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世界中医药学会联合会
World Federation of Chinese Medicine Societies

SCM **-20**

道地药材通则

General rule for genuine medicinal materials

（征求意见草案，CD）

世界中联国际组织标准
International Standard of WFCMS

20**-**-**发布实施
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前　言

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本文件的起草程序遵守了世界中医药学会联合会发布的 SCM1.1-2021 《标准化工作导则第 1 部分：标准制修订与发布》。

本文件由世界中医药学会联合会翻译专业委员会承担翻译，翻译人员为***。若发生异议，以中文文本为准。

引　言

近年来，中医药被越来越多国家认可，并逐渐走向国际发展之路，成为新时代全球文化交流互鉴的载体之一。优质中药材是推进中医药国际化发展的根本保障。道地药材是药材质优效佳的代名词。然而，道地产区划分的模糊性、加工生产技术的主观性及国际品质标准缺失等问题，导致对道地药材的判定缺少严格的标准与规范，成为阻碍中医药相关健康产业国际化发展的重要原因。为规范道地药材品质，统一全球道地药材判定标准，更好地满足药材品质多元化的市场需求，道地药材质量评价指南的制定迫在眉睫，对于保障患者安全、促进国际贸易、提升行业规范、推动科学研究、增强消费者信任以及促进可持续发展等方面都具有重要意义。

本文件以道地药材理论为指导，以各药材产地国的药典及标准为基础，并在中医药全球化背景下借鉴 ISO 9001:2015、ISO 18662-1: 2017、ISO 18662-2: 2020、ISO 18664: 2015、ISO 19617: 2018、ISO/TS 21310: 2020、ISO 22258: 2020、ISO 22590: 2020 等国际标准和规范，规定了道地药材的要求、检验方法、检验规则等，从而为道地药材产业提供保障，促进海内外中医药文化的传承与创新。

为保障中医药产品在国际市场的认可度，中医药的国际标准化和规范化成为发展方向。为了更好地统一全球道地药材判定标准，满足普通中药材及道地药材市场分级的需要，《道地药材通则》应运而生。

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道地药材通则

1 范围

本文件规定了道地药材基本要求、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和评价。

2 规范性引用文件

下列文件中的内容通过文中的规范性引用而构成本文件必不可少的条款。其中，注日期的引用文件，仅该日期对应的版本适用于本文件；不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

GB/T 3095 环境空气质量标准

GB/T 5084 农田灌溉水质标准

GB/T 5749 生活饮用水卫生标准

GB/T 15618 土壤环境质量 农用地土壤污染风险管控标准

GB/T 18596 畜禽养殖业污染物排放标准

GB/T 20014 良好农业规范

ISO 9001 Quality management systems — Requirements

ISO 18662-1 Traditional Chinese medicine—Vocabulary—Part 1: Chinese Materia Medica

ISO 18662-2 Traditional Chinese medicine—Vocabulary—Part 2: Processing of Chinese Materia Medica

ISO 18664 Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine

ISO 19609-1 Traditional Chinese Medicine—Quality and safety of raw materials and finished products made with raw materials —Part 1: General requirements

ISO 19609-2 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

ISO 19617 Traditional Chinese medicine-General requirements for the manufacturing process of natural products

ISO/TS 21310 Traditional Chinese medicine—Microscopic examination of medicinal herbs

ISO 21371 Traditional Chinese Medicine -Labelling requirements of products intended for oral or topical use

ISO 22258 Traditional Chinese medicine Determination of pesticide residues in natural products by gas chromatography

ISO 22283 Traditional Chinese medicine—Determination ofaflatoxins in natural product by LC-FLD

ISO 22590 Traditional Chinese medicine-Determination of sulfur dioxide in natural

products by titration

ISO 928:1997, Spices and condiments — Determination of total ash

ISO 939:2021, Spices and condiments — Determination of moisture content

3 术语和定义

下列术语和定义适用于本文件。

3.1

中药材

用于传统中医的植物、动物和矿物来源的原料和产品，这些原料和产品在传统中医理论指导下应用，包括中药材、中药饮片和中成药等。

[来源：ISO 18662-1，3.1]

