

5.2 Characterizing Categories

5.2.1 Official Name

designator (B.3.4.1) of herbal medicament (3.2) which is defined in a pharmacopoeia or national authorized document(s) in each country

NOTE 1 **official name** (5.2.1) **characterizing category** (A.2.3.3) that is valid for representation of a herbal medicament (3.2) is: { official names of herbal medicaments addressed in pharmacopoeias }.

NOTE 2 **values** (3.19) for **official name** (5.2.1) are addressed in some references listed in bibliography [47-55] but not limited to them.

NOTE 3 **official name** (5.2.1) **characterizing category** (A.2.3.3) that are valid for representation of a herbal medicament (3.2) with: { source identifier }, { country identifier }, { language identifier }, { script identifier }, { jurisdiction domain }, { jurisdiction type }.

NOTE 4 **source identifier** (B.3.8.10), **country identifier** (B.3.8.9), and **language identifier** (B.3.8.8) are defined in ISO 1087-1:2000 [1]. **script identifier** (3.3) is defined in IETF RFC 5646 [10]. **jurisdiction domain** (3.5) and **jurisdiction type** (3.6) are defined in Cause 3 of this Technical Specification.

NOTE 5 **values** (3.19) for **country identifier** (B.3.8.9), **language identifier** (B.3.8.8) and **script identifier** (3.3) are respectively addressed in ISO 3166-1:2006 [15], ISO 3166-2:2007 [16], ISO 3166-3:1999 [17], ISO 639-1:2002 [11], ISO 639-2:1998 [12], ISO 639-3:2007 [13], and ISO 15924:2004 [14].

NOTE 6 **country identifier** (B.3.8.9) and **language identifier** (B.3.8.8) has better to be specified within IETF language tag defined in IETF RFC 5646 [10].

NOTE 7 Although in rare case, officially regulated **term** (B.3.4.3) designates different herbal medicament (3.2) **objects** (B.3.1.1) in a same country: one is in medicinal product domain, and another is in medical education domain [49,51,52]. This is the reason why **jurisdiction type** (3.6) is prepared.

NOTE 8 Some pharmacopoeia define "**official name** (5.2.1) in Latin" besides "**official name** (5.2.1) in country official language", but those "Latin names" are not **scientific names** (5.2.3). Therefore, they vary among pharmacopoeias, in other words, there are lots of **synonyms** (B.3.4.19).

NOTE 9 Some pharmacopoeias often define "**official names** (5.2.1) in country language" at different levels on hierarchical relations among a group and the name of top node represents other **subordinate concepts** (B.3.2.14). However, there is no "**official name** (5.2.1) in Latin" equivalent for those names of subordinates. Such situation has the risks of confusion in the base if top word and subordinate words are morphologically similar in their **form of a language** (3.4) [50-52,54].

5.2.2 Vernacular Name

designator (B.3.4.1) of **origin** (5.2.4), **source** (5.2.7) or herbal medicament (3.2) in a **form of a language** (3.4) that ordinary people use in a certain country or locality, especially one that is not officially authorized **official name** (5.2.1) or **scientific name** (5.2.3)

NOTE 1 **vernacular name** (5.2.2) **characterizing category** (A.2.3.3) that is valid for representation of a herbal medicament (3.2) is: { vernacular name }.

NOTE 2 **values** (3.19) for **vernacular name** (5.2.2) are addressed in some references listed in bibliography [25-36] but not limited to them.

NOTE 3 **vernacular name** (5.2.2) **characterizing category** (A.2.3.3) that are valid for representation of a herbal medicament (3.2) includes: { country identifier }, { language identifier }, { script identifier }.

NOTE 4 **country identifier** (B.3.8.9), and **language identifier** (B.3.8.8) are defined in ISO 1087-1:2000 [1]. **script identifier** (3.3) is defined in IETF RFC 5646 [10].

NOTE 5 **values** (3.19) for **country identifier** (B.3.8.9), **language identifier** (B.3.8.8) and **script identifier** (3.3) are respectively addressed in ISO 3166-1:2006 [15], ISO 3166-2:2007 [16], ISO 3166-3:1999 [17], ISO 639-1:2002 [11], ISO 639-2:1998 [12], ISO 639-3:2007 [13], and ISO 15924:2004 [14].

NOTE 6 **country identifier** (B.3.8.9) and **language identifier** (B.3.8.8) has better to be specified within IETF language tag defined in IETF RFC 5646 [10].

