indicators	
		5.7	Exogenous quality control indicators	
		5.8	Processing methods	
6	Production management	6.1	Production environment	This document specifies the requirements for the production environment, harvesting, and processing methods during the production process.
		6.2	Harvesting	
		6.3	Processing methods	
7	Inspection rules	7.1	Sampling methods	This document specifies the main contents for batches, sampling methods, and testing items.
		7.2	Testing items	
8	Acceptance criteria	/	/	This document provides a scientific description, analysis, and judgment for the evaluation of Daodi medicinal materials.
9	Labeling, packaging, storage, transportation	9.1	Labeling	This document specifies the basic requirements for labeling, packaging, storage, and transportation of Daodi medicinal materials.
		9.2	Packaging	
		9.3	Storage	
		9.4	Transportation	
10	Documentation management and product traceability	10.1	Documentation management	This document specifies the basic requirements for documentation management and product traceability of Daodi medicinal materials.
		10.2	Product traceability	

Based on the search conducted, no international organization or body has yet established a general quality standard for Daodi medicinal materials. This draft standard is the first of its kind internationally, designed to meet the market demands and development of Daodi medicinal materials.

IV. Handling and Basis for Major Divergent Opinions

Opinions were solicited from enterprises and research institutions through meetings, emails, and other means. Responses to the opinions were provided accordingly. A total of 19 comments were received, of which 11 were adopted. Details are as follows:

No.	Standard Clause	Comment	Proposed Unit/ Individuals	Proposed Comments (Filled by Draft Unit)	Notes
20	(Ⅰ) Application	The term "nation member" is unclear and requires revision.	Wang Mei (Netherlands)	Accepted. Revised to "ISO nation member".	
21	(Ⅰ) Application	Should be revised as: 3. The project leader and the co-project leader of the submitted proposal shall be from different countries.	Wang Mei (Netherlands)	Not accepted. The project leader and co-project leader are separate roles. Not accepted. The original text is already clear.	
22	(Ⅰ) Application	Should be revised as: 4. The same project leader may not submit more than two proposals within the current year.	Wang Mei (Netherlands)	Not accepted. "more than and including two proposals" should be explicitly stated.	
23	(Ⅲ) Review conclusion and feedback	1.If the review conclusion is "recommended project" 2.If the review conclusion is "not recommended project"	Wang Mei (Netherlands)	Not accepted. The original text is already clear.	
24	English translation	After the Chinese version is finalized, translate it into English, and I will review it again.	Wang Mei (Netherlands)	Accepted.	
25	The third paragraph	Recommend to change the double em dashes to single em dashes in "the world's largest standards developer—ISO" and "the Traditional Chinese	Tasly Pharmaceutical Group Co.,Ltd. He Yi	Not accepted. The original text complies with the usage requirements for Chinese	

		medicine—Pulse wave format submitted by WFCMS".		punctuation marks.	
26	(Ⅰ) Application	"Submit application materials" is recommended to clarify whether paper documents, stamped originals, etc. are required.	Tasly Pharmaceutical Group Co.,Ltd. He Yi	Not accepted. After the formal review, the documents will be subject to certain revisions. Currently, only electronic scanned documents are collected.	
27	(Ⅰ) Application	"1. There must be one project leader (PL) registered with WFCMS for the submitted proposal." is recommended to revise to "The project proposer (PL) must be registered with WFCMS."	Tasly Pharmaceutical Group Co.,Ltd. He Yi	Not accepted. Not all project leaders are registered with WFCMS; experts from other countries may engage in the development of the standard.	
28	(Ⅰ) Application	"2. A proposal may have multiple co-project leaders (Co-PL), but each nation member may appoint only one project leader." is recommended to revise to "A proposal may have multiple co-proposers (Co-PL), but each nation member may appoint only one co-proposer."	Tasly Pharmaceutical Group Co.,Ltd. He Yi	Accepted and revised.	
29	(Ⅰ) Application	"3. The project leaders of the submitted proposal shall come from at least two countries." is recommended to revise to	Tasly Pharmaceutical Group Co.,Ltd. He Yi	Accepted. The expression of numbers has been uniformly revised.	

		“3. The project proposers of the submitted proposal shall come from at least two countries.”			
30	(Ⅰ) Application	“4. The same project leader may submit no more than two proposals within the current year (including two).” is recommended to revise to “4. The same proposer shall not submit more than two proposals within the current year (including two).”	Tasly Pharmaceutical Group Co.,Ltd. He Yi	Accepted. The expression of numbers has been uniformly revised.	
31	(Ⅰ) Application	“5. Category A liaison organizations do not accept proposals that have already been submitted to the Chinese counterpart of ISO/TC 249 in the current year. Please refrain from submitting the same proposal to multiple channels.” is recommended to revise to “5. Category A liaison organizations do not accept proposals that have already been submitted to the domestic technical counterpart of ISO/TC 249 in the current year. Please refrain from submitting the same proposal to multiple channels.”	Tasly Pharmaceutical Group Co.,Ltd. He Yi	Not accepted. As an international organization, WFCMS does not have a distinction between “domestic and international”.	
32	(Ⅱ) Review	“The project leader is required to attend a defense.” is recommended to revise to “Depending on the review requirements, the project proposer or co-proposer shall attend	Tasly Pharmaceutical Group Co.,Ltd. He Yi	Accepted and revised.	

		the defense."			
33	References	In the references, Ecological Suitability Regionalization of Chinese Medicinal Materials (Second Edition) should be listed as published in 2017.	Chengdu University of TCM Chen Shilin	Accepted and revised.	
34	2.Normative references	In the normative references, it is recommended to clearly indicate the dates or version numbers for the last three documents (Pharmacopoeia of the People's Republic of China, GAP, GAC Guidelines), such as Pharmacopoeia of the People's Republic of China (2020 Edition).	Chengdu University of TCM Chen Shilin	Accepted. The version number has been indicated.	
35	English translation	Some English terms are missing (e.g., the English for "3.1 Chinese medicinal materials"). The English translation should be consistent throughout the document (e.g. the translation of Daodi medicinal materials). The accuracy of certain terms should be carefully reviewed (e.g., "Daodi production region", "identification of botanical origin of Chinese medicinal materials").	Chengdu University of TCM Chen Shilin	Accepted. The English translation of the entire text has been carefully reviewed and examined.	
36	6.1 batch	In section 6.1 "Batch", is there any requirement regarding the quantity	Chengdu University of TCM Chen Shilin	Not accepted. The number of batches cannot	

				be clearly defined due to variations in the value and size of each medicinal material; it should be adjusted according to the specific type of medicinal material.	
37	English translation	Some English translations need to be unified and refined for better accuracy.	Chengdu University of TCM Chen Shilin	Accepted. The English translation of the entire text has been unified and refined.	
38	2 Normative references	The standard places emphasis on the Pharmacopoeia of the People's Republic of China. However, as an international standard, how could its international attribute be reflected? Revision is needed.	Chengdu University of TCM Chen Shilin	Accepted. A description of the international applicability of the Pharmacopoeia of the People's Republic of China has been added.	

V. Other Matters to Be Specified

None.