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Health informatics — Categorial structure for representation of herbal medicaments in terminological systems

Informatique de santé — Structure catégorielle pour la représentation de médicaments à base de plantes dans les systèmes terminologiques

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Foreword

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The committee responsible for this document is ISO/TC 215, *Health informatics.*

Introduction

Medicinal or *pharmaceutical products* (3.11, 3.12) derived from plants have complicated backgrounds and a wide range of uses in traditional and western medicine.

Medicinal plants contain many constituent substances and the content of these substances differ throughout parts of some plants. Medicinal plants may be used individually or in combination with other medicinal plants[32]–[63]. The combination of medicinal plants and the rules and methods used to achieve this combination is conventionally called a "formula." The constituents of formulas are determined by the species of the source materials, which parts of the plants are used, and the quantity of each source material used. The quantity of active substances used directly influences the efficacy and side effects of herbal medicines.

A *medicine regulatory agency* (3.10) controls pharmacopoeias that define the "requisites" for each herbal *pharmaceutical* and/or *medicinal product* and the "name" by which the product is to be referred. It should be noted that a pharmacopoeia does not define a product itself, but rather its "design" under its "common name." In other words, pharmacopoeias define "a set of concepts" with a "common name" and regulate the fundamental characteristics of a certain group of *pharmaceutical* or *medicinal products*.

However, there are many *synonyms*, *homonyms* and *polysemes* used in pharmacopoeias: the same species of source material is often represented by different expressions, and *vice versa*. In addition, a single "common name" often designates different compositions of formulas in different pharmacopoeias[28]–[30], [52]–[63]. Disagreement on the definitions of "sets of concepts" and "common names" of herbal medicines in various *terminological resources* (3.7)[10] have caused confusion in international trade which increases risk of harm to patients and negative impact to scientific research including clinical tests.

This problem should be resolved by standardization, while according respect to each pharmacopoeia and avoiding market distortion. ISO 860[2] has already proposed an approach to this issue in preparing the harmonization of necessary concepts before "term standardization." This approach implicitly requires the prior building of a well-structured backbone, i.e. "a set of concepts" for terms. For this purpose, ISO 1087-1, EN 12264 and ISO 17115 [4] –[7] define the structures of concepts and provide the necessary terms that designate the elements of concept structures. This framework is called "categorial structure."

This document uses a *categorial structure* to represent the concepts required in order to contribute to both international harmonization and supporting the ability to *map* with appropriate *semantic correspondence* between the terms on herbal medicines in various pharmacopoeias. Please refer to ISO 17115:2007, Annex A, as well as ISO 1087-1.

This document provides initial guidance to those developing and implementation systems to represent herbal medicaments. Users should understand that this work has identified several issues, which require further investigation in order to develop a future International Standard:

— need to clarify and describe the relationship of the concepts described in the categorial structure to existing standards including IDMP; where there are differences, ISO 11238 IDMP should be followed;

— definitions used in this document are those used in some cultures, countries and areas of clinical practice (e.g. traditional medicine) which use words differently to that of IDMP (see Annex B);

— these variations may also arise from the focus on terminological and ontological specifications rather than pharmaceutical concepts; there is a recognized need to undertake further work to clarify these definitions and to identify where there is

  — more than one term is used to describe a single thing and agree on synonyms or preferred terms,

  — single term used with different meanings in different contexts, and

- a need to define a term or concept not currently defined or confusing, e.g. active substance, herbal substance, botanical substance, source material and source;

- the relationship between medicinal regulatory agencies and pharmacopoeia;

- the use of the term concept has been used in this document from a terminological perspective not from a pharmaceutical one and this requires clarification.

Health informatics — Categorial structure for representation of herbal medicaments in terminological systems

1 Scope

The document aims to

a) specify the minimal *characterizing generic concepts* in *herbal medicament* (3.2) within *terminological systems* (3.8), that are required for terms used to identify of herbal medicines regulated by *medicine regulatory agencies* (3.10), and

b) facilitate the consistency and interoperability of the *terms* and their designating concepts in *terminological systems*.

In order to achieve these goals, this document specifies the minimal *compositional concept representation* of herbal medicament for use in *terminological systems* (3.8), while expressing *semantic links* and *characterizing categories* for *formal definitions*, with a set of *domain constraints* in the *subject field*[6] [7].

Herbal medicaments (3.2) can be classified into

1) single herbal medicament (SHM), and

2) herbal medicament composed of several kinds of SHM.

NOTE Single herbal medicament is composed of only one herbal medicament. Herbal medicament composed of several kinds of *SHMs* is conventionally called “formula.” This document is not intended to include the mixture of formulae.

The specific intended use of this *compositional concept representation* is to

— provide a well-structured backbone for *terminological systems*,

— clarify the synonymy, homonymy and polysemy across different clinical specialties and terminological resources,

— promote meaningful exchange of information among different terminological systems,

— promote consistency and interoperability or re-use of terms among different terminological systems,

— facilitate the representation of herbal medicines in a manner suitable for computer processing,

— support developers and maintainers of *terminological resources* (3.7) to facilitate conformance,

— support knowledge management on herbal medicines with facilitating analysis of concerned data, and

— support the reduction of confusion in trade and of health hazard in consequence.

The following topics are out of scope for this document:

— any implementation models or database schemas, and manufacturing models;

— any models or frameworks for quality control, and models for chemical and physical characteristics;

— any individual pharmaceutical or medicinal products, and combinations use with modern medicines.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1087-1, ISO 17115, EN 12264 and the following apply.