NOTE 7 **vernacular name** (5.2.2) is not official, however, it is often like **official name** (5.2.1) and is commonly used in international trading. In addition, some of **vernacular name** (5.2.2) are polysemic. As a result, the extents of **polysemy** (B.3.4.24) refer not only to **HB-SNM** (4.3) but also **origin** (5.2.4) and **source** (5.2.7). Consequently, **vernacular names** (5.2.2), **official names** (5.2.1), name of **origin** (5.2.4) and name of **source** (5.2.7) may be lead to confusion in identification of herbal medicament (3.2) and related **objects** (B.3.1.1).

5.2.3 Scientific Name

designator (B.3.4.1) of **origin** (5.2.4) used by scientists, especially the name of taxonomic node of a creature

NOTE 1 **scientific name** (5.2.3) **characterizing category** (A.2.3.3) that is valid for representation of a HB-SNM (4.3) is: { scientific name of origin addressed in authorized terminological resources }.

NOTE 2 **scientific name** (5.2.3) **characterizing category** (A.2.3.3) that are valid for representation of a HB-SNM (4.3) with: { source identifier }, { type specimen }, { kind of type }.

NOTE 3 **source identifier** (B.3.8.10) is defined in ISO 1087-1:2000 [1]. **type specimen** (3.8) and **kind of type** (3.9) are defined in Cause 3 of this Technical Specification.

NOTE 4 **values** (3.19) for **source identifier** (B.3.8.10) **characterizing category** (A.2.3.3) that is valid for representation of a HB-SNM (4.3) is: [International Code of Botanical Nomenclature | International Code of Nomenclature of Bacteria | International Code of Zoological Nomenclature | International Mineralogical Association Official List of Mineral Names].

NOTE 5 **values** (3.19) for **scientific name** (5.2.3) are addressed in terminological resources specified with **source identifier** (B.3.8.10). Those resources are respectively maintained by International Botanical Congress [18], International Committee on Systematics of Prokaryotes [19], International Commission on Zoological Nomenclature [20], and International Mineralogical Association, Commission on New Minerals and Mineral Names / Commission on New Minerals, Nomenclature and Classification [21].

NOTE 6 “**official name** (5.2.1) in Latin” is quite different from **scientific name** (5.2.3). **scientific name** (5.2.3) is fundamentally unique in its domain due to the design of a terminology and the maintenance policy about those.

NOTE 7 In rarely, **designation** (B.3.4.1) with **binomial system** (3.7) with suffixed cannot identify what this living thing is. In such case, other **designator** (B.3.4.1) and/or **botanical feature** (5.2.5) **characterizing category** (A.2.3.3) may be utilized in order to identify **origin** (5.2.4), as a result, in identification of **source** (5.2.7) and HB-SNM (4.3) **object** (B.3.1.1).

5.2.4 Origin

plant, animal, or mineral of which part is interested as raw material for herbal medicament (3.2)

NOTE 1 **origin** (5.2.4) is officially designated by **scientific name** (5.2.3).

NOTE 2 **values** (3.19) for **origin** (5.2.4) are addressed in some references listed in bibliography [24-39,47-55] but not limited to them.

NOTE 3 **origin** (5.2.4) **characterizing category** (A.2.3.3) that is formally valid for representation of a HB-SNM (4.3) with: { kingdom }, { part of interest }.

NOTE 4 **values** (3.19) for { part of interest } subordinate **characterizing categories** (A.2.3.3) of **origin** (5.2.4) are described in some references listed in bibliography [25-39,47-55] but not limited to them.

NOTE 4 **origin** (5.2.4) **characterizing category** (A.2.3.3) that is recommended for valid representation of a HB-SNM (4.3) with: { botanical feature }.

NOTE 5 **origin** (5.2.4) is designated whether **scientific name** (5.2.3) or **vernacular name** (5.2.2). **origin** (5.2.4) is identified by **botanical feature** (5.2.5), this is helpful especially when its **scientific name** (5.2.3) is **polysemy** (B.3.4.24). **origin** (5.2.4) predetermines the **characteristics** (B.3.2.4) of **source** (5.2.7), and then HB-SNM (4.3) **object** (B.3.1.1).

5.2.5 Botanical Feature

biological and morphological features of a particular plant

NOTE 1 **botanical feature** (5.2.5) **characterizing category** (A.2.3.3) that is valid for representation of a HB-SNM (4.3) includes, but not limited to: { habit }, { geographical distribution }, { morphology }, { size }, { color }, { flowering time }, { vegetation }, { life cycle }.

