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Traditional Chinese medicine — Herbal decoction apparatus

Médecine traditionnelle chinoise — Appareil décoction herbe-médicinale

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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 documents 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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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 249, *Traditional Chinese medicine*.

Introduction

This International Standard has been developed in response to worldwide demand for herbal decoction apparatus traded internationally. There is a wide variety of herbal decoction apparatus currently available commercially, but there are no standards guiding their manufacture. Increased use of decoctions as a means of administering herbal medicine, as well as growing patients' expectations and concerns regarding safety and quality, have given rise to the need to improve the safety and quality of herbal decoction apparatus through implementation of an International Standard.

There are two main types of herbal decoction apparatus in common use. According to the structure of herbal decoction apparatus, it can be divided into hermetic decoction apparatus and non-hermetic decoction apparatus

The primary aim of this International Standard is to ensure the safety and quality of both non-hermetic decoction apparatus and hermetic decoction apparatus.

Traditional Chinese medicine — Herbal decoction apparatus

1 Scope

This International Standard specifies the general requirements of herbal decoction apparatus with design pressures less than 0,1MPa. It includes both hermetic and non-hermetic decoction apparatus.

It is applicable to the herbal decoction apparatus for individual herbal formula prescriptions and for commercial use as well as private use. It also applies to the decocting part of the integrated apparatus of decoction and package.

2 Normative references

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

ISO/IEC Guide 37:2012, *Instructions for use of products by consumers*

ISO 780, *Packaging – Distribution packaging — Graphical symbols for handling and storage of packages*

ISO 16528-1:2007, *Boilers and pressure vessels — Part 1: Performance requirements*

ISO 16528-2:2007, *Boilers and pressure vessels — Part 2: Procedures for fulfilling the requirements of ISO 16528-1*

ISO 21469:2006, *Safety of machinery — Lubricants with incidental product contact — Hygiene requirements*

IEC 60204-1:2009, *Safety of machinery — Electrical equipment of machines — Part1: General requirements*

3 Terms and definitions

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

3.1
herbal decoction apparatus
device that produces the herbal liquid by extracting medicinal herb pieces with water and heat

3.2
hermetic decoction apparatus
container that is hermetic during decoction with the decoction pressure higher than the atmospheric pressure

3.3
non-hermetic decoction apparatus
container that is non-hermetic and open to the atmosphere with decoction pressure equal to atmospheric pressure

4 Requirements

4.1 Material

4.1.1 Any material that is in direct contact with the decoction shall be non-toxic, corrosion resistant, non-shedding, high temperature resistant, and shall not cause chemical reactions, absorption with the decoction, or release of substances. It shall be in accordance with the corresponding hygienic standard.

4.1.2 The lubricant shall be in accordance with the rules given in ISO 21469:2006, Clause 5.

4.2 Surface quality

4.2.1 The outside surface of the decoction apparatus shall be neat and easy to clean. The surface coating after the anti-corrosion treatment of the parts shall be neat, smooth, and non-shedding.

4.2.2 The surface roughness of the metal parts that are in contact with the decoction shall be less than 0,8 μm.

4.2.3 The surface of a non-metal decoction container that is contact with the decoction as well as of the sealing elements shall be bright and clean, smooth and free of bubbles.

4.2.4 The material name and flow direction in the pipeline shall be marked where the external pipelines connect.

4.3 Performance

4.3.1 The performance of the hermetic container of the herbal decoction apparatus shall be in accordance with the rules given in ISO 16528-1:2007, 7.4 and 7.5 and ISO 16528-2:2007, Clause 5.

4.3.2 The pipeline system, easy to clean and dismantle as well as with flexible valves switch, shall have no blind pipe. The residues shall be less than 20 ml.

4.3.3 The minimum diameter for the pipe from decoction container to decoction outlet shall not be less than 15 mm.

4.3.4 The seal of the lubricating device of the decoction apparatus shall be dependable with no leakage.

4.3.5 The decocting time can be set with the timing error values no greater than 1 %.

4.3.6 The decocting temperature of the herbal decoction apparatus can be free set, automatically controlled and displayed with the measuring error values less than ± 1°C.

