
**Traditional Chinese medicine —
Controlled vocabulary on Japanese
Kampo crude drugs**

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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 documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

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

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Introduction

Kampo medicine is the traditional medicine of Japan. Ancient Chinese medicine was first introduced to Japan around 1 600 years ago, but Kampo medicine has developed independently from ancient Chinese medicine for the past 500 years. In the medication therapy of Kampo medicine, physicians prescribe medicinal products based on Kampo formulae that consist of various crude drugs based on Kampo medicinal theory.

The crude drugs in this document are the natural materials that are used as components of Kampo formulae in Japan. They are defined and regulated by the Japanese Pharmacopoeia and the Japanese official addendum for crude drug standards. The crude drugs used in Japan are often different from those used in China and other countries with respect to origins, part(s) of interest, and processing. In addition, there are large numbers of synonyms and homonyms among names for crude drugs.

This situation could not be ignored during the standardization of contemporary terminology for medicinal products or the latest drug information management. Rather, it is feasible that such a situation could also be considered in international standardization. However, this has yet to be achieved in ISO/TC 249.

Therefore, this document gives the terms of crude drugs used in Japanese Kampo medicine with contemporary methodologies specified in ISO deliverables and conforming to related standards on drug information management to avoid market distortion and health hazards.

Using controlled vocabulary for crude drugs with accurate expressions according to definitions of national pharmacopoeias and related documents published by national Medicines Regulatory Authorities is a fundamental step in ensuring health safety, both in medical care and in trade. The information provided by this document is expected to decrease barriers to trade.

Any formulae or traditional medicines that are not controlled by the Japanese Pharmacopoeia and related official documents published by the Medicinal Regulatory Authorities in Japan are out of the scope of this document.

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1 Scope

This document gives names for crude drugs used in Kampo formulae with concepts (or definitions) that are designated by the names to ensure safety and to facilitate international trade, including source materials and intermediate products/materials. Those names are aligned with the names for both the intermediate products and the medicinal products that are manufactured in accordance with the definitions and/or designs. This document is applicable to crude drugs “as concepts (or definitions)” used in Kampo medicine.

This document excludes the following:

- individual manufactured drug names for medicinal products “as things” derived from crude drugs;
- medicinal materials (Materia Medica) “as things”, or traditional medicines that are not regulated by the Japanese Pharmacopoeia or the related official documents published by the Medicinal Regulatory Agency, the Ministry of Health Labour and Welfare of Japan.

2 Normative references

There are no normative references in this document.

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 <https://www.electropedia.org/>

3.1

natural material

naturally presenting object or substance in the real world, part of which is utilized for a medicinal purpose

Note 1 to entry: It is from plants, animals, or minerals, and usually expressed as a Latin name (scientific name).

3.2

part of interest

medicinal part

part of a *natural material* (3.1) that is utilizable for *crude drug* (3.3)

3.3

crude drug

natural medicine used as a component of a *Kampo formula* (3.6) and defined or authorized in the Japanese Pharmacopoeia^[23] and the Japanese official addendum for crude drug standards^[24]

Note 1 to entry: *Crude drug* (3.3) that was derived from a plant corresponds to HB-SNM (herbal medicament made of single natural material) in Reference [18].

Note 2 to entry: A *crude drug* (3.3) has several medicament forms, including pieces for decoction, cut crude drug, or powdered crude drug in the Japanese Pharmacopoeia.