



**International
Standard**

ISO 24049

**Traditional Chinese medicine —
Aconitum carmichaelii parent
root tuber**

*Médecine traditionnelle chinoise — Tubercule parent d'Aconitum
carmichaelii*

**First edition
2025-10**

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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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 document 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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This document was prepared by Technical Committee ISO/TC 249, *Traditional medicine*, Subcommittee SC 1, *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

Aconitum carmichaelii parent root tuber (*Aconiti Radix*, Chuanwu) is the dried parent root of *Aconitum carmichaelii* Debx in the *Ranunculaceae* family. It is a high-value and an important source of medicinal herb with characteristic analgesic and anti-inflammatory activities. It is first-mentioned in *Shen Nong Ben Cao Jing* and widely used in China, Korea and other countries for a long history.

Modern pharmacological studies show that *Aconitum carmichaelii* parent root tuber has good therapeutic effects on inflammation, pain, tumours, immune diseases and cardiovascular diseases. The chemical composition of *Aconitum carmichaelii* parent root tuber is complex, mainly containing diterpenoid alkaloids, polysaccharide, volatile oil, flavonoids and saponins. At present, aconitine-type diterpenoid alkaloids are the main characteristic compounds and principal pharmacological ingredients of *Aconitum carmichaelii* parent root tuber. Therefore, aconitine, mesaconitine, and hypaconitine are used as the marker compounds of *Aconitum carmichaelii* parent root tuber in Chinese Pharmacopoeia^[2] and Hong Kong Standard for Chinese Medicinal Materials^[9].

It's well known for its clinical benefits, as well as its high toxicity. The toxic components of *Aconitum carmichaelii* parent root tuber are also its active components. The high toxicity risk and narrow therapeutic range limit the medicinal application on a larger scale. Diester alkaloids such as aconitine and hypaconitine have cardiovascular toxicity, nervous-system toxicity and digestive-system toxicity. In recent years, a few phenomena appeared in the market for aconite products: fake and inferior goods flood the market; many products are not processed in accordance with the traditional process, increasing the risk related to drug safety. These not only affect the market environment, but also the safety of clinical medication.

At present, *Aconitum carmichaelii* parent root tuber and related products are restricted in international trade by many countries because of the risk of toxic ingredients. Aconitine poisoning caused by improper use has been reported from time to time. There are various causes of aconite poisoning, including overdoses, inadequate processing, aconitum contamination in other herbs, and dispensing errors. What's more, hidden toxic *Aconitum* alkaloids, such as yunaconitine, crassicauline A and 8-deacetyl-yunaconitine, were detected instead of aconitine, hypaconitine, and mesaconitine in the urine samples of the aconitum poisoning patients in Hong Kong. These hidden toxic *Aconitum* alkaloids have been found in commonly used *Aconitum* herbs, including *Aconitum carmichaelii* parent root tuber. Therefore, these alkaloids also should be included in the quality and safety control standards for *Aconitum* herbs.

However, the standards for *Aconitum carmichaelii* parent root tuber are not yet harmonized at an international level and regulatory authorities in many nations do not adequately differentiate highly toxic forms from less-toxic forms (or even non-toxic forms) of *Aconitum carmichaelii* parent root tuber. Effectively controlling and supervising the quality and safety of this medicinal material and expanding its international market requires more accurate quality control and standardized procedures at every stage.

Therefore, an International Standard is required for the quality control of *Aconitum carmichaelii* parent root tuber and related products to ensure the safe use of these medical materials. The establishment of an International Standard can help improve the safety of *Aconitum carmichaelii* parent root tuber, make the quality of its products stable and controllable, ensure safe and effective application of these medicinal materials in clinical practices, benefit people's health and reduce the occurrence of adverse events.

As national implementation can differ, national standards bodies are invited to modify the values given in [5.5](#), [5.6](#), [5.7](#) and [5.8](#) in their national standards. Examples of national and regional values are given in [Annex B](#).

Traditional Chinese medicine — *Aconitum carmichaelii* parent root tuber

1 Scope

This document specifies minimum requirements and test methods for *Aconitum carmichaelii* parent root tuber.

This document applies to *Aconitum carmichaelii* parent root tuber that is sold and used as natural medicines in international trade, including Chinese materia medica (whole medicinal materials) and decoction pieces derived from this plant.

Processing methods and processed products of *Aconitum carmichaelii* parent root tuber are excluded.

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.

ISO 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

ISO/TS 21310, *Traditional Chinese medicine — Microscopic examination of medicinal herbs*

ISO 21371, *Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use*

ISO 22217, *Traditional Chinese medicine — Storage requirements for raw materials and decoction pieces*

ISO 22258, *Traditional Chinese medicine — Determination of pesticide residues in natural products by gas chromatography*

ISO 23191, *Traditional Chinese medicine — Determination of selected *Aconitum* alkaloids by high-performance liquid chromatography (HPLC)*

ISO 23723:2021, *Traditional Chinese medicine — General requirements for herbal raw material and materia medica*

3 Terms and definitions

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

***Aconitum carmichaelii* parent root tuber**

unprocessed dried parent root tuber of *Aconitum carmichaelii* Debx.