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

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
herbal substance
botanical substance
source material (context: pharmacy)
source (context: pharmacy)
physical matter of the plant used as medicines, including plant, algae, fungi or lichen, used in whole or in part

Note 1 to entry: In this document, *herbal substance* (3.1) is used in the meaning of *source material*. The ingredients of it are determined by the *part(s) of interest* (3.3) of an origin.

Note 2 to entry: The definitions of "herbal substance" in E.1.3 (herbal substance), E.1.5 (herbal substance, according to the pharmacopoeia), E.1.6 (herbal preparation), E.2.1 (European Directives: Article 30, 31, 32) and E.2.2 (European Pharmacopoeia) in ISO/TS 19844:2015, Annex E[26] are different from the definition in this document. The former definitions should be respected when implementing an IDMP family or referring to European Pharmacopoeia. Where IDMP applies in the jurisdiction, IDMP definitions should be given priority.

3.2
herbal medicament
minimal concepts for representation of regulated design or identification of *pharmaceutical products* (3.12) or *medicinal products* (3.11) made of *herbal substance(s)* (3.1)

Note 1 to entry: This document does not mention any individual *pharmaceutical products* (3.12) or *medicinal products* (3.11). *Herbal medicament* (3.2) designates the "design" or the concepts of herbal *pharmaceuticals* or *medicinal products* at an abstract or design level regulated by *medicine regulatory agencies* (3.10). Pharmacopoeias defined them with their name, therefore, that are also regulated by *medicine regulatory agencies*.

Note 2 to entry: This document does not include the mixture of formulas.

3.3
part of interest
medicinal part
partofinterest
part of the plant that is intended for use as a *herbal substance* (3.1)

EXAMPLE Seed, root, rhizome, stem, bark, leaf, bud, flower, fruit.

3.4
assistant material
adjuvant material
substance added during processing in order to enhance the therapeutic usefulness of pharmaceutical *herbal medicament* (3.2) treatment

Note 1 to entry: "*Adjuvant*" in this context does not mean the adjuvant in modern scientific parlance, rather, is used to support elution of bioactive substrates, enhancing efficacy and reducing toxicity, flavouring and taste masking, or as a filler.

EXAMPLE Rice wine, liquor, vinegar, honey.

3.5
value
<terminological resources> designation of a characterizing concept as an instance of a concept of a characterizing category

Note 1 to entry: This definition can be rewritten: *designation* of an *individual concept* as a member of the *extension* of a *generic concept*, or accurately, a *characterizing generic concept*. This term is not explicitly defined both in either EN 12264 or ISO 17115, but can only be derived speculatively from the relations between terms and definitions contained therein.

EXAMPLE Number, controlled or regulated vocabulary or code, object identifier, regulated description.

Note 2 to entry: *Value domain*, *i.e. characterizing generic concept* or *characterizing category* is defined as the *values* (3.5) shall be allowed to be used in a particular *context* (3.6). Please also refer to *context* (3.6) and Annex A.

3.6
context
related conditions and situations that provide a useful understanding and meaning of a subject

Note 1 to entry: ISO 1087-1 also defines this term as "text which illustrates a *concept* or the use of a *designation*." However, this document adopts the definition in ISO/TR 17119 because of its clear and direct illustration as well as the fact that it is not limited to text.

Note 2 to entry: *Context* (3.6) may contain multiple viewpoints according to its definition because the definition of *value domain* said in its note that the *context* includes a *superordinate concept* and a *semantic link*. Also, *semantic link* means any types of *associative relation* that includes *sequential relation*, *temporal relation*, *causal relation*, *etc*. Please also refer to *value* (3.5) and Annex A.

[SOURCE: ISO/TR 17119:2005, 2.5 — modified]

3.7
terminological resource
<healthcare> controlled set of terms in healthcare

Note 1 to entry: A terminological resource is usually designed and controlled for use with computers for specific healthcare purpose such as data entry, aggregation, retrieval and analysis.

[SOURCE: ISO 17117-1:—, 3.4.1]

3.8
terminological system
<healthcare> structured human and machine-readable representation of healthcare concepts and relationships

Note 1 to entry: Every terminological system shall be at least organized by hierarchical relations.

Note 2 to entry: Every terminological system shall have term representations of healthcare concepts for human-readability.

Note 3 to entry: Terminological system may have associative relations and definitions.

Note 4 to entry: Terminological system is used directly or indirectly to describe health conditions and healthcare activities, and allow their subsequent retrieval for analysis.

[SOURCE: ISO 17117-1:—, 3.4.2]

3.9
medical domain
field of action, thought or influence related to the science or practice of medicine or a sub-specialization of medicine

Note 1 to entry: *Medical domain* (3.9) can be recognized as a facet of *subject field*. It provides one of the factors that compose a *context* (3.6), and affects the *values* (3.5) bound to *semantic links*. See also the examples in 5.1.

Note 2 to entry: Modern medicine is also an *instance of a concept* of *medical domain* (3.9) as a *characterizing category*.

EXAMPLE Modern medicine, Ayurveda, traditional African medicine, traditional Australian medicine (Aboriginal), traditional Canadian medicine, Chinese medicine or traditional Chinese medicine, traditional Japanese medicine (Kampo), traditional Korean, Mongolian, New Zealand (Maori), Thailand, Tibetan, Unani, or Vietnamese medicine, and so on.

Note 3 to entry: Conceptual representation shall be free from multilingual expressions but *medical domain* (3.9) would also affect the expressions in a certain script(s)[19] of a language and the related factors[15]–[22].