4.4 Electrical safety

4.4.1 The continuity of the protective grounding circuit of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 8.2.3.

4.4.2 The insulation resistance of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 18.3.

4.4.3 The voltage of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 18.4.

4.4.4 The push-buttons of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 10.2.

4.4.5 The indicator lights and displays of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 10.3.

4.4.6 The wiring of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, Clause 13.

4.4.7 The marking, warning signs and reference designations shall be in accordance with the rules in IEC 60204-1:2009, Clause 16.

4.5 Machinery safety

4.5.1 The hermetic decoction apparatus shall give an alarm and stop heating automatically when the decocting temperature reaches 120°C.

4.5.2 For the hermetic decoction apparatus, a safety valve shall be located on the top of the decoction container with the set pressure not higher than 1,05 times of the maximum working pressure.

4.5.3 For the hermetic decoction apparatus, the hydraulic testing pressure of the decoction container shall be no less than 1,25 times the design pressure.

4.5.4 For the non-hermetic decoction apparatus, a full water test shall be performed.

4.5.5 A warning sign to indicate the presence of a hot surface, as specified in ISO 7010:2011[1)], Table 2, W017, shall be put on the outside surface of the herbal decoction apparatus. See Figure 1.

Figure 1 — ISO 7010-W017: Warning; Hot surface

1) This sign is available at https://www.iso.org/obp/ui/#iso:grs:7010:2:W017.

5 Test methods

5.1 Material test

5.1.1 Check the certificate of conformity of the material. When there is no certificate, the material shall be tested in accordance with the testing methods given in the corresponding material standard.

5.1.2 Check the certificate of conformity of the lubricant.

5.2 Surface quality test

5.2.1 Confirm that the outside surface quality meets the requirements in 4.2.1 with the naked eye.

5.2.2 Test with the surface roughness measuring instrument to control that the surface roughness of the metal parts that are in contact with the decoction are less than 0,8 µm (4.2.2).

5.2.3 Confirm that the surface of the non-metal parts that are in contact with the decoction meets the requirements in 4.2.3.

5.2.4 Confirm that the marking of the externally connected pipelines meets the requirements of 4.2.4 with the naked eye.

5.3 Performance test

5.3.1 Hermetic container test

The hermetic container test shall be in accordance with the rules given in ISO 16528-1:2007, 7.4 and 7.5 and ISO 16528-2:2007, Clause 5.

5.3.2 Pipeline system and valve test

Check the pipeline installation and the easy dismounting conditions. Place the herbal decoction apparatus on level ground and connect it to one end of the pipeline of the packaging component. Place the other end of the pipeline lower than the decoction outlet.

Add a nominal capacity of water to the decoction container, then perform the valve switch test. Open the valve to let the water flow until no more water comes out. Place a bowl at the outlet and then incline the herbal decoction apparatus more than 10 degrees towards the outlet.

Measure the water volume in the bowl with a 50 ml measuring cup and compare this value to the specified value.

5.3.3 Pipeline diameter test

Measure the minimum bore diameter in the pipeline.

5.3.4 Loading test

Add 50 % of nominal capacity of drinking water to the decoction container. With the decocting temperature in the hermetic condition set at the maximum working temperature, and the decocting time set at 40 min, start the apparatus. Conduct the loading test in accordance with 5.3.6, 5.3.7, 5.5.1 and 5.5.2.

5.3.5 Leakage test of lubricating system

After the loading test, clean the sealing part with clean white cotton cloth and check the leakage condition of the lubricating system.

5.3.6 Decocting timing error test

Set the decocting time on the machine to 600 s. Using a stopwatch, simultaneously measure the decocting time elapsed. Calculate the decocting timing error according to Formula (1)

$$\partial = \frac{|600 - t|}{600} \times 100\ \% \tag{1}$$

where

∂ is the percentage of decocting time;

600 is the decocting time set on the machine, expressed in seconds (s);

t is the decocting time elapsed as measured by the stopwatch, expressed in seconds (s).