3.2

道地药材

经过中医临床长期应用优选出来，产在特定地域，与其它地区所产同种中药材相比，品质和疗效更好且质量稳定，具有较高知名度的中药材。

3.3

道地产区

有确切的本草文献记载，所产药材具有百余年甚至以上的应用推崇历史，并被历代医家所认可，得到行业公认的道地药材产地。

3.4

中药基原鉴定

应用本草学、中药学和植物、动物或矿物形态、显微特征、分类学等方面的知识，对中药的基原或原料进行鉴定，确定药材基原正确的学名或复方及其制剂的饮片基原和配伍组分，以保证在应用中品种准确的方法。

3.5

可追溯性

指通过记录的识别码，对商品或行为的历史、使用或位置予以追踪的能力。

[来源：ISO 9001，]

4 要求

4.1 本草考证

对道地药材历史沿革做本草考证的信息应包括：

a) 道地性信息：历代本草、医籍、方书、史志等历史文献对主产区的记载与变迁，表明具有悠久栽培或野生采收历史、特定生态环境且古今公认的核心道地产区信息；

b) 产地加工信息：历史文献中道地药材的生产、采收、加工信息；

c) 药材优质特性信息：历史文献中关于判断药材品质优劣的传统经验，历代医家推崇的药材感官指标及外观形态特征信息。

4.2 道地产区

道地产区范围应符合历史文献中记载的其行政区域及自然分布区，以及与历史文献记载产区的生态因子具有最大相似度的区域。

4.3 基原

道地药材基原应符合 ISO 18662-1 要求，且与产地国及历史文献规定的基原一致。

4.4 性状特征

道地药材性状应符合 ISO 具体品种质量标准的规定。如尚无相应 ISO 具体品种质量标准，性状应符合产地国历史文献记载和传统经验；显微应符合 ISO 19609-1 的规定，色谱应符合 ISO 19609-2 的规定，光谱特征应符合 ISO/TS 21310 的规定。

4.5 水分及灰分

道地药材水分及灰分含量应符合产地国具体品种项下规定。

4.6 内源性质量控制指标

a) 内源性有效物质含量：道地药材浸出物指标、指标性（有效）成分含量应符合产地国具体品种项下规定；

b) 内源性毒害物质限量：道地药材内源性毒性有害物质应符合产地国具体品种项下规定。

4.7 外源性质量控制指标

道地药材重金属及有害元素限量、农药残留限量、真菌毒素限量、二氧化硫含量应符合产地国具体品种项下规定。

5 方法

5.1 本草考证

通过系统查阅产地国历代本草、医籍、地方志、药学文献及相关研究资料，结合文献来源可靠性、记载一致性、内容连续性和现代调查资料，对道地药材的道地性信息、产地加工信息和优质特性信息进行比对、归纳与综合判定，形成相应结论。

5.2 道地产区

道地产区划分应以该药材道地性形成并被稳定记载的主要历史时期为依据，结合现行行政区划进行界定。不同历史阶段地理范围记载不一致时，应以记载连续性强、范围相对明确、行业认同度高且能够与现行产区实际对应的历史时期为准

5.3 基原鉴定

通过考证中药材在古代文献中的记载及历史演变，明确其鉴别特征，据此观察植物形态，并核对文献和标本，结合产地国分类学知识，药材色谱或光谱信息，基因标记信息，以及 ISO 18662-1 中规定的中药材标准术语，最终确定中药材的正确学名。

5.4 性状特征

道地药材的性状应优先按照相应 ISO 具体品种质量标准中规定的性状项目及判定要求执行；如尚无相应 ISO 具体品种质量标准，则应依据产地国历史文献记载和传统经验，