3.10
Medicine Regulatory Agency
institutional body that, according to the legal system under which it has been established, is responsible for the granting of marketing authorization for *medicinal products* (3.11)

[SOURCE: ISO 11615:2012, 3.1.53]

3.11
medicinal product
any substance or combination of substances that may be administered to human beings to treat or prevent disease

Note 1 to entry: Medical products are used to make a medical diagnosis or to restore, correct or modify physiological functions

Note 2 to entry: In this document, the scope of medicinal products is generally restricted to human beings. It is recognized that they could be applied also to animals but this is not the intended scope of this document.

[SOURCE: ISO 11615:2012, 3.1.49 — modified]

3.12
pharmaceutical product
qualitative and quantitative composition of *medicinal products* (3.11) in the dose form approved for administration in line with the regulated product information

[SOURCE: ISO 11615:2012, 3.1.58]

4 Abbreviated terms

HM *herbal medicament* (3.2)

SHM single *herbal medicament* (3.2)

5 Single herbal medicament (SHM)

5.1 Overview

The single herbal medicament (SHM) is the key component of herbal medications. The diagram below identifies the *characterizing categories*, which represent a *SHM* in *terminological systems*.

In the compositional concept representation, a single *herbal medicament* (3.2) has semantic links to the following characterizing categories: *Origin* (5.2.1), *PartOfInterest* (5.2.2) and *Processing* (5.2.3). These

are specified in 5.2. The semantic links among them are specified in 5.3. The relations of them are illustrated in a concept diagram in Figure 1.

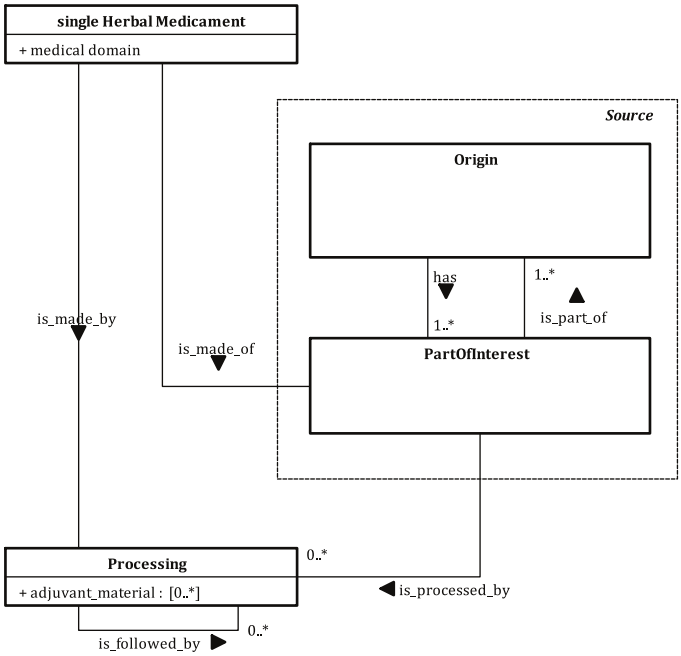


Figure 1 — Concept representation of single herbal medicament

A *source* or *source material* (3.1) is *PartOfInterest* (5.2.2) of *Origin* (5.2.1). The resultant material after *Processing* (5.2.3) is a single herbal medicament, *SHM*.

Some *medicines regulatory agencies* (3.10) allow that the *Origin* (5.2.1) is not restricted to a single species. *SHM* has its official names in a pharmacopeia or related documents according to the definition therein.

EXAMPLE 1 The Chinese Pharmacopoeia defines that "Rhei Radix et Rhizoma" shall be made from one or some of { *Rheum palmatum* L. or *Rheum tanguticum* Maxim. ex Balf or *Rheum officinale* Baill }[57].

EXAMPLE 2 The Chinese and European pharmacopoeias define the controlled term "Cimicifugae Rhizoma" to designate different species with different medicinal uses[43] [57]. See also the examples in 5.3.1.

NOTE There exist *synonyms*, *homonyms* and *polysemes* among the expressions in pharmacopoeias[52]-[63]. Kew's "Medicinal Plant Name Services" is helpful for identifying these (www.kew.org/mpns; Royal Botanic Gardens)[28]-[30].

5.2 Characterizing categories

5.2.1 Origin

Name of characterizing category: Origin		
Description: *Origin* (5.2.1) is the *characterizing category*, which contains the *designations* of "medicinal plants" as the *characterizing concepts* that are required in the *SHM.* Appropriate *value(s)* (3.5) is/are bound to the *semantic links* in concerned *contexts* (3.6) by a *domain constraint.*		
Values: The *values* shall have been previously defined in pharmacopoeias or related documents in each nation and authorized respectively by each *medicinal regulatory agency* (3.10); some of the pharmacopoeias are listed in References [52] to [63]. The *values* shall be the *designations* of { *Origin* } in the expression of scientific name.		
Semantic Link from	Semantic Link name	Semantic Link to
Origin	has	PartOfInterest (3.3)
PartOfInterest	isPartOf (5.3.2)	Origin
NOTE 1 Scientific name is based on International Code of Nomenclature for algae, fungi, and plants (Melbourne Code)[27]. NOTE 2 There exist many *synonyms* and *homonyms* among the expressions in pharmacopoeias[28]–[30], [52]–[63]. Different scientific names that are potentially used by different pharmacopoeias for the same species. These are reported WHO/WPRO-related work and Kew's service is helpful for identifying canonical name of plant[28]–[30]. The version of the code system should also be noted, because taxonomic concepts in botany may change over time.		