NOTE 2 some subordinate **characterizing categories** (A.2.3.3) listed in NOTE 1 may be used in combination with each other.

NOTE 3 some **values** (3.19) for **botanical feature** (5.2.5) and its subordinate **characterizing categories** (A.2.3.3) are described in some references listed in bibliography [25-28,32-36,39,48,50,52] but not limited to them.

NOTE 4 **botanical feature** (5.2.5) belongs to **origin** (5.2.4) in the representation of a HB-SNM (4.3).

5.2.6 Harvest

collection of factors during harvest of **natural material** (3.1), that influence **characteristics** (B.3.2.4) of **source** (5.2.7)

NOTE 1 **harvest** (5.2.6) **characterizing category** (A.2.3.3) that are valid for representation of a HB-SNM (4.3) includes, but not limited to: { region }, { season }, { weather }, { age }, { condition }, { cultivation }, { initial procedure }.

NOTE 2 some **values** (3.19) for **harvest** (5.2.6) and its subordinate **characterizing categories** (A.2.3.3) are described in some references listed in bibliography [25-28,32-36,39,48,50,52] but not limited to them.

NOTE 3 **harvest** (5.2.6) qualifies the **characteristics** (B.3.2.4) of **source** (5.2.7), and then HB-SNM (4.3) **object** (B.3.1.1).

5.2.7 Source

part of **origin** (5.2.4) that is utilized as raw material for herbal medicament (3.2)

NOTE 1 **source** (5.2.7) **characterizing category** (A.2.3.3) that is valid for representation of a HB-SNM (4.3) includes: { part of origin }; and { origin }.

NOTE 2 **part of origin** (3.13) is defined in Cause 3 of this Technical Specification.

NOTE 3 **values** (3.19) for **part of origin** (3.13) subordinate **characterizing categories** (A.2.3.3) of **origin** (5.2.4) are described in some references listed in bibliography [25-39,47-55] but not limited to them.

NOTE 4 **source** (5.2.7) **characterizing category** (A.2.3.3) that is recommended for valid representation of a HB-SNM (4.3) with: { basic characteristics }, { harvest }.

NOTE 5 **values** (3.19) for **source** (5.2.7) are addressed in some references listed in bibliography [24-39,47-55] but not limited to them.

NOTE 6 **source** (5.2.7) is characterized by **harvest** (5.2.6) and can be identified by **basic characteristics** (5.2.9). **source** (5.2.7) provides **constituent** (5.2.10). **source** (5.2.7) may be processed by **processing** (5.2.8). **processing** (5.2.8) may modify **constituent** (5.2.10).

5.2.8 Processing

minimum unit of making **source** (5.2.7) ready to be used with preserving or improving of their **characteristics** (B.3.2.4) on medicament in some way

NOTE 1 **processing** (5.2.8) **characterizing category** (A.2.3.3) that are valid for representation of a HB-SNM (4.3) includes: { processing type }, { processing method }, and { adjuvant material }.

NOTE 2 **processing type** (3.13), **processing method** (3.14) and **adjuvant material** (3.15) are defined in Cause 3 of this Technical Specification.

NOTE 3 **values** (3.19) for **processing** (5.2.8) and its subordinate **characterizing categories** (A.2.3.3) are described in some references listed in bibliography [25,39,48,50,52] but not limited to them.

NOTE 4 **processing** (5.2.8) processes **source** (5.2.7) with or without **adjuvant material** (3.15). **processing** (5.2.8) affects **basic characteristics** (5.2.9) of **source** (5.2.7). **processing** (5.2.8) may modify **constituent** (5.2.10).

5.2.9 Basic Characteristics

macroscopic or organoleptic **characteristics** (B.3.2.4) of **source** (5.2.7) or HB-SNM (4.3)

NOTE 1 This definition implies that HB-SNM (4.3) is a product after **processing** (5.2.8). Some **processing** (5.2.8) changes **basic characteristics** (5.2.9).

NOTE 2 **basic characteristics** (5.2.9) **characterizing category** (A.2.3.3) that are valid for representation of a **source** (5.2.7) or a HB-SNM (4.3) includes, but not limited to: { shape }, { size }, { colour }, { gloss }, { texture }, { heaviness }, { smell }, { taste }, { condition }.

NOTE 3 some subordinate **characterizing categories** (A.2.3.3) listed in NOTE 2 may be used in combination with each other.