明确其性状描述及判定依据。显微、色谱和光谱鉴别分别应按照 ISO 19609-1、ISO 19609-2 和 ISO/TS 21310 进行检测；相应 ISO 具体品种质量标准另有规定的，应按其规定执行。

5.5 水分及灰分

道地药材水分及灰分应分别按照 ISO 939:2021 及 ISO 928:1997 规定的方法进行检测。

5.6 内源性质量控制指标

道地药材浸出物指标、指标性（有效）成分含量、内源性毒性有害物质检测按 ISO 19609-2 结合产地国具体品种规定的方法。

5.7 外源性质量控制指标

道地药材中的外源性质量控制指标测定方法详见表 1。

表 1　外源性质量控制指标检测方法

质量控制指标	测定方法
铅、镉、铜、砷、汞	按 ISO 18664 中规定的重金属及有害元素测定方法测定
农药残留含量	按 ISO 22258 结合产地国品种项下规定的方法测定
真菌毒素限量	按 ISO 22283 中规定的真菌毒素测定方法测定
二氧化硫含量	按 ISO 22590 中规定的二氧化硫测定方法测定。

6　生产要求与证实方法

道地药材的采收年限和采收时间应依据古代文献记载、现代研究结果以及产地国现行药典、标准或技术规范综合确定，并结合品种特性、质量形成规律和当地生产实践进行判定。相关结论应有生产记录、采收记录或其他可追溯材料予以证实。

道地药材的生产和加工过程应符合 ISO 18662-2 的规定，并结合古代文献记载、产地国现行生产加工规范及传统加工特点，明确关键生产加工环节及其控制要求。相关要求的符合性应通过生产操作规程、批次加工记录、工艺参数记录或现场核查资料予以证实。

生产过程记录应符合 ISO 19617 的要求，特定药材可结合 GB/T 20014.7 的相关规定执行。记录应覆盖种植、采收、产地加工、贮藏及流通等关键环节，并具有真实性、完整性和可追溯性。相关记录应作为符合性证明材料保存。

7　生产环境要求与检测方法

7.1　环境要求

生产场所大气环境质量应符合 GB 3095 二类区要求；土壤环境质量应符合 GB 15618 的要求；农田灌溉水或环境水质量应符合 GB 5084 的要求；饲养用水应符合 GB 5749 的要求；畜禽养殖业污染物排放应符合 GB 18596 的要求。

7.2　环境检测

生产场所周围大气、水体、土壤检测，应按方法表 1 方法进行检测。其中植物类道地药材符合上述 a）、b）、c）项，养殖动物类道地药材符合 a）、b）、d）、e）项。

表 2　生产环境检测方法

检测项目	参考标准
a) 大气环境质量监测	GB 3095
b) 土壤环境质量监测	GB 15618
c）农田灌溉水或环境水质量检测	GB 5084
d）饲养用水质量检测	GB 5749
e) 畜禽养殖业污染物排放质量检测	GB 18596

8　检验规则

8.1　检验类型

药材检验：用于道地药材产品符合性判定、批次质量控制和监督抽查。药材检验项目主要包括基原、性状特征、内源性控制指标、外源性质量控制指标以及采收加工方法等与样品质量直接相关的项目。

生产环境与生产管理核查：用于对本草考证、道地产区、生产环境、生产管理及相关追溯信息进行确认。该类项目可通过文件审查、现场核查、记录检查及必要时的抽样检测进行评价。对相对稳定的生产环境条件，不必在每批次产品检验时重复检测，但在首次判定、产地变更、生产条件发生显著变化或监督评价需要时，应进行核查或复核。

8.2　抽样方法

试样的抽样方法应按 ISO 19609-1 中规定的抽样原则执行。

8.3　判定规则

道地药材的判定，应参照 8.1 的检验类型，按照 8.2 的规定进行抽样检验，按照 8.3 的规定进行抽样检验，样品的本草考证、产区、基原、生产管理、性状特征、内源性控制指标、外源性质量控制指标、采收加工方法符合表 3 的要求，为道地药材。

