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Traditional Chinese medicine — Determination of aristolochic acids in natural products by high-performance liquid chromatography (HPLC)

Médecine traditionnelle chinoise — Dosage des acides aristolochiques dans les produits naturels par chromatographie liquide haute performance (CLHP)

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Foreword

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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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

Aristolochic acids, a class of chemical compounds with renal toxicity, carcinogenic and mutagenic toxicity, are widely distributed in over 350 species of plant from around the world, many of which have been used as natural products to treat gout, arthritis, rheumatism and acute inflammation of the skin; some species from North America have been used to treat snake bites. Clinical practice and research have confirmed that long-term use of natural products containing aristolochic acids can cause chronic renal failure and renal tubules, and natural products containing aristolochic acids have been prohibited and restricted to use in clinics in many counties. Aristolochic acid toxicity is of great concern worldwide.

Safety and efficacy are basic requirements for the use of natural medicines. Although many natural products containing aristolochic acids have been strictly controlled in clinics, some are still used as raw herbal materials or to produce manufactured products such as asarum, Kaempfer dutchmanspipe root, Herba Aristolochiae mollissimae, German birthwort, American snakeroot and Indian Aristolochia tagala. In addition, some prohibited plant medicines are easily confused or misused during manufacturing, which can cause large safety concerns in the application of natural products.

This document is beneficial for effectively supervising and reducing the toxic side effects of natural-medicine-derived products and ensuring their safety and efficacy in clinical use.

The high-performance liquid chromatography (HPLC) method is applied in organizations in such places as Europe, China, the United States of America, Japan and the Republic of Korea for the determination of aristolochic acid I, both qualitatively and quantitatively. The HPLC method is recommended internationally for the qualitative determination of aristolochic acid I in natural products.

Traditional Chinese medicine — Determination of aristolochic acids in natural products by high-performance liquid chromatography (HPLC)

1 Scope

This document specifies a method for using high-performance liquid chromatography (HPLC) to determine the presence of aristolochic acid I in natural products.

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.

World Health Organization, *Quality control methods for herbal materials*. World Health Organization, 2011

3 Terms and definitions

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

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

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

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

3.1
raw herbal material
medicinal part of medicinal plants after *preliminary processing* (3.2)

3.2
preliminary processing
physical technique of converting medicinal part of medicinal plants into *raw herbal material* (3.1)

3.3
extract
preparation containing the active ingredient of a substance from *raw herbal material* (3.1) in concentrated form based on the standardized production process and meeting certain quality standards

4 Abbreviated terms

DAD	diode array detector
HPLC	high-performance liquid chromatography
UV	ultraviolet absorption
LC-MS	liquid chromatography-mass spectrometry