NOTE 4 **values** (3.19) for the subordinate **characterizing categories** (A.2.3.3) of **basic characteristics** (5.2.9) are described in some references listed in bibliography [25,26,28,32-36,48,50,52-54] but not limited to them.

NOTE 5 **basic characteristics** (5.2.9) belong to **source** (5.2.7) and HB-SNM (4.3) respectively, in the representation of a HB-SNM (4.3). **processing** (5.2.8) affects **basic characteristics** (5.2.9) of **source** (5.2.7) and changes it into **basic characteristics** (5.2.9) of HB-SNM (4.3). **basic characteristics** (5.2.9) is helpful to identify **source** (5.2.7) and HB-SNM (4.3).

5.2.10 Constituent

substance (3.16) present within a **source** (5.2.7) or a herbal medicament (3.2) [modified from ISO/FDIS 11238]

NOTE 1 Constituents can be not only chemical substances that have **biomedical effect** (5.2.12) but also impurities, degradants, markers or signature substances. [modified from ISO/FDIS 11238] [45]

- **source** (5.2.7) may contain not only degradation substance but also precursor, unstable substance in pathway of biochemical series of reactions, and derivatives

NOTE 2 The latter part of the NOTE in the definition in ISO/FDIS 11238 [45] "Constituents shall have an associated role and amount. Constituent specifications shall be used to describe components as well as limits on impurities or related substances for a given material" is handled in **laboratory test profile** (5.2.11) in this Technical Specification.

NOTE 3 **constituent** (5.2.10) **characterizing category** (A.2.3.3) that are valid for representation of a herbal medicament (3.2) includes: { substance name }, { substance structure }, { related substances }, { physical characteristics }, { chemical characteristics }; and { biomedical effect }.

NOTE 4 some **values** (3.19) for the subordinate **characterizing categories** (A.2.3.3) of **constituent** (5.2.10) are described in some references listed in bibliography [25-29,31-38,47-53,55] but not limited to them.

NOTE 5 **constituent** (5.2.10) is contained in herbal medicament (3.2). **constituent** (5.2.10) is provided from **source** (5.2.7). **constituent** (5.2.10) may be modified, destroyed or degraded by **processing** (5.2.8). **constituent** (5.2.10) is detected by laboratory test result(s) or the **laboratory test profile** (5.2.11) of them. Some of **constituents** (5.2.10) determine or influence **biomedical effect** (5.2.12) of a herbal medicament (3.2).

5.2.11 Laboratory Test Profile

collection of analyzing test results on a **source** (5.2.7) or a herbal medicament (3.2)

NOTE 1 **laboratory test profile** (5.2.11) **characterizing category** (A.2.3.3) that are valid for representation of a herbal medicament (3.2) includes: { test purpose }, { test method }, { test procedure }, { reference data }, { result(s) of a test }, { permissible limit }, { system adequacy }.

NOTE 2 { permissible limit } subordinate **characterizing category** (A.2.3.3) of **laboratory test profile** (5.2.11) implies that { result(s) of a test } subordinate **characterizing category** (A.2.3.3) of **laboratory test profile** (5.2.11) shall have an **semantic link** (A.2.2.3) to amount.

NOTE 3 some **values** (3.19) for the subordinate **characterizing categories** (A.2.3.3) of **laboratory test profile** (5.2.11) are described in some references listed in bibliography [28,29,32-38,47,52-55] but not limited to them.

NOTE 4 Needless to say, each government keeps the right to independently decide the official **values** (3.19) of those **characterizing categories** (A.2.3.3) within each country, in order to protect life and health of their citizens. Governmental decision is out of scope of this Technical Specification. This Technical Specification only intend to clarify the extent and degree of identification, biomedical activity and impurities in order to provide additional information for estimation of reliabilities of **biomedical effect** (5.2.12).

NOTE 5 **laboratory test profile** (5.2.11) detects **constituent** (5.2.10) contained in **source** (5.2.7) or herbal medicament (3.2). Some of detected **constituent** (5.2.10) affects **biomedical effect** (5.2.12) of a herbal medicament (3.2).

5.2.12 Biomedical Effect

consequent reaction in body of living thing caused by **constituent(s)** (5.2.10) contained a herbal medicament (3.2)

NOTE 1 Main interest is focused on human but many pharmacological reports utilize animals or animal's cells in fundamental research to speculate effects to human body.