表 3　道地药材判定

抽检项目	参考条目（本文件）
本草考证	4.1
道地产区	4.2
基原	4.3
生产管理	4.4
性状特征	4.5
内源性控制指标	4.6
外源性质量控制指标	4.7
加工方法	7

8.4 复检规则

任一判定项目标达不到本文件要求的样品，按照本文件要求的抽样方法重新抽样并复检。若复检样品检测指标达到本文件要求，则判定为道地药材；若不能达到本文件的要求，不应判定为道地药材。

9 标签、包装、贮藏与运输

9.1 标签

道地药材应在包装上贴有追溯标签或挂有追溯吊牌及道地药材标签，追溯标签与吊牌应符合产地国中药材追溯通用标识规范的要求。标签内容及格式应符合 ISO 21371 的规定。

9.2 包装

道地药材的包装材料应无毒、无害、清洁、干燥、无污染、无异味、无破损，应符合 ISO 19609-1 中对药材包装的规定及产地国中药材包装技术规范。

9.3 贮藏

道地药材的储藏条件应符合 ISO 19609-1 中对药材贮藏的规定及产地国中药材仓库技术规范的要求，以保证药材的质量及活性成分的稳定性。储存时应分批次存放，合理控制温度、湿度、防霉、防虫、防蛀等。仓储作业和仓储管理应符合产地国中药材仓储管理规范和产地国仓储作业规范的要求。

9.4 运输

道地药材运输应符合 ISO 19609-1 中对药材运输条件的规定。采收后宜及时运输到加工场地，及时清洁装载容器和运输工具；运输和临时存放措施应保证中药材品质维持，不产生新污染及杂物混入，严防淋雨、泡水等。

10 文件管理及产品可追溯性

10.1 文件管理

生产组织应具有道地药材生产及采收加工相关技术规程，及有关的证明文件，如基地相关证明文件（如土地证或土地租赁合同、合作协议）、相关生产加工许可证书及检眼报告等。检验报告保留期限应在产品销售后留存 3 年及以上。

10.2 产品可追溯性

生产组织应依据 ISO 9001 质量管理体系关于可追溯性的要求，建立包括产品种源、生产、加工、包装、运输、贮藏等全过程的可追溯体系以及可追溯的批号系统，实现从原料到成品、成品到原料双向可追溯。

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Foreword

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing organization of this document shall not be held responsible for identifying any or all such patent rights.

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Introduction

In recent years, traditional Chinese medicine (TCM) has been increasingly recognized by more countries and is gradually advancing toward international development, becoming one of the carriers for global cultural exchange and mutual learning in the new era. High-quality Chinese medicinal materials are the fundamental guarantee for promoting the internationalization of TCM. genuine medicinal materials are synonymous with superior quality and efficacy. However, the ambiguity in delimiting genuine production areas, the subjectivity of processing and production techniques, and the absence of internationally harmonized quality standards have resulted in a lack of rigorous criteria and specifications for determining genuine medicinal materials, which has become an important factor hindering the international development of TCM-related health industries. Therefore, it is imperative to formulate guidelines for the quality evaluation of genuine medicinal materials in order to standardize their quality, unify the global criteria for their determination, and better meet diversified market demands for medicinal material quality. Such efforts are of great significance for ensuring patient safety, promoting international trade, improving industry norms, advancing scientific research, enhancing consumer confidence, and fostering sustainable development.

Guided by the theory of genuine medicinal materials and based on the pharmacopoeias and standards of countries of origin for individual medicinal materials, this document also draws on international standards and specifications such as ISO 9001:2015, ISO 18662-1:2017, ISO 18662-2:2020, ISO 18664:2015, ISO 19617:2018, ISO/TS 21310:2020, ISO 22258:2020, and ISO 22590:2020 under the background of TCM globalization. It specifies the requirements, test methods, and inspection rules for genuine medicinal materials, thereby providing support for the genuine medicinal materials industry and promoting the inheritance, innovation, and dissemination of TCM culture both domestically and internationally.

