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Traditional Chinese medicine — General requirements for herbal raw material and materia medica

Médecine traditionnelle chinoise — Exigences générales relatives aux matières premières issues des plantes et à la matière médicale

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Foreword

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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

Chinese herbal medicine, as an important component of traditional Chinese medicine, is widely used in many countries because of its high value to human health and huge market. The annual sales of Chinese herbal medicine are worth more than USD 16 billion and are increasing at a rate of 10 % to 20 % per year, with great future potential. Such great opportunities for trade call for International Standards specifying the requirements for herbal medicines, in order to ensure their quality and safety, and to avoid misuse due to varietal complexity, harmful foreign matter and adverse drug reactions.

There are specific standards for important species, such as ISO 20409 for *Panax notoginseng* root and rhizome. However, it is impractical to develop one-on-one standards for the thousands of species of herbal medicine used in traditional Chinese medicine in the different traditions and regions. It is preferable to have one International Standard of general requirements for herbal medicine, because herbal medicines have many aspects in common.

The purpose of this document is to:

a) provide a standard for the species not covered in the existing International Standards for single species of herbal medicine;

b) provide an outline and reference for International Standards for single species of herbal medicine.

The principles that were followed in preparing this document are as follows:

1) cover all general requirements of herbal medicine recorded by national, regional and organizational pharmacopoeia, such as the *Pharmacopoeia of the People's Republic of China*,[1] the *Japanese Pharmacopoeia*,[2] the *Korean Pharmacopoeia*[3] and the *European Pharmacopoeia*[4];

2) distill the common characteristics of herbal medicine and formulate general requirements;

3) fully consider and respect the testing method and specific requirements on national or regional pharmacopoeias, legislation and standards.

The general requirements do not define general limit values. Annex A provides additional information as it lists the monographs for specific herbs in national and regional pharmacopoeias, including the items that are covered, meaning that limit values can be searched.