NOTE 2 **biomedical effect** (5.2.12) **characterizing category** (A.2.3.3) that are valid for representation of a herbal medicament (3.2) includes: { medical domain type }, { effect type }, { effect }, { precondition }.

NOTE 3 **medical domain type** (3.17) is defined in Cause 3 of this Technical Specification.

NOTE 4 { effect type } subordinate **characterizing category** (A.2.3.3) of **biomedical effect** (5.2.12) is able to be roughly classified into "preferred" and "not preferred". More specified classification of biomedical effects varies [25-29,32-38] because issues can be classified in several way from point of view. See Annex E.

NOTE 5 { precondition } subordinate **characterizing category** (A.2.3.3) of **biomedical effect** (5.2.12) has at least two sides of aspect; physical and mental status of patient or targeted living things before or without intervention, and factors that is brought about by intervention(s).

NOTE 6 **values** (3.19) for the subordinate **characterizing categories** (A.2.3.3) of **biomedical effect** (5.2.12) are described in some references listed in bibliography [25-29,32-38,47-52,54] but not limited to them.

NOTE 7 **biomedical effect(s)** (5.2.12) arise from **constituent** (5.2.10) contained in herbal medicament (3.2), with depending on **dosage** (5.2.13).

5.2.13 Dosage

act, manner, and amount of using medicinal(s)

NOTE 1 **dosage** (5.2.13) **characterizing category** (A.2.3.3) that are valid for representation of a herbal medicament (3.2) includes, but not limited to: { dose }, { dose unit }, { dose form }, { route }, { frequency }, { period }.

NOTE 2 **dose form** (3.18) is defined in Cause 3 of this Technical Specification.

NOTE 3 some **values** (3.19) for the subordinate **characterizing categories** (A.2.3.3) of **dosage** (5.2.13) are described in some references listed in bibliography [25-29,32-38,47-52,54] but not limited to them.

NOTE 4 **dosage** (5.2.13) affects **biomedical effect** (5.2.12).

5.3 Semantic Links

5.3.1 hasOfficialName

semantic link (A.2.2.3) between the herbal medicament (3.2) and **official name** (5.2.1) which the herbal medicament (3.2) has

NOTE 1 **official name** (5.2.1) should be qualified by { official names of herbal medicaments addressed in pharmacopoeias } with **source identifier** (B.3.8.10), **country identifier** (B.3.8.9), **language identifier** (B.3.8.8), **script identifier** (3.3), **jurisdiction domain** (3.5), and **jurisdiction type** (3.6) if needed [49,51,52,54].

NOTE 2 Every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.2 hasScientificName

semantic link (A.2.2.3) between **origin** (5.2.4) and **scientific name** (5.2.3) which **origin** has

NOTE 1 **scientific name** (5.2.3) should be qualified by { scientific name of origin addressed in authorized terminological resources } with **source identifier** (B.3.8.10), **type specimen** (3.8) and **kind of type** (3.9), if needed.

NOTE 2 Every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.3 hasVernacularName

semantic link (A.2.2.3) between the herbal medicament (3.2) or **origin** (5.2.4) or **source** (5.2.7) and **vernacular name** (5.2.2) which the herbal medicament (3.2) or **origin** (5.2.4) or **source** (5.2.7) has

NOTE **vernacular name** (5.2.2) should be qualified by { vernacular name } with **source identifier** (B.3.8.10), **country identifier** (B.3.8.9), **language identifier** (B.3.8.8), **script identifier** (3.3).

5.3.4 hasSynonym

semantic link (A.2.2.3) between a certain name and other name(s) within the relation of **synonymy** (B.3.4.19)

NOTE 1 Occurrence of **synonymy** (B.3.4.19) may be classified three types: (i) **official name** (5.2.1) and other **official names** (5.2.1), a certain **scientific name** (5.2.3) and other **scientific names** (5.2.3), (ii) a certain **vernacular name** (5.2.2) and other **vernacular names** (5.2.2), (iii) a certain **vernacular name** (5.2.2) and **official names** (5.2.1) or **scientific names** (5.2.3).

NOTE 2 **polysemes** (B.3.4.24) also occur in some cases.