5.2.2 PartOfInterest

Name of characterizing category: PartOfInterest		
Description: *PartOfInterest* (5.2.2) is the *characterizing category,* which contains the *designations* of *"part(s) of interest (3.3)"* as the *characterizing concepts* that are required in the *SHM.* Appropriate *value(s)* (3.5) is/are bound to the *semantic links* in concerned *contexts* (3.6) by a *domain constraint.*		
Values: The *values* shall have been previously defined in pharmacopoeias or related documents in each nation and authorized respectively by each *medicine regulatory agency* (3.10); some of the pharmacopoeias are listed in References [52] to [63]. The *values* shall be the *designations* of { part(s) of interest }.		
Semantic Link from	Semantic Link name	Semantic Link to
PartOfInterest	isPartOf (5.3.2)	Origin (5.2.1)
PartOfInterest	isProcessedBy (5.3.3)	Processing (5.2.3)
PartOfInterest is not always limited to one. It varies by nation and *medical domain* (3.9). Because the ingredients of *source* (3.1) are determined by the *PartOfInterest(s)* of *Origin(s)*, they shall always be identified simultaneously.		

EXAMPLE 1 "Ginseng" [*as source*] in < Kampo > [*medical domain*] is the < root > [*PartOfInterest*] which *isPartOf* < *Panax ginseng* C.A.Mey > [*Origin*][63].

EXAMPLE 2 "Ginseng" [*as source*] in < Chinese medicine > [*medical domain*] is the < root > and < rhizome > [*PartOfInterest*] which *isPartOf* < *Panax ginseng* C.A.Mey > [*Origin*][57].

EXAMPLE 3 "Sana" [*as source*] in < Unani > [*medical domain*] is the < leaf > [*part of interest*] *isPartOf* < *Cassia angustifolia* Vahl > [*Origin*][55].

EXAMPLE 4 "Sanna" (*or* má-kăam kàek) [*as source*] in <traditional Thai medicine> [*medical domain*] is the <leaf> and <pod> [*PartOfInterest*] which *isPartOf* <*Cassia angustifolia* Vahl> [*Origin*][62].

NOTE See also 5.3.1.

5.2.3 Processing

Name of characterizing category: Processing		
Description: *Processing* (5.2.3) is the *characterizing category* which contains the *designations* of "processing methods" as the *characterizing concepts*, that are required in the SHM. Appropriate *value(s)* (3.5) is/are bound to the *semantic links* in concerned *contexts* (3.6) by a *domain constraint.*		
Value: The *values* shall have been previously defined in pharmacopoeias or related documents in each nation and authorized respectively by each *Medicinal Regulatory Agency* (3.10); some of the pharmacopoeias are listed in References [52] to [63]. The *values* shall be the designations of { processing methods }.		
Semantic Link from	Semantic Link name	Semantic Link to
PartOfInterest	isProcessedBy (5.3.3)	Processing
Processing	isFollowedBy (5.3.4)	Processing
PartOfInterest(s) shall be always identified simultaneously with *Origin(s)* (5.2.1) as *source* (3.1). NOTE *Processing* is occasionally performed with *assistant material* (3.4), which is specified if necessary.		

EXAMPLE 1 "Ginseng root and rhizome" [*as source*] *isProcessedBy* < removing fibrous root > [*Processing*] *isFollowedBy* < sun-dry > [*Processing*][57].

EXAMPLE 2 "Rhubarb root and rhizome" [*as source*] *isProcessedBy* < removing root hair > [*Processing*] *isFollowedBy* < removing epidermis > [*Processing*] *isFollowedBy* < sun-dry > [*Processing*][57].

5.3 Semantic links

5.3.1 isMadeOf

Name of semantic link: isMadeOf		
Context: terminology - semantic content - herbal medicament (at high level of concept) **Context:** *Origin* (5.2.1) - *PartOfInterest* (5.2.2) - *SHM* in a certain *medical domain* (3.9)		
Description: A *semantic link*, which indicates the relationship between *SHM* and the *PartOfInterest(s).*		
Concept from	Semantic Link name	Concept to
SHM	isMadeOf	PartOfInterest
PartOfInterest(s) shall always be identified simultaneously with *Origin(s)* as *source* (3.1). Every terminological phrase of *herbal medicaments* (3.2) complying with this document shall have this *semantic link.* NOTE There exist *polysemes* among the expressions in pharmacopoeias[28]–[30], [52]–[63]. Some *designations* in different pharmacopoeias appear quite the same when expressed using specific multi-byte letters[19], [30] ,[52]–[63].		

EXAMPLE 1 "Glycyrrhizae Radix et Rhizoma" [*as SHM*] in < Chinese medicine > [*medical domain*] *isMadeOf* {{ < root > or < rhizome > } [*PartOfInterest*] of { < *Glycyrrhiza uralensis* Fisher > or < *Glycyrrhiza inflata* Bat. > or < *Glycyrrhiza glabra* L. > } [*Origin*]} [*source*][57].

EXAMPLE 2 "Glycyrrhizae Radix" [*as SHM*] in < Kampo > [*medical domain*] *isMadeOf* { < root > [*PartOfInterest*] of { < *Glycyrrhiza uralensis* Fisher > or < *Glycyrrhiza glabra* L. > } [*Origin*]} [*source*][63].

NOTE These two *designations* appear same when expressed using specific multi-byte letters[19].

EXAMPLE 3 "Cimicifugae Rhizoma" [*as SHM*] in < European medicines > [*medical domain*] *isMadeOf* { < rhizome > [*PartOfInterest*] of < *Cimicifuga racemosa* (L.) Nutt. > [*Origin*]} [*source*][43].