To enhance the recognition of TCM products in the international market, the international standardization and normalization of TCM have become a key direction of development. In order to better unify the global criteria for determining genuine medicinal materials and to meet the needs for market grading of both ordinary Chinese medicinal materials and genuine medicinal materials, these General Rules for genuine Medicinal Materials have been developed.

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General rule for genuine medicinal materials

1 Scope

This document specifies the basic requirements, test methods, inspection rules, determination rules, labelling, packaging, storage, transportation, document management, and product traceability for genuine medicinal materials.

This document applies to the determination and evaluation of genuine medicinal materials.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 928:1997, Spices and condiments — Determination of total ash
ISO 939:2021, Spices and condiments — Determination of moisture content
GB/T 3095 Ambient air quality standard
GB/T 5084 Standards for irrigation water quality
GB/T 5749 Standards for drinking water quality
GB/T 15618 Soil environmental quality — Risk control standard for soil contamination of agricultural land
GB/T 18596 Discharge standard of pollutants for livestock and poultry breeding
GB/T 20014 Good agricultural practice
ISO 9001 Quality management systems — Requirements
ISO 18662-1 Traditional Chinese medicine—Vocabulary—Part 1: Chinese Materia Medica
ISO 18662-2 Traditional Chinese medicine—Vocabulary—Part 2: Processing of Chinese Materia Medica
ISO 18664 Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine
ISO 19609-1 Traditional Chinese Medicine—Quality and safety of raw materials and finished products made with raw materials —Part 1: General requirements
ISO 19609-2 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
ISO 19617 Traditional Chinese medicine-General requirements for the manufacturing process of natural products
ISO/TS 21310 Traditional Chinese medicine—Microscopic examination of medicinal herbs
ISO 21371 Traditional Chinese Medicine -Labelling requirements of products intended

for oral or topical use
ISO 22258 Traditional Chinese medicine Determination of pesticide residues in natural products by gas chromatography
ISO 22283 Traditional Chinese medicine—Determination ofaflatoxins in natural product by LC-FLD
ISO 22590 Traditional Chinese medicine-Determination of sulfur dioxide in natural products by titration

3 Terms and definitions

The following terms and definitions apply to this document.

3.1
Chinese medicinal material
raw material and product of plant, animal, or mineral origin used in traditional Chinese medicine under the guidance of TCM theory, including Chinese medicinal materials, decoction pieces, and Chinese patent medicines.
[Source：ISO 18662-1，3.1]

3.2
genuine medicinal materials
Chinese medicinal materials that have been selected through long-term TCM clinical application, are produced in specific geographical regions, and, compared with the same medicinal materials produced in other regions, exhibit better quality, more reliable efficacy, stable quality, and high recognition.

3.3
genuine production area
production area of genuine medicinal materials that is clearly documented in materia medica literature, has enjoyed a history of recognized use and esteem for more than one hundred years or longer, has been acknowledged by physicians through successive dynasties, and is widely recognized by the profession.

3.4
authentication of the origin of Chinese medicinal materials
method for identifying the origin or source materials of Chinese medicinal materials by applying knowledge of materia medica, pharmacognosy, and the morphology, microscopic characteristics, and taxonomy of plants, animals, or minerals, so as to determine the correct scientific name of the medicinal material or, in the case of compound preparations and their decoction pieces, the botanical origin and compatible components, thereby ensuring the accuracy of the material used in practice.