5.3.5 designatesHB

semantic link (A.2.2.3) between **official name** (5.2.1) and the herbal medicament (3.2) which **official name** (5.2.1) designates, or, **semantic link** (A.2.2.3) between **vernacular name** (5.2.2) and the herbal medicament (3.2) which **vernacular name** (5.2.2) designates

NOTE There are lots of **synonyms** (B.3.4.19), **polysemes** (B.3.4.24), and **homonyms** (B.3.4.25). A **vernacular name** (5.2.2) often designates **origin** (5.2.4), the **source** (5.2.7) from it, and the herbal medicament (3.2) made of the **source** (5.2.7).

5.3.6 designatesOrigin

semantic link (A.2.2.3) between **scientific name** (5.2.3) and **origin** (5.2.4) which **scientific name** (5.2.3) designates, or, **semantic link** (A.2.2.3) between **vernacular name** (5.2.2) and **origin** (5.2.4) which **vernacular name** (5.2.2) designates

NOTE There are lots of **synonyms** (B.3.4.19), **polysemes** (B.3.4.24), and **homonyms** (B.3.4.25). A **vernacular name** (5.2.2) often designates **origin** (5.2.4), the **source** (5.2.7) from it, and the herbal medicament (3.2) made of the **source** (5.2.7).

5.3.7 designatesSource

semantic link (A.2.2.3) between **official name** (5.2.1) and **source** (5.2.7) which **official name** (5.2.1) designates, or, **semantic link** (A.2.2.3) between **vernacular name** (5.2.2) and **source** (5.2.7) which **vernacular name** (5.2.2) designates

NOTE There are lots of **synonyms** (B.3.4.19), **polysemes** (B.3.4.24), and **homonyms** (B.3.4.25). A **vernacular name** (5.2.2) often designates **origin** (5.2.4), the **source** (5.2.7) from it, and the herbal medicament (3.2) made of the **source** (5.2.7).

5.3.8 isMadeOfSource

semantic link (A.2.2.3) between the herbal medicament (3.2) and **source** (5.2.7) of which the herbal medicament (3.2) is made of

NOTE 1 **source** (5.2.7) shall be qualified by **part of origin** (3.11) and **source** (5.2.4), and recommended with **harvest** (5.2.6) and **basic characteristics** (5.2.9). In this **context** (B.3.6.10), **scientific name** (5.2.3) of **origin** (5.2.4) shall be referred as a result.

NOTE 2 Every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.9 isPartOfOrigin

semantic link (A.2.2.3) between **source** (5.2.7) and **origin** (5.2.4) of which **source** (5.2.7) is

NOTE 1 **origin** (5.2.4) shall be qualified with: { kingdom }, { part of interest }; and { scientific name }, { botanical feature }.

NOTE 2 Every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.10 predetermines

semantic link (A.2.2.3) between **origin** (5.2.4) and **source** (5.2.7) of which characteristics **origin** (5.2.4) genetically predetermines, as a consequence, especially biomedical active **substances** (3.16) that **source** (5.2.7) contains

5.3.11 hasBotanicalFeature

semantic link (A.2.2.3) between **origin** (5.2.4) and **botanical feature** (5.2.5) which **origin** (5.2.4) has

NOTE 1 **botanical feature** (5.2.5) shall be qualified with, but not limited to: { habit }, { geographical distribution }, { morphology }, { size }, { flowering time }, { vegetation }, { life cycle }.

NOTE 2 In monographs or textbooks on identification of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.12 isIdentifiedByBotanicalFeature

semantic link (A.2.2.3) between **origin** (5.2.4) and **botanical feature** (5.2.5) by which **origin** (5.2.4) is identified

NOTE 1 In rarely, **designation** (B.3.4.1) with **binomial system** (3.7) with suffixed cannot identify living things. In such case, other **designator** (B.3.4.1) and/or **botanical feature** (5.2.5) **characterizing category** (A.2.3.3) may be utilized in order to identify **origin** (5.2.4), as a result, in identification of **source** (5.2.7) and HB-SNM (4.3) **object** (B.3.1.1).

NOTE 2 Ordinary people who harvest **natural materials** (3.1) do not necessarily use **scientific names** (5.2.3) in **binomial system** (3.7) but **vernacular names** (5.2.2) and **botanical features** (5.2.5). Anyway, **scientific names** (5.2.3) are also defined majorly from morphological features.

5.3.13 isCharacterizedByHarvest

semantic link (A.2.2.3) between **source** (5.2.7) and **harvest** (5.2.6) by which **source** (5.2.7) is characterized

NOTE 1 **harvest** (5.2.6) shall be qualified with, but not limited to: { region }, { season }, { weather }, { age }, { condition }, { cultivation }; and { initial procedure }.

