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Traditional Chinese medicine — Controlled vocabulary on Japanese Kampo crude drugs

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Foreword

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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*.

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.

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.

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].

4 Conformance

The medicinal products based on Kampo formulae use crude drugs, whose origins are correctly identified in the Japanese Pharmacopoeia or in the Japanese official addendum for crude drug standards.

In Japan, manufacturers are obligated to express the names of crude drugs of the medicinal product based on Japanese Kampo formulae using Latin, English, or Japanese names defined by the Japanese Pharmacopoeia or the Japanese official addendum for crude drug standards.

See also 6.2.1, 6.2.3, and 7.1.

5 Abbreviated terms and symbols

5.1
JP

Japanese Pharmacopoeia[23]. This abbreviation is used for referencing the source in 7.2.1 to 7.2.130.

NOTE The superscript symbol <JP> (5.3) does not refer to <Japanese Pharmacopoeia>. See from 3.7 to 3.9 and 5.3.

5.2
Non-JP

The Japanese standards for non-Pharmacopoeial crude drugs (non-JP crude drug standards)[24]. This abbreviation is used for referencing the source in 7.2.1 to 7.2.130.

5.3
<JP>

The superscript symbol <JP> is added to a string of letters that expresses the crude drugs in Kampo medicine (3.5) except for those in Japanese Katakana (Reference [16], Kana411) in this document. See 3.7, 3.8 and 3.9.

NOTE 1 The superscript symbol <JP> has three efficacies: 1) it focuses attention on recognizing the meaning; 2) prohibits conversions of the letters; and 3) helps to distinguish between homonyms and polysemes[6].

NOTE 2 Such superscript symbols are very useful in distinguishing the names defined by the Medicines Regulatory Authorities[12][13][14] in each nation or area. The reasons are illustrated in examples below.

NOTE 3 The superscript symbol <JP> is not the abbreviation of <Japanese Pharmacopoeia> but of <Japan>. It means the addenda and related official documents published by the Japanese Medicines Regulatory Authorities including Japanese Pharmacopoeia. See 3.7 to 3.9.

EXAMPLE 1 The meaning (or the designated concept) of 漢字<JP> is not equivalent to that of 汉字 in Chinese, although the letters in the two strings can be converted to each other.

EXAMPLE 2 ANGELICAE RADIX<JP>, Japanese Angelica Root<JP>, and 当帰<JP> are defined as the root of *Angelica acutiloba* Kitagawa or *Angelica acutiloba* Kitagawa var. *sugiyamae* Hikino (*Umbelliferae*), usually after being passed through hot water (7.2.9). That is different from 当归 in Chinese, which is defined as the root of *Angelica sinensis* (Oliv.) Diels in Reference [19], 3.38.

EXAMPLE 3 BUPLEURI RADIX<JP>, Bupleurum Root<JP> and, 柴胡<JP> are defined as the root of *Bupleurum falcatum* Linné (Umbelliferae) (7.2.29). That is different from 柴胡 in Chinese, which is defined as the root of *Bupleurum chinense* DC. or *Bupleurum scorzonerifolium* Willd. In Reference [19], 3.86.

EXAMPLE 4 SINOMENI CAULIS ET RHIZOMA<JP>, Sinomenium Stem and Rhizome<JP>, and 防已<JP> are defined as the climbing stem and rhizome of *Sinomenium acutum* Rehder et Wilson (Menispermaceae), usually cut transversely (7.2.117). This is different from 防己 in Chinese, which is defined as dried root of *Stephania tetrandra* in Reference [19], 3.452.

6 Preparation of terminological entries

6.1 Organization of preparatory work

6.1.1 Target group and subject delimitation

The target group was defined according to References [12] and [18]. The target domain or subjects are specified in the Introduction. Consequently, the constraints or preconditions described in 6.2.1, 6.2.3, and 6.2.4 are applied.

6.1.2 Types of referencing source

JP and Non-JP are developed by the Ministry of Health, Labour, and Welfare, the Medicines Regulatory Agency in Japan, who define the standards for crude drugs from several viewpoints, including pharmacognosy, physiology, and chemistry. Therefore, their types of reference sources come under the following categories as specified in Reference [11], 4.3.5.2:

a) legal documents;

b) standards;

c) documents generally recognized by the scientific community.