3.5
traceability
ability to trace the history, application, or location of an item or activity by means of recorded identification.
[Source：ISO 9001]

4 Requirements

4.1 Textual research on materia medica

The information obtained through materia medica textual research on the historical evolution of genuine medicinal materials shall include:

a) Information on genuine attributes: records and changes concerning the principal production areas in historical materia medica works, medical books, formula books, local chronicles, and other historical literature, demonstrating a long history of cultivation or wild harvesting, a specific ecological environment, and information on core genuine production areas recognized both historically and in modern times;

b) Information on origin-based processing: historical records concerning the production, harvesting, and processing of genuine medicinal materials;

c) Information on superior quality characteristics: traditional experience recorded in historical documents for judging medicinal material quality, as well as information on the sensory indicators and external morphological characteristics of medicinal materials favored by physicians through successive dynasties.

4.2 genuine production area

The scope of a genuine production area shall conform to the administrative region and natural distribution area recorded in historical documents, as well as to areas whose ecological factors show the highest similarity to those of the production area recorded in historical documents.

4.3 Origin

The origin of genuine medicinal materials shall comply with the requirements of ISO 18662-1 and shall be consistent with the origin stipulated by the country of origin and historical literature.

4.4 Macroscopic and identification characteristics

The macroscopic characteristics of genuine medicinal materials shall comply with the provisions of the relevant ISO species-specific quality standard. Where no such ISO species-specific quality standard is available, the macroscopic characteristics shall conform to the historical literature and traditional experience of the country of origin. Microscopic characteristics shall comply with ISO 19609-1, chromatographic characteristics shall comply with ISO 19609-2, and spectroscopic characteristics shall comply with ISO/TS 21310.

4.5 Moisture and total ash

The moisture content and total ash content of genuine medicinal materials shall comply with the requirements specified for the relevant species in the country-of-origin standard.

4.6 Endogenous quality control indicators

a) Content of endogenous active substances: the extractive values and the contents of

marker (active) constituents of genuine medicinal materials shall comply with the requirements specified for the relevant species in the country-of-origin standard;

b) Limits for endogenous toxic and harmful substances: endogenous toxic and harmful substances in genuine medicinal materials shall comply with the requirements specified for the relevant species in the country-of-origin standard.

4.7 Exogenous quality control indicators

The limits for heavy metals and harmful elements, pesticide residues, mycotoxins, and sulfur dioxide in genuine medicinal materials shall comply with the requirements specified for the relevant species in the country-of-origin standard.

5 Methods

5.1Textual research on materia medica

By systematically consulting historical materia medica works, medical books, local chronicles, pharmaceutical literature, and related research materials from the country of origin, and by taking into account the reliability of document sources, consistency of records, continuity of content, and modern survey data, information on the genuine attributes, origin-based processing, and superior quality characteristics of genuine medicinal materials shall be compared, summarized, and comprehensively evaluated to reach relevant conclusions.

5.2 genuine production area

The delimitation of genuine production areas shall be based on the principal historical period during which the genuine character of the medicinal material was formed and stably recorded, in combination with the current administrative divisions. Where the recorded geographical scope differs across historical periods, the historical period characterized by stronger continuity of records, relatively clearer boundaries, higher industry recognition, and better correspondence to the actual present-day production area shall prevail.

5.3 Authentication of origin

Through textual research on the records and historical evolution of Chinese medicinal materials in ancient literature, their identification characteristics shall be clarified. On this basis, plant morphology shall be observed and verified against literature and voucher specimens. Combined with the taxonomic knowledge of the country of origin, chromatographic or spectroscopic information of the medicinal material, gene marker information, and the standard terminology for Chinese medicinal materials specified in ISO 18662-1, the correct scientific name of the Chinese medicinal material shall be finally determined.

5.4 Macroscopic and identification characteristics

The macroscopic characteristics of genuine medicinal materials shall, as a priority, be evaluated in accordance with the macroscopic examination items and determination

requirements specified in the relevant ISO species-specific quality standard. Where no such ISO species-specific quality standard is available, the description of macroscopic characteristics and the basis for determination shall be established according to the historical literature and traditional experience of the country of origin. Microscopic, chromatographic, and spectroscopic identification shall be conducted in accordance with ISO 19609-1, ISO 19609-2, and ISO/TS 21310, respectively; where the relevant ISO species-specific quality standard provides otherwise, that standard shall prevail.