NOTE 2 In monographs or textbooks on identification and/or quality of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.14 isIdentifiedByBasicCharacteristics

semantic link (A.2.2.3) between the herbal medicament (3.2) and **basic characteristics** (5.2.9) by which the herbal medicament (3.2) may be identified, or, **semantic link** (A.2.2.3) between **source** (5.2.7) and **basic characteristics** (5.2.9) by which **source** (5.2.7) may be identified

NOTE Ordinary people who trade **source** (5.2.7) or the herbal medicament (3.2) do not necessarily use **scientific names** (5.2.3) in **binomial system** (3.7) or **official names** (5.2.1), but **vernacular names** (5.2.2) and **basic characteristics** (5.2.9).

5.3.15 providesConstituent

semantic link (A.2.2.3) between **source** (5.2.7) and **constituent** (5.2.10) to which **source(s)** (5.2.7) provide(s)

NOTE 1 **constituent** (5.2.10) shall be qualified with: { substance name }, { substance structure }, { related substances }, { physical characteristics }, { chemical characteristics }; and { biomedical effect }.

NOTE 2 In official documents, monographs or textbooks on identification and/or pharmacological aspect of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.16 isProcessedByProcessing

semantic link (A.2.2.3) between **source** (5.2.7) and **processing** (5.2.8) by which **source** (5.2.7) is processed

NOTE 1 **processing** (5.2.8) shall be qualified with **processing type** (3.13), **processing method** (3.14) and **adjuvant material** (3.15).

NOTE 2 In monographs or textbooks on identification and/or quality of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.17 hasBasicCharacteristics

semantic link (A.2.2.3) between the herbal medicament (3.2) and **basic characteristics** (5.2.9) which the herbal medicament (3.2) has, or, **semantic link** (A.2.2.3) between **source** (5.2.7) and **basic characteristics** (5.2.9) which **source** (5.2.7) has

NOTE 1 **basic characteristics** (5.2.9) shall be qualified with, but not limited to: { shape }, { size }, { color }, { gloss }, { texture }, { heaviness }, { smell }, { taste }, { condition }.

NOTE 2 In monographs or textbooks on identification and/or quality of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3). In this **context** (B.3.6.10), **basic characteristics** (5.2.9) of **source** (5.2.7) and those of HB-SNM (4.3) should be described separately in order to avoid confusion.

5.3.18 areAffectedByProcessing

semantic link (A.2.2.3) between **basic characteristics** (5.2.9) and **processing** (5.2.8) by which **basic characteristics** (5.2.9) are affected

NOTE 1 **basic characteristics** (5.2.9) shall be qualified with, but not limited to: { shape }, { size }, { color }, { gloss }, { texture }, { heaviness }, { smell }, { taste }, { condition }.

NOTE 2 In monographs or textbooks on identification and/or quality of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3). In this **context** (B.3.6.10), **basic characteristics** (5.2.9) of **source** (5.2.7) and those of HB-SNM (4.3) should be described separately in order to avoid confusion.

5.3.19 isCharacterizedByProcessing

semantic link (A.2.2.3) between the herbal medicament (3.2) and **processing** (5.2.8) by which the herbal medicament (3.2) characterized

NOTE 1 **processing** (5.2.8) shall be qualified with **processing type** (3.13), **processing method** (3.14) and **adjuvant material** (3.15).

NOTE 2 **processing** (5.2.8) affects **basic characteristics** (5.2.9) of **source** (5.2.7), and may modify **constituent** (5.2.10) provided from **source** (5.2.7). Therefore both **basic characteristics** (5.2.9) and **constituent** (5.2.10) after **processing** (5.2.8) should be separately described in this **context** (B.3.6.10).

NOTE 3 In monographs or textbooks on processing and/or identification of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.20 isFollowedByProcessing

semantic link (A.2.2.3) among **processing(s)** (5.2.8) by which the previous **processing** (5.2.8) is followed

NOTE 1 **processing** (5.2.8) shall be qualified with **processing type** (3.13), **processing method** (3.14) and **adjuvant material** (3.15).

NOTE 2 Usually, a **processing** (5.2.8) is performed in a series of **processings** (5.2.8).

NOTE 3 In monographs or textbooks on processing and/or identification of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.21 modifiesConstituent

semantic link (A.2.2.3) between **processing** (5.2.8) and **constituent** (5.2.10) which **processing** (5.2.8) may modifies, destroys or degrade

NOTE 1 **constituent** (5.2.10) shall be qualified with: { substance name }, { substance structure }, { related substances }, { physical characteristics }, { chemical characteristics }; and { biomedical effect }.