6.1.3 Evaluation of reference sources

According to the descriptions in 6.1.2, the referencing sources of this document has been evaluated as follows:

a) the terminological data are the most reliable;

b) the author is the authority on medicine regulation in Japan;

c) the terminological data in the document is widely accepted in Japan and in the world.

6.2 Recording terminological data

6.2.1 Terminological entries

Terminological entries include the following in conformance with international terminology standards:

— Latin name of crude drug;

— English name of crude drug;

— Japanese name of crude drug respectively expressed both in Katakana letters (Kana 411[16]) and in Kanji letters (Hani 500[16]);

— String of Latin letters for expression of Japanese pronunciation;

— Crude drug defined by the scientific name(s) of the natural material(s) and the medicinal part with processing, as in Reference [18], Figure 1;

— Identification of the referencing source;

— Identifier of crude drug surrogated with the substance code for drug management in Japan.

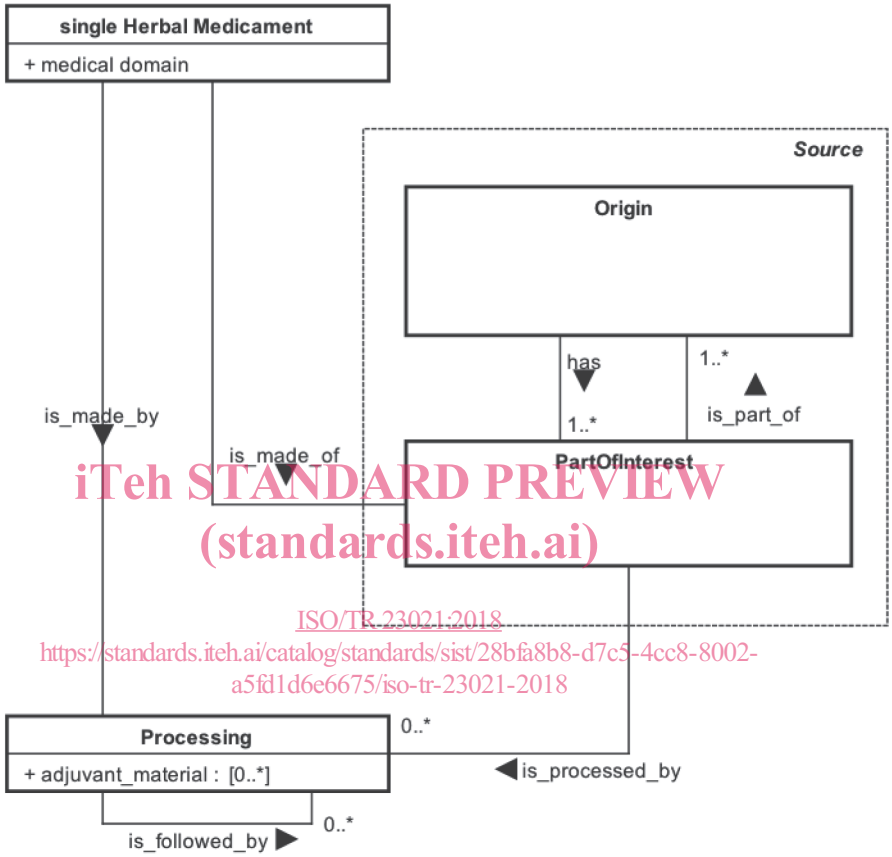
6.2.2 Backbone concepts

The backbone concepts for representation of crude drugs are based on ISO/TS 18062[18]. Its concept diagram is illustrated in Figure 1.

The first three items specified in 6.2.1 respectively correspond to the "name in Latin", "name in English", and "name in Country Language" within "Official Name" in the figure. The three sub-items in the fifth item of 6.2.1 respectively correspond to "Source", "Origin", and "Scientific Name."

Therefore, the data items specified in this doument are very feasible and conform to ISO/TS 18062[18] and IDMP*s*[12][13][14].

There are no vernacular names; in other words, all names defined in 7.2 in this document are controlled vocabulary.



