
**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*



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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

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*