



**International
Standard**

ISO 24825

**Traditional Chinese medicine —
General principles for the
establishment of herbal reference
substances**

*Médecine traditionnelle chinoise — Principes généraux pour
l'établissement de substances de référence à base de plantes
médicinales*

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Foreword

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This document was prepared by Technical Committee ISO/TC 249, *Traditional medicine*, SC1 *Traditional Chinese medicine*.

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Introduction

The herbal reference substance serves as a benchmark for resolving disputes related to the quality of herbal medicinal products (HMPs). This document outlines the principles for establishing herbal reference substances, considering the requirements of Chinese, European, Japanese, Korean and United States pharmacopoeia. Additionally, this document incorporates insights from ISO 17034, ISO Guide 30, ISO 33401, ISO 33403 and ISO 33405.

This document seeks to promote confidence among manufacturers, regulators and consumers by providing a common basis for evaluating and verifying the quality of HMPs. It ensures that the herbal reference substances used in quality inspections and dispute resolutions meet recognized standards, enhancing fairness and reliability. This document intends to ensure consistent quality and safe usage of HMPs. The aim of this document is to help enterprises establish comprehensive production and supply chain management systems, enhancing product safety and traceability. Moreover, this document seeks to play a significant role in harmonizing the different requirements to overcome the barriers to international trade, fostering the sustainable growth and positive reputation of the global HMPs market.

This document provides comprehensive guidance for herbal reference substances and encourages ongoing research, innovation and collaboration among stakeholders to iteratively refine the quality control and evaluation of herbal medicines.

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