Key

single Herbal Medicament	minimal concepts for representation of regulated design or identification of pharmaceutical products or medicinal products made of a single herbal substance
Origin	characterizing category, which contains the designations of "medicinal plants" as the characterizing concepts that are required in the single Herbal Medicament
PartOfInterest	characterizing category, which contains the designations of "part(s) of interest" as the characterizing concepts that are required in the single Herbal Medicament
Processing	characterizing category which contains the designations of "processing methods" as the characterizing concepts, that are required in the single Herbal Medicament

Figure 1 — Conceptual representation for a single herbal medicament (crude drug)[18]

6.2.3 Administrative information

This document itself does not require any conformity because it is a Technical Report. Japanese jurisdiction uses the following policy.

— The organization responsible for the terminological data of the crude drugs used in Kampo medicine and the Kampo formulae is The Minister of Health, Labour and Welfare of Japan, as the Medicines Regulatory Agency.

— Japanese names of crude drugs are expressed in the Japanese language with Japanese script. The codes are in accordance with ISO 639-1, ISO 3166-1 and ISO 15924.

— The Japanese names of crude drugs with the phonetic letters in Katakana (Kana 411[3]) are the canonical names in the JP and non-JP.

— Identifier for crude drugs are defined in the substance code for drug management in Japan and are regulated by The Minister of Health, Labour, and Welfare of Japan.

The identifier of crude drug is a unique code that designates a certain crude drug as a certain substance. In this sense, this substance code[26] could be used, such as the Substance ID specified in IDMPs. However, at the present time, the Medicines Regulatory Agency in Japan has not declared this to be acceptable.

6.2.4 Physicochemical identification

JP and Non-JP define the standards of crude drugs by several viewpoints, including term-related data, pharmacognosy, and physicochemical characteristics. See Annex A for examples.

Pharmacognosy includes (i) the appearance of the natural material to identify species, and (ii) several identification methods to identify component(s) or constituent(s). Thin-Layer Chromatography (TLC) and High Performance Liquid Chromatography (HPLC) are recognized as relevant methods. (iii) Gene analysis is an optional method for some substances when identification is difficult.

NOTE Microscopic morphology is also a reliable method for source materials. JP usually defines the spot of marker compound in TLC for each crude drug as the minimal requirement in the market. However, in actuality, the manufacturers in Japan make additional efforts by themselves.

Additionally, the JP and Non-JP define the limits of foreign substances, wrong species, wrong medicinal parts, pesticides, heavy metals, soil, and so on.

6.2.5 Systematic order

Systemic order is arranged according to the Latin names of crude drugs.

7 Controlled vocabulary on Japanese Kampo crude drugs

7.1 General

Taking into account 6.2.1 and 6.2.3, the terms defined in 7.2 can be utilized correctly and meaningfully.

Again, the Latin name of crude drug is defined in pharmacopoeias, but is not the scientific name of the natural material. The Japanese name of the crude drug in ideographic expression, i.e. Kanji expression, utilizes the letters in accordance with Hani 500[16]. The Latin name, English name, and Japanese name of crude drugs in Kampo medicine are expressed with the superscript symbol **<JP>**, if needed.

Japanese jurisdiction uses the intention of designating the crude drugs defined in JP and non-JP and their definitions presented in 7.2 based on the designators.

7.2 Term list

7.2.1

Latin name:	ACHYRANTHIS RADIX<JP>
English name:	Achyranthes Root<JP>
Japanese name in Katakana:	ゴシツ
Japanese name in Kanji:	牛膝<JP>
Japanese pronunciation:	Goshitsu
Definition:	The dried root of *Achyranthes fauriei* Leveillé et Vaniot or *Achyranthes bidentata* Blume (*Amaranthaceae*)
Referencing source:	JP
Substance code:	120098

7.2.2

Latin name:	ADEPS SUILLUS<JP>
English name:	Lard<JP>
Japanese name in Katakana:	トンシ
Japanese name in Kanji:	豚脂<JP>
Japanese pronunciation:	Tonshi
Definition:	The fat obtained from *Sus scrofa* Linné var. *domesticus* Gray (*Suidae*)
Referencing source:	JP
Substance code:	001455