5.3.7 Working temperature test

5.3.7.1 In the loading test, when the boiling lasts for 1 min in the non-hermetic decoction apparatus, check the margin of error values between the display temperature of the herbal decoction apparatus and 100 °C.

5.3.7.2 For the hermetic herbal decoction apparatus, observe whether the heating stops when the temperature reaches the setting temperature. The setting temperature is defined as the temperature that the operator sets on the machine before decocting. When it reaches the setting temperature, the temperature will not rise anymore.

5.4 Electrical safety test

5.4.1 The continuity testing of the protective grounding circuit of electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 18.2.

5.4.2 The insulation resistance testing of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 18.3.

5.4.3 The voltage test of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 18.4.

5.4.4 The push-buttons of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 10.2.

5.4.5 The indicator lights and displays of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 10.3.

5.4.6 The wiring of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, Clause 13.

5.4.7 The marking, warning signs and reference designations shall be in accordance with the rules in IEC 60204-1:2009, Clause 16.

5.5 Machinery safety test

5.5.1 In the loading test for the hermetic herbal decoction apparatus, observe whether or not an alarm goes off and if the apparatus automatically stops heating when the decocting temperature reaches 120°C.

5.5.2 Heat the decoction container at maximum power, and record the indicator value when the safety valve opens.

5.5.3 Non-destructive examination is fulfilled by hydraulic testing. Perform the hydraulic testing of the hermetic decoction container in accordance with ISO 16528-1:2007, 7.4 and 7.5 and ISO 16528-2:2007, Clause 5.

5.5.4 Visual examination is fulfilled by a full water test. For the non-hermetic decoction container, fill it up with water and perform the full water test in accordance with the rules given in ISO 16528-1:2007, 7.4 and 7.5 and ISO 16528-2:2007, Clause 5.

5.5.5 Check that the warning sign (4.5.5), indicating a hot surface, is present on the outside surface of the machine.

6 Inspection rules

6.1 Delivery inspection

The product is able to be delivered after each apparatus is tested, one by one, in accordance with all the requirements of this International Standard by the quality inspector of the factory. The inspected product shall be delivered accompanied by a product qualification certificate. The apparatus should be repaired and a re-test conducted if any non-conformities are found during the inspection. The product shall be considered as disqualified if there is still a non-conformity after the re-test.

6.2 Pattern inspection

6.2.1 Pattern inspection conditions

The pattern inspection shall be given under one of the following conditions:

a) when testing a new model or approval of production of a new product;

b) when significant changes in structure, technology or material may affect the performance of products;

c) when recommencing production after stopping production of products for over one year;

d) when there is a significant difference between the results of the delivery test (6.1) and the last pattern inspection;

e) every two years while the apparatus is in continuous production.

6.2.2 Pattern inspection items

The pattern inspection shall conform to all requirements of this International Standard. Items for which the test conditions are unavailable at the manufacturer's site are allowed to be tested on the user site.

6.2.3 Sampling

10 % (no less than 3 products) of the qualified products of the delivery test shall be selected randomly for samples. Select one of the samples for the pattern inspection.

6.2.4 Conformity test

Where the test results do not conform with the requirements given in 4.4.1 to 4.4.3 and in 4.5.1 to 4.5.4, the pattern inspection can be considered as unsatisfactory. If the sample test (of the selected samples in 6.2.3) results in a non-conformity, the test will be taken again for the samples selected. If the pattern inspection is still considered as unsatisfactory, it is demonstrated to be a non-conformity.

7 Labels, instructions for use, and storage

7.1 Labels

7.1.1 Product name-plates shall be put on a distinctive part of the product and include the following contents

a) product model and name;

b) the primary specification: the volume of the decoction container;

c) the name of manufacturer;

d) the production date and manufacturing identification number;

e) product executive standard number.

7.1.2 Packaging-pictorial marking for handling of goods shall be in accordance with ISO 780.

7.2 Instructions for use

Instructions for use shall be in accordance with ISO/IEC Guide 37:2012.

7.3 Storage

After packaging, the product shall be kept in a dry, ventilated, and non-corrosive room or a sheltered place instead of in the open air.

Bibliography

[1] ISO 7010:2011, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

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