EXAMPLE 4 "Cimicifugae Rhizoma" [*as SHM*] in < Chinese medicine > [*medical domain*] *isMadeOf* { < rhizome > [*PartOfInterest*] of { < *Cimicifuga heracleifolia* Kom. > or < *Cimicifuga dahurica (Turcz.)* Maxim. > or < *Cimicifuga foetida* L. > } [*Origin*]} [*source*][57].

5.3.2 isPartOf

Name of semantic link: isPartOf		
Context: terminology - semantic content - herbal medicament (at high level of concept)		
Context: *Origin* (5.2.1) - *PartOfInterest* (5.2.2) in a certain *medical domain* (3.9)		
Description: A *semantic link*, which indicates the relationship between *PartOfInterest(s)* and *Origin(s).*		
Concept from	Semantic Link name	Concept to
PartOfInterest	isPartOf	Origin
Every terminological phrase of herbal medicaments (3.2) complying with this document shall have this *semantic link*.		

EXAMPLES See 5.2.2.

5.3.3 isProcessedBy

Name of semantic link: isProcessedBy		
Context: terminology - semantic content - herbal medicament (at high level of concept)		
Context: *Origin* (5.2.1) - *PartOfInterest* (5.2.2) - *Processing* (5.2.3) - *SHM* in a certain *medical domain* (3.9)		
Description: A *semantic link*, which indicates the relationship between a *PartOfInterest* and the method of *Processing* used.		
Concept from	Semantic Link name	Concept to
PartOfInterest	isProcessedBy	Processing
Terminological phrase of herbal medicaments (3.2) complying with this document should have this *semantic link* if needed.		

EXAMPLES See 5.2.3.

5.3.4 isFollowedBy

Name of semantic link: isFollowedBy		
Context: terminology - semantic content - herbal medicament (at high level of concept)		
Context: *Processing* (5.2.3) - *Processing* (5.2.3) in a certain *medical domain* (3.9)		
Description: A *semantic link*, which indicates the sequence relationship between one *Processing* and another.		
Concept from	Semantic Link name	Concept to
Processing	isFollowedBy	Processing
Terminological phrase of herbal medicaments (3.2) complying with this document should have this *semantic link* if needed.		

EXAMPLES See 5.2.3.

5.3.5 isMadeBy

Name of semantic link: isMadeBy		
Context: terminology - semantic content - herbal medicament (at high level of concept)		
Context: *SHM* - *Processing* (5.2.3) in a certain *medical domain* (3.9)		
Description: A *semantic link*, which indicates the relationship between a *SHM* and the *Processing* used upon it. This *semantic link* would be utilized in need to mention the *Processing* used, especially for delimiting other *SHMs* made of quite same *source* (3.1) but by different *Processing*.		
Concept from	Semantic Link name	Concept to
SHM	isMadeBy	Processing
Terminological phrase of herbal medicaments (3.2) complying with this document should have this *semantic link* if needed.		

6 Herbal medicament composed of SHMs

6.1 Overview

In the *compositional concept representation*, *herbal medicament composed of SHMs* has *semantic links* to the following *characterizing categories*: *required SHM* (6.2.1) with *amount* (6.2.2).

Additional *characterizing categories* are required to identify the *herbal medicament composed of SHMs*. The two distinct *characterizing categories* are specified in 6.2. The *semantic links* between these are specified in 6.3, except redundancies specified in 5.3.

The relations mentioned above are illustrated in a *concept diagram* in Figure 2.

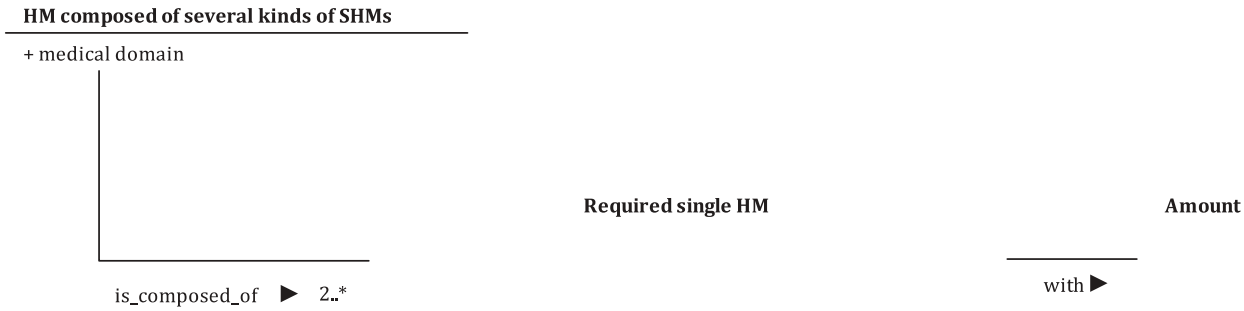


Figure 2 — Concept representation of herbal medicament composed of SHMs

6.2 Characterizing categories

6.2.1 Required SHM

Name of characterizing category: Required SHM		
Description: *Required SHM* (6.2.1) is the *characterizing category*, which contains the *designations* of the "*individual instances of Required SHM*" as the *characterizing concepts* that are required in the *herbal medicament composed of SHMs.* Appropriate *values* (3.5) are bound to the *semantic links* in concerned *contexts* (3.6) by a *domain constraint.*		
Value: The *values* shall have been previously defined in pharmacopoeias or related documents in each nation and authorized respectively by each *medicinal regulatory agency* (3.10); some of the pharmacopoeias are listed in References [52] to [63]. The *values* shall be the designations of { SHM } required in the Herbal medicament composed of SHM.		
Semantic Link from	Semantic Link name	Semantic Link to
Herbal medicament composed of SHMs	isComposedOf (6.3.1)	Required SHM
NOTE 1 An *herbal medicament composed of SHM* is called a "formula" in some pharmacopoeias[52]–[59]. NOTE 2 There exist *polysemes* among the expressions in pharmacopoeias[28]–[30], [52]–[63]. Some *designations* in different pharmacopoeias appear quite the same when expressed using specific multi-byte letters[19], [52]–[63]. These are reported WHO/WPRO-related work[30].		