7.2.3

Latin name:	AKEBIAE CAULIS<JP>
English name:	Akebia Stem<JP>
Japanese name in Katakana:	モクツウ
Japanese name in Kanji:	木通<JP>
Japanese pronunciation:	Mokutsu
Definition:	The dried climbing stem of *Akebia quinata* Decaisne or *Akebia trifoliata* Koidzumi (*Lardizabalaceae*), usually cut transversely
Referencing source:	JP
Substance code:	120161

7.2.4

Latin name:	ALISMATIS TUBER<JP>
English name:	Alisma Tuber<JP>
Japanese name in Katakana:	タクシャ
Japanese name in Kanji:	沢瀉<JP>
Japanese pronunciation:	Takusha
Definition:	The dried tuber of *Alisma orientale* Juzepczuk (*Alismataceae*), from which periderm has been usually removed
Referencing source:	JP
Substance code:	120125

7.2.5

Latin name: ALPINIAE OFFICINARI RHIZOMA<JP>
English name: Alpinia Officinarum Rhizome<JP>
Japanese name in Katakana: リョウキョウ
Japanese name in Kanji: 良姜<JP>
Japanese pronunciation: Ryokyo
Definition: The dried rhizome of *Alpinia officinarum* Hance (*Zingiberaceae*)
Referencing source: JP
Substance code: 120229

7.2.6

Latin name: AMOMI SEMEN<JP>
English name: Amomum Seed<JP>
Japanese name in Katakana: シュクシャ
Japanese name in Kanji: 縮砂<JP>
Japanese pronunciation: Shukusya
Definition: The dried seed mass of *Amomum xanthioides* Wallich (*Zingiberaceae*)
Referencing source: JP
Substance code: 120114

7.2.7

Latin name: ANEMARRHENAE RHIZOMA<JP>
English name: Anemarrhena Rhizome<JP>
Japanese name in Katakana: チモ
Japanese name in Kanji: 知母<JP>
Japanese pronunciation: Chimo
Definition: The dried rhizome of *Anemarrhena asphodeloides* Bunge (*Liliaceae*)
Referencing source: JP
Substance code: 120127

7.2.8

Latin name: ANGELICAE DAHURICAE RADIX<JP>
English name: Angelica Dahurica Root<JP>
Japanese name in Katakana: ビャクシ
Japanese name in Kanji: 白芷<JP>
Japanese pronunciation: Byakushi
Definition: The dried root of *Angelica dahurica* Bentham et Hooker filius ex Franchet et Savatier (*Umbelliferae*)
Referencing source: JP
Substance code: 002421

7.2.9

Latin name:	ANGELICAE ACUTILOBAE RADIX<JP>
English name:	Japanese Angelica Root<JP>
Japanese name in Katakana:	トウキ
Japanese name in Kanji:	当帰<JP>
Japanese pronunciation:	Toki
Definition:	The dried root of *Angelica acutiloba* Kitagawa or *Angelica acutiloba* Kitagawa var. *sugiyamae* Hikino (*Umbelliferae*), usually after being passed through hot water
Referencing source:	JP
Substance code:	520794

7.2.10

Latin name:	ARALIAE CORDATAE RADIX<JP>
English name:	Aralia Root<JP>
Japanese name in Katakana:	ワキョウカツ
Japanese name in Kanji:	和羌活<JP>
Japanese pronunciation:	Wakyokatsu
Definition:	The dried root of *Aralia cordata* Thunberg (*Araliaceae*)
Referencing source:	Non-JP
Substance code:	120231

7.2.11

Latin name:	ARALIAE CORDATAE RHIZOMA<JP>
English name:	Aralia Rhizome<JP>
Japanese name in Katakana:	ドクカツ
Japanese name in Kanji:	独活<JP>
Japanese pronunciation:	Dokukatsu
Definition:	The dried rhizome of *Aralia cordata* Thunberg (*Araliaceae*)
Referencing source:	JP
Substance code:	120217

7.2.12

Latin name:	ARCTII FRUCTUS<JP>
English name:	Burdock Fruit<JP>
Japanese name in Katakana:	ゴボウシ
Japanese name in Kanji:	牛蒡子<JP>
Japanese pronunciation:	Goboshi
Definition:	The dried fruit of *Arctium lappa* Linné (*Compositae*)
Referencing source:	JP
Substance code:	120194