
**Traditional Chinese medicine — Inner
pack of decoction pieces**

Médecine traditionnelle chinoise — Sachet interne des décoctions

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Contents

	Page
Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Physical property requirements for inner pack of decoction pieces.....	2
5 Requirements for inner pack materials of decoction pieces.....	3
6 Setting of packing dose specifications.....	3
6.1 Setting principles.....	3
6.2 Specification requirements.....	4
6.3 Other requirements.....	4
7 Requirements for labels.....	4
8 Requirements for quick response (QR) codes.....	5
8.1 QR code area.....	5
8.2 QR code scanning results.....	5
9 Requirements for colour codes.....	6
Annex A (informative) Specifications and corresponding colour codes for inner pack of decoction pieces.....	7
Bibliography.....	8

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was 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.

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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. 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*, *Panaxis 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	Aluminium 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
		Glass container	Glass
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	$\pm 3,5$ %
6	250 g, 500 g, 1 000 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.

7.5 No words, audio/visual or other unapproved materials should be inserted into the decoction pieces package to introduce or publicize the product or the enterprise.

7.6 The label of decoction pieces shall at least contain the following information:

- a) trademark;
- b) name (in accordance with standardized names listed in ISO 18668-2);
- c) Latin binomial name and part;
- d) place of production;
- e) preparation method;
- f) packing weight;
- g) barcode (including QR code) (in accordance with ISO 18668-1, ISO 20333, ISO 23963-1 and ISO 23963-2);
- h) product batch number;
- i) date of production;
- j) expiry date (if necessary);
- k) storage condition;
- l) usage warnings;
EXAMPLE Forbidden for pregnant and lactating women.
- m) manufacturing enterprise;
- n) the quality standard implemented.

8 Requirements for quick response (QR) codes

8.1 QR code area

For fast recognition, the QR code area should be bigger than one sixteenth of the area of the inner pack material. The QR code should be attached to the inner pack material with adhesive stickers and labels or be directly printed on the inner pack material.

8.2 QR code scanning results

QR code scanning results shall follow ISO 23963-1 and ISO 23963-2 and at least include the following information:

- a) enterprise name;
- b) product name;
- c) product bar code;
- d) product category;
- e) codes for decoction pieces based on ISO 18668-1 and ISO 18668-2;
- f) brand;
- g) specification/type;

- h) place of production;
- i) preparation method
- j) expiry date (if necessary);
- k) storage condition
- l) storage methods based on ISO 22217;
- m) net content;
- n) executive standards (relevant standards);
- o) description of products (effect);
- p) enterprise website;
- q) manufacture factory;
- r) production address;
- s) period of validity for records.

9 Requirements for colour codes

9.1 Colour code application principles: The application of colour codes should follow the principle of markedness and obvious chromatic aberration. Different varieties of the same specification should use the same colour. Specifications of inner pack of decoction pieces and their corresponding colour code are presented in [Annex A](#).

9.2 The colour code shall be attached to the packing bag or label and marked on the central area of the inner pack material in the form of a colour stripe. The area of the colour strip should be bigger than one fourth of the area of the inner pack material.

9.3 Colour codes adopt the following printing methods:

- a) Print different colours directly on the inner pack. This method is applicable to inner pack that uses colour stripe printing labels and directly prints dedicated labels on transparent plastic bags.
- b) Use self-adhesive papers with several different underpaintings to print labels. Each colour represents a specification. This method is applicable to inner packs with labels attached, such as fully-transparent plastic bags.