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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

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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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Traditional Chinese medicine — Controlled vocabulary on Japanese Kampo crude drugs

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 Pharmacopeia[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 Pharmacopeia.

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3.4
origin
definition of *crude drug* (3.3), including the name of the *natural material* (3.1) and the *part of interest* (3.2) for medicinal use

3.5
kampo medicine
traditional medicine that has been developed in Japan

Note 1 to entry: Ancient Chinese medicine was introduced to Japan around 1 600 years ago; since around 500 years ago, Japanese Kampo medicine has developed independently of China.

3.6
kampo formula
combination of *crude drugs* (3.3) defined or authorized by the Medicines Regulatory Agency in Japan

3.7
Latin name of crude drug
Latin name of crude drug defined or authorized in Japanese Pharmacopeia and Japanese official addendum for crude drug standards

Note 1 to entry: The Latin name of crude drug defined in each pharmacopoeia is sometimes different, although its origin has the same scientific name as the *natural material* (3.1) and part of interest (3.2). Usually, it is based on the combination of Latin genus names of the natural material and its part of interest.

Note 2 to entry: The symbol $^{<JP>}$ is added as superscript to the Latin name of crude drugs used in *Kampo medicine* (3.5) in this document to distinguish crude drugs in Kampo medicine from those in the Chinese Materia Medica in Reference [19], 2.1. For example, the Latin name BUPLEURI RADIX$^{<JP>}$ (7.2.29) is defined as the root of *Bupleurum falcatum* Linné (*Umbelliferae*), but the Latin name Bupleuri Radix in Chinese Materia Medica in Reference [19], 3.86, is defined as the root of *Bupleurum chinense* DC. or *Bupleurum scorzonerifolium* Willd. See 5.3.

3.8
English name of crude drug
English name of the crude drug defined or authorized in the Japanese Pharmacopeia and the Japanese official addendum for crude drug standards

Note 1 to entry: Usually, the English name of the crude drug is based on the combination of English genus names of the *natural material* (3.1) and its *part of interest* (3.2).

Note 2 to entry: The symbol $^{<JP>}$ has been added as superscript to the English names of crude drugs used in *Kampo medicin*e (3.5) in this document for the same reason as in. See 5.3.

3.9
Japanese name of crude drug
Japanese name of the crude drug defined or authorized in the Japanese Pharmacopeia and the Japanese official addendum for crude drug standards

Note 1 to entry: The Japanese name is described by a string of Japanese phonetic letters in Katakana (Reference [16], Kana411) and/or the Japanese ideographic letters Kanji (Reference [16], Hani 500).

Note 2 to entry: The symbol $^{<JP>}$ has been added as a superscript to strings of Kanji letters in this document; firstly to distinguish Kanji letters from simplified Chinese characters (簡体字) (Reference [16], Hans 501) or traditional Chinese characters (繁体字) (Reference [16], Hant 502) due to their similar shapes and because most of these letters can be converted to each other. This situation proposes another reason that “convertible strings” of names can define different crude drugs. *Homonym*[6] or *polyseme*[6] can cause health hazards. See 5.3.

3.10
identifier of crude drug
unique code which designates a particular *crude drug* (3.3)

Note 1 to entry: The identifier of crude drug is defined by the substance code for drug management in Japan[26] or by the substance code in Japan standard commodity classification (JSCC)[27].

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