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Traditional Chinese medicine — Inner pack of decoction pieces

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Foreword

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This document was prepared prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Packing material used for the inner pack of decoction pieces should meet basic quality criteria, because the inner packaging comes into direct contact with the decoction pieces. At present, there are no internationally recognized standards that define the specifications for inner packaging. Therefore, the inner packaging is often not standardized, not in compliance with hygienic requirements, not suitable for the packaging of medicines and not applicable to the nature of decoction pieces. Hence, the inner pack should be standardized to ensure the quality, safety and efficacy of decoction pieces.

In view of the current situation where there is often no inner pack of decoction pieces or the inner pack is not in compliance with relevant requirements, this document promotes the harmonisation of packaging for decoction pieces, leading to reduced trade barriers. This document, along with ISO 18668-1, ISO 18668-2 and ISO 20333, can promote the process of standardization, informatization and modernization of Chinese medicines.

Traditional Chinese medicine — Inner pack of decoction pieces

1 Scope

This document specifies requirements for the inner pack of decoction pieces of Chinese medicines, including packaging materials, physical properties, specifications and labels.

This document is applicable to the manufacturing, inspection, operation, circulation, use, supervision and management of inner pack of decoction pieces.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO 15378, *Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP)*

ISO 18668-1:2016, *Traditional Chinese medicine — Coding system for Chinese medicines — Part 1: Coding rules for Chinese medicines*

ISO 18668-2, *Traditional Chinese medicine — Coding system for Chinese medicines — Part 2: Codes for decoction pieces*

ISO 20333, *Traditional Chinese medicine — Coding rules for Chinese medicines in supply chain management*

ISO 21371, *Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use*

ISO 22217, *Traditional Chinese medicine —Storage requirements for raw materials and decoction pieces*

ISO 23963-1, *Traditional Chinese medicine — Requirements for process traceability systems in Chinese materia medica and decoction pieces — Part 1: Components*

ISO 23963-2, *Traditional Chinese medicine — Requirements for process traceability system of Chinese materia medica and decoction pieces — Part 2: Electronic labelling*

ASTM D3981, *Standard specification for polyethylene films made from medium-density polyethylene for general use and packaging applications*

ASTM D4635, *Standard specification for plastic films made from low-density polyethylene and linear low-density polyethylene for general use and packaging applications*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
inner pack
package in direct contact with *decoction pieces* (3.2)

3.2
decoction piece
prescription medicinal processed from Chinese Materia Medica in accordance with traditional Chinese medicine and processing methods for Chinese medicines, which can be directly used in clinical practice or the production of prepared medicines

[SOURCE: ISO 18668-1:2016, 3.3, modified — "under guidance" replaced by "in accordance with". Note 1 to entry has been merged into the definition.]

3.3
colour code
different colours used on the package or label of *decoction pieces* (3.2) for indicating different specifications, including *colour card* (3.4) number, RGB and HEX/HTML

3.4
colour card
specific colour definitions are provided by different companies and are used for colour communication systems in various areas, including printing, textile, plastics, drawing and digital technology

3.5
inner pack materials
materials which are used to manufacture the packaging bags which are in direct contact with the *decoction pieces* (3.2)

4 Physical property requirements for inner pack of decoction pieces

4.1 The physical properties shall be in accordance with ISO 15378, ASTM D3981 and ASTM D4635 and. Bags for the inner pack of decoction pieces shall be sealed air tight and the surface shall be clean and without any damage, aging or foreign matter attached, delamination or other abnormalities.

4.2 Visual inspection shall be under natural light, the surface of packaging should be smooth without pleats.

4.3 For continuous inner packaging, the connection part between two adjacent packages should be transparent and its length shall be ≥20 mm.

4.4 For high-cost decoction pieces, effective measures such as double packaging shall be taken to avoid losses and contamination resulting from damaged packaging in the process of storage and transportation due to loading and unloading collision.

High-cost decoction pieces may include *Ophiocordyceps sinensis* also commonly known as *Cordyceps sinensis*, *Panacis ginseng*, *Gastrodia elata* and other similar decoction pieces.

4.5 Decoction pieces for toxic, anesthetic and psychotropic shall be double packaged and marked notably with a corresponding warning sign on the inner pack.

Decoction pieces for toxic, anesthetic and psychotropic uses may include realgar, *Datura stramonium* flower, *Aconitum brachypodum* root and other similar ones.