EXAMPLES See 6.2.2.

6.2.2 Amount

Name of characterizing category: Amount		
Description: *Amount* (6.2.2) is the *characterizing category*, which contains the *designations* of each "quantity" of the individual *Required SHMs* as the *characterizing concepts* that are required for specifying such quantities. Appropriate *values* (3.5) are bound to the *semantic links* in concerned *contexts* (3.6) by a *domain constraint*.		
Value: The *values* shall have been previously defined in pharmacopoeias or related documents in each nation and authorized respectively by each *medicine regulatory agency* (3.10); some of the pharmacopoeias are listed in References [52] to [63] The *values* shall be the *designations* for specifying each { quantity } of individual *Required SHMs*		
Semantic Link from	Semantic Link name	Semantic Link to
Required SHM	with (6.3.2)	Amount
Amount (6.2.2) should be specified with unit. NOTE The unit system recommended for use is The International System of Units, i.e. ISO 80000 family. Other relevant expressions can be used. If their meaning is equivalent and there is possibility of misunderstandings or misinterpretations.		

EXAMPLE 1 "Maren Wan" [*Herbal medicament composed of SHMs*] in < Chinese medicine > [*medical domain*] *isComposedOf* (6.3.1) the following: { < Cannabis Semen > [*Required SHM*] *with* < 200 g > [*Amount*]; < Armeniaceae Semen Amarum > [*Required SHM*] *with* < 100 g > [*Amount*]; < Rhei Radix et Rhizoma > [*Required SHM*] *with* < 200 g > [*Amount*]; < Aurantii Fructus Immaturus > [*Required SHM*] *with* < 200 g > [*Amount*]; < Magnoliae Officinalis Cortex > [*Required SHM*] *with* < 100 g > [*Amount*]; < Paeoniae Radix Alba > [*Required SHM*] *with* < 200 g > [*Amount*] }[58].

EXAMPLE 2 "Kālameghāsava" [*Herbal medicament composed of SHMs*] in < Ayurveda > [*medical domain*] *isComposedOf* (6.3.1) the following: { < Andrographis paniculata > [*Required SHM*] *with* < 250 g > [*Amount*]; < Jaggery > [*Required SHM*] *with* < 400 g > [*Amount*]; < Potable water > *with* < 1000 ml > [*Amount*]; < Woodfordia fruticosa > [*Required SHM*] *with* < 40 g > [*Amount*]; < Swertia chirata > [*Required SHM*] *with* < 10 g > [*Amount*]; < Picrorhiza kurroa > [*Required SHM*] *with* < 10 g > [*Amount*]; < Azadirachta indica > [*Required SHM*] *with* < 10 g > [*Amount*]; < Zingiber officinale > [*Required SHM*] *with* < 10 g > [*Amount*]; < Terminalia chebula > [*Required SHM*] *with* < 10 g > [*Amount*]; < Fagonia cretica > [*Required SHM*] *with* < 10 g > [*Amount*]; < Trichosanthes cucumerina > [*Required SHM*] *with* < 10 g > [*Amount*]; < Pterocarpus santalinus > [*Required SHM*] *with* < 10 g > [*Amount*]; < Vetiveria zizanioides > [*Required SHM*] *with* < 10 g > [*Amount*]}[54].

NOTE 1 The terms "Maren Wan" and "Kālameghāsava" are defined in their respective pharmacopoeias, with compositions of successive *Required SHMs*; the design of an herbal medicament composed of SHMs and its "name" are defined simultaneously in pharmacopoeias. Here, the "name" does not designate a specific individual *medicinal product* (3.11) but its fundamental design. Consequently, to allow manufacturers to compete freely in the market, "name" cannot be a brand or proprietary name; rather, it is often utilized as the "common name" of a certain group of *Medicinal Products*.

NOTE 2 There are many *synonyms* and *homonyms* among the names of *SHMs* in pharmacopoeias. There are also *polysemes* among the names of *herbal medicament composed of SHMs*, at least, in some expressions or symbols, i.e. *designation*[28]–[30], [52]–[63].

6.3 Semantic links

6.3.1 isComposedOf

Name of semantic link: isComposedOf		
Context: terminology - semantic content - herbal medicament (at high level of concept)		
Description: A *semantic link* which indicates the relationship between an *herbal medicament composed of SHMs* and the *Required SHMs* used to create the medicament.		
Concept from	Semantic Link name	Concept to
Herbal medicament composed of SHMs	isComposedOf	Required SHM
Every terminological phrase of *herbal medicaments* (3.2) complying with this document shall have this *semantic link*.		

EXAMPLE See 6.2.2.

