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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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This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

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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.