5 Requirements for inner pack materials of decoction pieces

5.1 Inner pack materials shall be purchased from qualified manufacturing enterprises, which obtained a licence to produce packaging material for food and medical use. Toxic materials with "chlorine" and recycled toxic materials shall be prohibited. It is recommended to use packaging products that are breathable and non-toxic, such as plant fibres, or polypropylene materials with a stronger chemical structure, which can be degraded in a short time without polluting the environment, and which can be recycled.

EXAMPLE Packaging material manufacturers which fulfill the BRCGS packaging materials standard are qualified to deliver packaging material for the inner packaging of decoction pieces.

5.2 Inner pack materials and containers shall be selected in accordance with the properties of decoction pieces, which shall not have chemical reaction with the content decoction pieces and shall not affect the quality of the decoction pieces.

5.3 Inner pack materials shall be non-toxic, sterile, clean, dry, without contamination and transparent or partially transparent, to keep decoction pieces visible from outside. The reuse of packaging material for packaging and the use of toxic materials is prohibited. In addition, inner pack materials shall possess certain characteristics of permeability, moisture-resistance, pressure-resistance and environmental friendliness, and should be recyclable or degradable.

5.4 Inner pack materials of decoction pieces shall be disposable.

5.5 Types of inner pack materials which should be used, and the relevant scope of their applications are shown in Table 1.

Table 1 — Types of inner pack materials

Scope	Type	Subtype	Material
Suitable for decoction pieces which do not easily become mouldy or damaged by worms	Polyethylene plastic film	—	Plastic
Suitable for decoction pieces susceptible to mould and worm, including decoction pieces with essential oils, high-cost decoction pieces and toxic decoction pieces	Polyethylene blown film for packaging applications	Paperboard composite film	Paper and plastic
		Fibre composite film	Fibre and plastic
		Multi-layer composite film	Plastic and plastic
		Aluminium foil composite film	Aluminum and plastic
Suitable for temporary packaging not covered by Annex A	Paperboard film	Paperboard film	Paper
		Wax-paperboard film	Wax and paper
Suitable for decoction pieces with essential oils	Containers	Metal containers	Metal
		Glas container	Glas
NOTE See ASTM D3981 and ASTM D4635.			

6 Setting of packing dose specifications

6.1 Setting principles

Set the minimum number of specifications to the maximum extent possible to meet the needs of the clinician's prescription.

6.2 Specification requirements

6.2.1 There are 15 inner pack weight specifications for decoction pieces: 1 g, 3 g, 5 g, 6 g, 9 g, 10 g, 12 g, 15 g, 30 g, 50 g, 75 g, 250 g, 500 g, 1 000 g and >1 000 g.

6.2.2 Deviation requirements: deviation of packaging amount of inner pack decoction pieces shall be consistent with the requirements of Table 2.

Test method of packing weight variation for the specifications of 1 g to 30 g: taking 10 test packages and weighing the weight of the content of every package respectively (the weight that is weighed shall be with an accuracy of 1 % of the weight taken) and then comparing the packing weight of each package to the marked packing weight. No more than two packages can exceed the permitted packing weight variation and none of them can surpass twice the permitted variation.

Test method of packing weight variation for the specifications of ≥ 250 g: taking three test packages and weighing them respectively (the weight that is weighed shall be with an accuracy of 1 % of the weight taken) and calculating the packing weight of each package and the average packing weight both of which shall be in accordance with relevant requirements in Table 2. If one of them does not satisfy the requirement, then another three test samples will be checked and all the three of them should conform to the requirements.

Table 2 — Requirements on packing weight deviation of decoction pieces with inner pack

Item number	Marked weight or packing weight	Permitted deviation from the marked number
1	1 g	±10 %
2	3 g and 5 g	±6 %
3	6 g, 9 g and 10 g	±5 %
4	12 g, 15 g and 30 g	±4 %
5	50 g and 75 g	±3,5 %
6	250 g, 500 g, 100 g and >1 000 g	±3 %

6.3 Other requirements

For any decoction piece whose dosage unit is not considered in terms of weight, such as centipede (one), there should not be inner pack weight specifications. Such decoction pieces should be processed as per the dosage stated in the prescription.

7 Requirements for labels

7.1 A label should be printed on or marked on the inner pack of decoction pieces and shall follow the requirements of ISO 11615 and ISO 21371.

7.2 The letters or characters on the label should be clear and easy to recognize. The expression should be scientific, standardized and accurate and the marking should be clear and visible. There should be no faded lettering and no loosely attached labels. Any addition or modification should not be made by means of pasting, cutting or altering.

7.3 National or regional regulations can apply to the labels of toxic, psychotropic and narcotic decoction pieces.

7.4 For decoction pieces with special requirements on storage, the requirements should be marked on the notable place of the label.