6.3.2 with

Name of semantic link: with		
Context: terminology - semantic content - herbal medicament (at high level of concept)		
Description: A *semantic link* which indicates the relationship between the *Amount* and the *Required SHM* used in the *herbal medicament composed of SHMs.*		
Concept from	Semantic Link name	Concept to
Required SHM	with	Amount
Every terminological phrase of *herbal medicaments* (3.2) complying with this document should have this *semantic link*.		

EXAMPLE See 6.2.2.

7 Conformity

To be conformant with EN 12264, ISO 17115 and this document, any *terminological system* (3.8) utilizing the *categorial structure* for the representation of herbal medicaments shall provide the following:

— categories that organize the health care objects for representation of herbal medicaments in the terminological system and subdividing their representation in the domain;

— a list of the semantic links (or representations of relations) authorized by domain constraints;

— the goal of the terminological system for which the categorial structure is set;

— a list of minimal domain constraints required by the goal of the categorial structure.

The categorial structure that is requested by this document is as follows:

a) the goal of the *terminological system* (3.8) for which the *categorial structure* is set;

b) *Categorial structure* for single herbal medicament (3.2), which shall consist of

   1) *isMadeOf* (5.3.1) to *PartOfInterest* (5.2.2),

   2) *isPartOf* (5.3.2) to *Origin* (5.2.1), and

   3) *isMadeBy* (5.3.5) to *Processing* (5.2.3) if needed;

c) *Categorial structure* for herbal medicament composed of several kinds of *SHMs*, which shall consist of

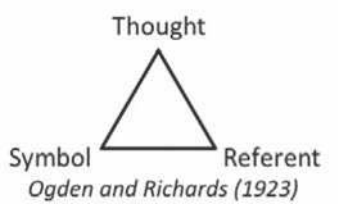
   1) *isComposedOf* (6.3.1) to *Required SHM* (6.2.1), and

   2) *with* (6.3.2) to *Amount* (6.2.2).

Annex A
(informative)

Commentary on the high level terms and concepts in categorial structure

A.1 Semiotic triangle



NOTE Reproduced with permission (see Reference [1]).

Figure A.1 — Semiotic triangle

Figure A.1 was published in 1923[1], but is still useful in understanding the framework described above. The semiotic triangle consists of a symbol (designation[5]), a reference (concept), a referent (object) and the relationship between these.

The clarification of the relationships between *terms* and *concepts* will also provide an environment for consistency in controlled vocabulary, interconnectivity and interoperability among *terminologies*[6]-[13]. In addition, it will provide the flexibility to bind a *term* to its *concept*[1]-[7] in a terminology. This type of methodology is essential in modernized *terminological systems* (3.8).

A.2 High-level concept structure in categorial structure

The framework of categorial structure is defined by ISO 17115 and ISO 1087-1 but originally developed by CEN as EN 12264[5]-[7].

A *concept* in a *concepts system* is a unit of knowledge created by a unique combination of *characteristics*. *Concepts* are not necessarily bound to particular languages. They are influenced by the social or cultural background, which often leads to different categorizations.

A *characteristic* is the abstraction of a property of an *object* or of a set of *objects*. An *object* is anything perceivable or conceivable that may be material, immaterial or imagined. The pairing of a *semantic link* and a *characterizing concept*, as an attribute-value pair, is called "*composite characteristic*." A *characterizing concept* or *value* (3.5) is expressed by a *designation* of a *specific concept* or an *individual concept*. An *individual concept* is corresponds to only one *object*, whereas a *specific concept* has a *generic relation* to a certain *generic concept*.

In a *generic relation*, a *generic concept* has a narrower *intension* and a wider *extension* than its *specific concepts*. A *generic concept* is also called a "*category*," and the *specific concept* is a member of the *extension* of it. In other words, a *specific concept* is an *instance of a (generic) concept*.

A *generic concept*, which contains *characterizing concepts* or *values* that the *semantic links* refer to, is called *characterizing generic concept*, *characterizing category*, or *value domain*. *Values* in a *value domain* shall be valid in a certain *domain* or *subject field*. Consequently, *value domains* are influenced by the certain *context* (3.6) in a certain *generic relations* to a certain *generic concept* in a certain *domain*. These rules are called "*domain constraints*."

The minimal set of *domain constraints* in a certain *domain* therefore specifies the distinctions of the *concept system* in a certain *domain*. When representing a *concept system*, such minimal set is called a *categorial structure* of the *concept system* in the *domain*. A *categorial structure* is described by the combination of *semantic links* and their *characterizing categories*.

A.3 Binding terms and concepts

Concepts, *terms*, and *objects* shall validly correspond with each other in the Semiotic Triangle. *Individual concepts* and the corresponding objects are designated by terms and/or codes in a *terminological system* in accordance with its *concept system*. A term is a verbal *designation* of a *general concept* in a specific *subject field* or *domain*.

A *general concep*t corresponds to two or more objects, which form a group by reason of common properties, e.g. 'tower.' In contrast, an *individual concept* is designated by an *appellation*, e.g. 'the Eiffel Tower.'

The *general concept* for the objects in the group 'tower' consists of a combination of several *semantic links* and their *characterizing categories*. However, the *values* or *characterizing concepts* have not yet been specified until *domain* is specified.

The *value* 'the Eiffel Tower' becomes specifiable when "the towers in France" is included in the targeted *subject field*, and thus the necessary values are contained in the *value domain* in the *concept system*.

