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

Médecine traditionnelle chinoise — Dosage des métaux lourds dans les herbes médicinales utilisées dans la médecine traditionnelle chinoise

Reference number
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Foreword

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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

Heavy metals are natural constituents of the environment, and are commonly detected in air, water and soil. However, technical and industrial processes may release heavy metals into the environment, and they have gained attention as contaminants. At present, there is no uniformly accepted International Standard which defines maximum limits for heavy metals in materials used in Traditional Chinese Medicine (TCM), resulting in disputes about what levels should be considered acceptable in TCM materials.

ISO 18664 was developed in response to worldwide demand for harmonization of the determination of heavy metals in herbal medicines used in TCM. The International Standard is applicable to Traditional Medicine systems derived from ancient Chinese medicine.

For reference, the maximum limits of heavy metals in natural materials of TCM have been provided in Annex A.

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

1 Scope

This International Standard specifies determination methods of lead (Pb), arsenic (As), cadmium (Cd) and mercury (Hg) in herbal medicines used in Traditional Chinese Medicine (TCM). It is applicable to natural materials of TCM that are sold and used as food supplements, functional foods or natural medicines in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from plants or animals. It is not applicable to mineral drugs used in TCM.

This International Standard is not intended to set maximum limits (ML) for individual nations; rather, it is intended to give a reference for standardized testing method and risk assessment.

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 6561-2:2005, *Fruits, vegetables and derived products — Determination of cadmium content — Part 2: Method using flame atomic absorption spectrometry*

ISO 11212-1:1997, *Starch and derived products — Heavy metals content — Part 1: Determination of arsenic content by atomic absorption spectrometry*

ISO 11212-2:1997, *Starch and derived products — Heavy metals content — Part 2: Determination of mercury content by atomic absorption spectrometry*

ISO 11212-3:1997, *Starch and derived products — Heavy metals content — Part 3: Determination of lead content by atomic absorption spectrometry with electrothermal atomization*

ISO 11212-4:1997, *Starch and derived products — Heavy metals content — Part 4: Determination of cadmium content by atomic absorption spectrometry with electrothermal atomization*

ISO 11885:2007, *Water quality — Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES)*

ISO 17239:2004, *Fruits, vegetables and derived products — Determination of arsenic content — Method using hydride generation atomic absorption spectrometry*

ISO 17294-1:2004, *Water quality — Application of inductively coupled plasma mass spectrometry (ICP-MS) — Part 1: General guidelines*

ISO 17294-2:2003, *Water quality — Application of inductively coupled plasma mass spectrometry (ICP-MS) — Part 2: Determination of 62 elements*

ISO/TS 21033:2011, *Animal and vegetable fats and oils — Determination of trace elements by inductively coupled plasma optical emission spectroscopy (ICP-OES)*

ISO 27085:2009, *Animal feeding stuffs — Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum, arsenic, lead and cadmium by ICP-AES*

3 Terms and definitions

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

3.1
arsenic content
quantity of arsenic determined in accordance with the conditions specified in this method and expressed as arsenic (As), in micrograms per kilogram of the product as received

[SOURCE: ISO 11212-1:1997, 2.1]

3.2
mercury content
quantity of mercury determined in accordance with the conditions specified in this method and expressed as mercury (Hg), in micrograms per kilogram of the product as received

[SOURCE: ISO 11212-2:1997, 2.1]

3.3
lead content
quantity of lead determined in accordance with the conditions specified in this method and expressed as lead (Pb), in micrograms per kilogram of the product as received

[SOURCE: ISO 11212-3:1997, 2.1]

3.4
cadmium content
quantity of cadmium determined in accordance with the conditions specified in this method and expressed as cadmium (Cd), in micrograms per kilogram of the product as received

[SOURCE: ISO 11212-4:1997, 2.1]

4 Analytical methods

4.1 Instrumental methods

4.1.1 Atomic Absorption Spectrometry (AAS)

AAS methods can be used for the individual determination of lead, mercury, arsenic and cadmium in natural materials used in TCM. The detailed information is specified in the following documents.

ISO 6561-2:2005, *Fruits, vegetables and derived products — Determination of cadmium content — Part 2: Method using flame atomic absorption spectrometry*

ISO 11212-1:1997, *Starch and derived products — Heavy metals content — Part 1: Determination of arsenic content by atomic absorption spectrometry*

ISO 11212-2:1997, *Starch and derived products — Heavy metals content — Part 2: Determination of mercury content by atomic absorption spectrometry*

ISO 11212-3:1997, *Starch and derived products — Heavy metals content — Part 3: Determination of lead content by atomic absorption spectrometry with electrothermal atomization*

ISO 11212-4:1997, *Starch and derived products — Heavy metals content — Part 4: Determination of cadmium content by atomic absorption spectrometry with electrothermal atomization*

ISO 17239:2004, *Fruits, vegetables and derived products — Determination of arsenic content — Method using hydride generation atomic absorption spectrometry*

4.1.2 Inductively-Coupled Plasma-Atomic Emission Spectrometry (ICP-AES)

ICP-AES methods can be used for the simultaneous determination of lead, mercury, arsenic and cadmium in natural materials used in TCM. The detailed information is specified in the following documents.

ISO 11885:2007, *Water quality — Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES)*

ISO/TS 21033:2011, *Animal and vegetable fats and oils — Determination of trace elements by inductively coupled plasma optical emission spectroscopy (ICP-OES) — First Edition*

ISO 27085:2009, *Animal feeding stuffs-Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum, arsenic, lead and cadmium by ICP-AES — First Edition*

4.1.3 Inductively-Coupled Plasma Mass Spectrometry (ICP-MS)

ICP-MS methods can be used for the simultaneous determination of lead, mercury, arsenic and cadmium in natural materials used in TCM. The detailed information is specified in the following documents.

ISO 17294-1:2004, *Water quality — Application of inductively coupled plasma mass spectrometry (ICP-MS) — Part 1: General guidelines*

ISO 17294-2:2003, *Water quality — Application of inductively coupled plasma mass spectrometry (ICP-MS) — Part 2: Determination of 62 elements*

4.2 Comparison of instrumental methods

All of these instrumental methods have advantages and disadvantages. Table 1 below provides a tabular overview, including detection limits, sample throughout, linear dynamic range, interferences, precision, and ease of use, applicability, unattended use, method development, initial costs, operating costs, and cost per sample.

Table 1 — Comparison of various instrumental techniques

	FAAS	GFAAS	ICP-AES	ICP-MS
Detection limit (μg/L)	Very good for some elements Arsenic 150 Cadmium 0,8 Lead 15 Mercury 300	Excellent for most elements Arsenic 1 Cadmium 0,002 Lead 0,5 Mercury 0,6	Very good for some elements Arsenic 20 Cadmium 0,1 Lead 1 Mercury 1	Excellent for most elements Arsenic < 0,05 Cadmium < 0,05 Lead < 0,05 Mercury < 0,05
Analytical capability	Single element	Single element	Multi-element	Multi-element
Linear dynamic range	10^3	10^2	10^5	10^5
Precision	0,1 % to 1 %	1 % to 5 %	0,3 % to 2 %	1 % to 3 %
Interferences spectral	Few	Very few	Common	Few
Interferences chemical	Many	Many	Very few	Some
NOTE Comparison of various instrumental techniques is selected from The American Herbal Products Association (AHPA), Heavy Metals: Analysis and Limits in Herbal Dietary Supplements. AHPA, US, 2009.				