5.5 Moisture and total ash

The moisture content and total ash of genuine medicinal materials shall be determined in accordance with ISO 939:2021 and ISO 928:1997, respectively.

5.6 Endogenous quality control indicators

The extractive values, contents of marker (active) constituents, and endogenous toxic and harmful substances of genuine medicinal materials shall be determined according to ISO 19609-2 in conjunction with the methods specified for the relevant species in the country-of-origin standard.

5.7 Exogenous quality control indicators

The methods for determination of exogenous quality control indicators in genuine medicinal materials are given in Table 1.

Table 1 Test methods for exogenous quality control indicators

Quality control indicator	Test method
Lead, cadmium, copper, arsenic, mercury	Determined in accordance with the test methods for heavy metals and harmful elements specified in ISO 18664
Pesticide residues	Determined in accordance with ISO 22258 together with the methods specified for the relevant species in the country-of-origin standard
Mycotoxins	Determined in accordance with the mycotoxin test methods specified in ISO 22283
Sulfur dioxide	Determined in accordance with the sulfur dioxide test method specified in ISO 22590

6 Production requirements and methods of verification

The harvest age and harvest time of genuine medicinal materials shall be determined comprehensively on the basis of records in ancient literature, results of modern studies, and the currently effective pharmacopoeias, standards, or technical specifications of the country of origin, in combination with species characteristics, patterns of quality formation, and local production practices. Relevant conclusions shall be substantiated by production records, harvest records, or other traceable materials.

The production and processing of genuine medicinal materials shall comply with ISO

18662-2 and shall, in combination with records in ancient literature, current production and processing specifications of the country of origin, and traditional processing characteristics, clarify the key production and processing steps and their control requirements. Conformity with such requirements shall be verified through standard operating procedures, batch processing records, process parameter records, or on-site inspection materials.

Production records shall comply with ISO 19617. For specific medicinal materials, the relevant provisions of GB/T 20014.7 may also be applied as appropriate. Records shall cover key stages including cultivation, harvesting, origin-based processing, storage, and circulation, and shall be authentic, complete, and traceable. Such records shall be retained as documentary evidence of conformity.

7 Requirements for production environment and test methods

7.1 Environmental requirements

The ambient air quality of the production site shall comply with the requirements for Class II areas in GB 3095; the soil environmental quality shall comply with GB 15618; the quality of irrigation water for farmland or environmental water shall comply with GB 5084; the quality of water for animal breeding shall comply with GB 5749; and pollutant discharge from livestock and poultry breeding shall comply with GB 18596.

7.2 Environmental testing

The ambient air, water bodies, and soil surrounding the production site shall be tested in accordance with the methods specified in Table 2. Among them, plant-derived genuine medicinal materials shall comply with items a), b), and c), whereas farmed animal-derived genuine medicinal materials shall comply with items a), b), d), and e).

Table 2 Test methods for production environment

Test item	Reference standard
a) Monitoring of ambient air quality	GB 3095
b) Monitoring of soil environmental quality	GB 15618
c) Testing of irrigation water for farmland or environmental water quality	GB 5084
d) Testing of water quality for animal breeding	GB 5749
e) Testing of pollutant discharge quality for livestock and poultry breeding	GB 18596

8 Inspection rules

8.1 Types of inspection

Product inspection of medicinal materials: used for conformity determination of genuine medicinal material products, batch quality control, and supervision sampling

inspection. Inspection items mainly include origin, macroscopic characteristics, endogenous quality control indicators, exogenous quality control indicators, and harvesting and processing methods directly related to sample quality.