A.4 Contemporary management of terms and concepts

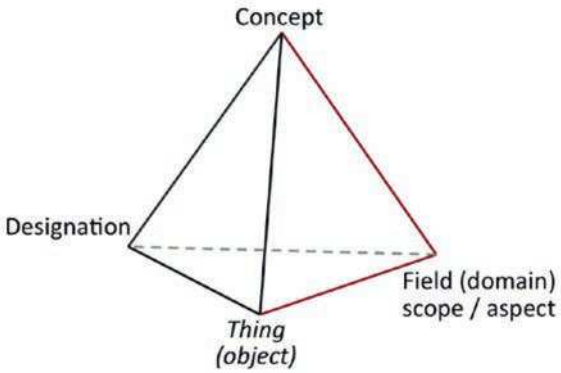


Figure A.2 — Domain constraint framework

A.4.1 Domain constraint

Such framework provides contemporary viewpoint on the relation between *terms* and *concepts* in a specific *domain*. *Categorial structure* adds on a new factor, *domain* or *field*, to the classical Semiotic Triangle in order to bind terms to concepts appropriately in a certain *field*.

This approach is not 'abstract' but rather very practical in social systems in real world.

A.4.2 Context constraint

Another important point of view, ISO 17115:2007, 2.3.3 points out that the *context constraint* (A.4.2) *characterizing generic concept*: *formal category* whose specialization by a *domain constraint* is allowed to be used as *characterizing concept* in a particular *context*.

In addition, its note mentioned that the *context* includes a *superordinate concept* and a *semantic link*. *Semantic link* is a "formal representation of a directed *associative relation* or *partitive relation* between two *concepts*" and "all relations except the *generic relation*." This means that a certain *characterizing generic concept* can be feasibly determined within the embedded whole of relations among other

individual concepts, that have specified *values* in the related *characterizing generic concepts* in a specific *domain*. This is the meaning of *context* defined in ISO 17115.

Under such a framework, the flexibility to bind a *term* to its *concept* in a terminology can be suitably achieved. This type of methodology is essential in modernized *terminological systems*. Within it and other related ISO documents[1]-[13], both the appropriate international harmonization and practical works in the real world can be rather easily accomplished, with specifications of 1) domains, 2) map capabilities, 3) map table(s) and/or rule(s) between concepts among terminological resources, 4) declaration of selecting designations and 5) directions and/or notes if needed.

A.5 Differences from IDMPs

In shortly speaking, although they use similar or same elements, these focuses are quite different from each other: the purposes of each, the information models for individual medicinal products or the conceptual backbone for terminological systems, *individual concept* or *general/generic concept* and for the *appellations* or *terms* in common within a domain.

Annex B
(informative)

Terms mapping between IDMPs

The relations between the Characterizing Categories in this document between the Classes in IDMPs (ISO 11238, ISO 11616 and ISO 11615) are shown in the following table in this annex.

The following terms defined or specified in this document do not designate any terms defined in IDMPs: herbal medicament (3.2), SHM (single herbal medicament; 5.2), Herbal medicament composed of SHMs (6.2), and Required SHM (6.2.1). The reason why is the definition of herbal medicament (3.2) in this document.

This annex does not refer the implementation guides of IDMPs because of the differences of the scopes. This document is developed in order to provide the backbone concept system in terminological systems but the implementation guides of IDMPs are developed for the identification of each medicinal product. This difference shows up in the 'objects' that are designated: designs or definitions in the former, and individual medicinal products in the latter. In other words, the difference of the objects is materials or not.

ISO 18062		**IDMPs**		
Clause #	**Heading**	**Doc #**	**Clause #**	**Heading**
3.1	herbal substance	ISO 11238	2.1.52 3.6.2.5	Source material
3.2	herbal medicament	-	-	-
3.3	part of interest	ISO 11238	Figure 8 in 3.6.2.5	PART of Source material
3.4	assistant material		Figure 22 in 3.7.9	one of STARTING_MATERIALs in Manufacturing
3.10	Medicine regulatory agency	ISO 11615	3.1.51	Medicine regulatory agency
3.11	medicinal product	ISO 11238 ISO 11615 ISO 11616	2.1.25 3.1.47 3.1.19	medicinal product
3.12	pharmaceutical product	ISO 11238 ISO 11615 ISO 11616	2.1.37 3.1.56 3.1.20	pharmaceutical product
5.2	**SHM**	—	—	—
5.2.1	Origin	ISO 11238	Figure 8 in 3.6.2.5	ORGANISM of Source material
5.2.2	PartOfInterest	ISO 11238	Figure 8 in 3.6.2.5	PART of Source material
5.2.3	Processing	ISO 11238	3.6.2.3 2.1.23 3.7.9	Modification Manufacturing

ISO 18062		IDMPs		
Clause #	**Heading**	**Doc #**	**Clause #**	**Heading**
6.2	**Herbal medicament composed of SHMs**	—	—	—
6.2.1	Required SHM	—	—	—
6.2.2	Amount	ISO 11238	Figure 7 in 3.6.2.4	AMOUNT

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[4] ISO 704, *Terminology work — Principles and methods*

[5] ISO 1087-1, *Terminology work — Vocabulary — Part 1: Theory and application*

[6] EN 12264, *Health informatics — Categorial structure for systems of concepts*

[7] ISO 17115:2007, *Health informatics — Vocabulary for terminological systems*

[8] ISO/TR 17119:2005, *Health informatics — Health informatics profiling framework*

[9] ISO/TS 17117:2002, *Health informatics — Controlled health terminology — Structure and high-level indicators*

[10] ISO 17117-1:—[1)], *Health informatics – Terminological resources — Part 1: Characteristics*

[11] ISO 25964-2, *Information and documentation — Thesauri and interoperability with other vocabularies — Part 2: Interoperability with other vocabularies*

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