Inspection of production environment and production management: used to verify textual research on materia medica, genuine production area, production environment, production management, and related traceability information. Such items may be evaluated through document review, on-site inspection, record examination, and, where necessary, sampling tests. For relatively stable production environmental conditions, repeated testing is not required for every product batch; however, verification or re-verification shall be conducted during the initial determination, when the production area changes, when production conditions change significantly, or when required for supervision and evaluation.

8.2 Sampling method

Sampling of test samples shall be conducted in accordance with the sampling principles specified in ISO 19609-1.

8.3 Determination rules

The determination of genuine medicinal materials shall, with reference to the inspection types specified in 8.1, be carried out by sampling in accordance with 8.2 and by evaluation in accordance with 8.3. Where the sample conforms to the requirements in Table 3 with respect to textual research on materia medica, production area, origin, production management, macroscopic characteristics, endogenous quality control indicators, exogenous quality control indicators, and harvesting and processing methods, it shall be determined to be a genuine medicinal material.

Table 3 Determination of genuine medicinal materials

Inspection item	Relevant clause (this document)
Textual research on materia medica	4.1
genuine production area	4.2
Origin	4.3
Production management	4.4
Macroscopic characteristics	4.5
Endogenous quality control indicators	4.6
Exogenous quality control indicators	4.7
Processing methods	7

8.4 Re-inspection rules

Where any determination item of a sample fails to meet the requirements of this document, re-sampling and re-inspection shall be conducted in accordance with the sampling method specified in this document. If the re-inspection sample meets the requirements of this document, it shall be determined as a genuine medicinal material;

otherwise, it shall not be determined as a genuine medicinal material.

9 Labeling, packaging, storage and transportation

9.1 Labeling

genuine medicinal materials shall bear a traceability label or a traceability tag, together with a genuine medicinal material label, on the package. The traceability label and tag shall comply with the general identification specifications for the traceability of Chinese medicinal materials in the country of origin. The content and format of the label shall comply with ISO 21371.

9.2 Packaging

The packaging materials for genuine medicinal materials shall be non-toxic, harmless, clean, dry, free from contamination, free from odor, and intact, and shall comply with the packaging requirements for medicinal materials specified in ISO 19609-1 as well as the technical specifications for the packaging of Chinese medicinal materials in the country of origin.

9.3 Storage

The storage conditions for genuine medicinal materials shall comply with the requirements for medicinal material storage specified in ISO 19609-1 and with the technical specifications for warehouses for Chinese medicinal materials in the country of origin, so as to ensure product quality and the stability of active constituents. Materials shall be stored in batches, with reasonable control of temperature and humidity and with measures for mold prevention, insect prevention, and pest control. Warehousing operations and warehouse management shall comply with the warehouse management specifications and warehousing operation specifications for Chinese medicinal materials in the country of origin.

9.4 Transportation

The transportation of genuine medicinal materials shall comply with the requirements for transportation conditions of medicinal materials specified in ISO 19609-1. After harvesting, the materials should be transported to the processing site in a timely manner, and loading containers and transport vehicles should be cleaned promptly. Transportation and temporary storage measures shall ensure maintenance of the quality of Chinese medicinal materials, prevent new contamination and the inclusion of foreign matter, and strictly prevent exposure to rain or soaking in water.

10 Document management and product traceability

10.1 Document management

The production organization shall possess technical procedures related to the production, harvesting, and processing of genuine medicinal materials, as well as

relevant supporting documents, such as documents relating to the production base (e.g., land ownership certificates or land lease agreements, cooperation agreements), relevant production and processing permits, and inspection reports. Inspection reports shall be retained for not less than three years after product sale.

10.2 Product traceability

In accordance with the traceability requirements of the ISO 9001 quality management system, the production organization shall establish a traceability system and a traceable batch-numbering system covering the entire process, including germplasm source, production, processing, packaging, transportation, and storage, so as to realize bidirectional traceability from raw materials to finished products and from finished products back to raw materials.

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