NOTE 2 In monographs or textbooks on identification and/or pharmacological aspect of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.22 containsConstituent

semantic link (A.2.2.3) between the herbal medicament (3.2) and **constituent** (5.2.10) which the herbal medicament (3.2) contains

NOTE 1 **constituent** (5.2.10) shall be qualified with: { substance name }, { substance structure }, { related substances }, { physical characteristics }, { chemical characteristics }; and { biomedical effect }.

NOTE 2 In official documents, monographs or textbooks on identification and/or pharmacological aspect of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.23 hasBiomedicalEffect

semantic link (A.2.2.3) between the herbal medicament (3.2) and **biomedical effect** (5.2.12) which the herbal medicament (3.2) has, or, **semantic link** (A.2.2.3) between **constituent** (5.2.10) and **biomedical effect** (5.2.12) which **constituent** (5.2.10) has

NOTE 1 **biomedical effect** (5.2.12) shall be qualified with: **medical domain type** (3.17), { effect type }, { effect }, { precondition }.

NOTE 2 Every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.24 arisesFromConstituent

semantic link (A.2.2.3) between **biomedical effect** (5.2.12) and **constituent** (5.2.10) from which **biomedical effect(s)** (5.2.12) arise(s)

NOTE 1 **constituent** (5.2.10) shall be qualified with: { substance name }, { substance structure }, { related substances }, { physical characteristics }, { chemical characteristics }; and { biomedical effect }.

NOTE 2 In documents on pharmacological aspect of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.25 dependsOnDosage

semantic link (A.2.2.3) between **biomedical effect** (5.2.12) and **dosage** (5.2.13) on which **biomedical effect(s)** depend(s)

NOTE 1 **dosage** (5.2.13) shall be qualified with, but not limited to: { dose }, { dose unit }, { dose form }, { route }, { frequency }, { period }.

NOTE 2 In documents on biomedical effects of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.26 hasLaboratoryTestProfile

semantic link (A.2.2.3) between the herbal medicament (3.2) and **laboratory test profile** (5.2.11) which the herbal medicament (3.2) has

NOTE 1 **laboratory test profile** (5.2.11) shall be qualified with: { test purpose }, { test method }, { test procedure }, { reference data }, { result(s) of a test }, { permissible limit }, { system adequacy }.

NOTE 2 In official documents, monographs or textbooks on identification and/or pharmacological aspect of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.27 detectsConstituent

semantic link (A.2.2.3) between **laboratory test profile** (5.2.11) and **constituent** (5.2.10) which **laboratory test profile** (5.2.11) detects

NOTE 1 **constituent** (5.2.10) shall be qualified with: { substance name }, { substance structure }, { related substances }, { physical characteristics }, { chemical characteristics }; and { biomedical effect }.

NOTE 2 In official documents, monographs or textbooks on identification and/or purity of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.28 isIdentifiedByLaboratoryTestProfile

semantic link (A.2.2.3) between the herbal medicament (3.2) and **biomedical effect** (5.2.12) by which the herbal medicament is identified by its **constituent** (5.2.10)

NOTE In this **context** (B.3.6.10), identification means to identify what it truly is, or discriminate forgeries.

5.3.29 isInspectedByLaboratoryTestProfile

semantic link (A.2.2.3) between the herbal medicament (3.2) and **biomedical effect** (5.2.12) by which the herbal medicament (3.2) is inspected by its **constituent** (5.2.10)

NOTE In this **context** (B.3.6.10), inspection means that inspection of impurities, amount of biomedical active **substances** (3.16), degree of biomedical activities, and so on.

6 Herbal medicaments composed of the herbal medicaments made of single natural material

6.1 Overview

In the formal concept representation system (A.2.5.1) for the subject field (B.3.1.2) of the herbal medicaments (3.2) that is composed of HB-SNMs (4.4) [B], the herbal medicaments (3.2) that is composed of HB-SNMs (4.4) [B] has semantic links (A.2.2.3) to the following characterizing categories (A.2.3.3): Required HB-SNM (6.2.2) [A], Constituent (5.2.10), Laboratory Test Profile (5.2.11), Biomedical Effect (5.2.12), in addition, Official Name (5.2.1) and Vernacular Name (5.2.2).

For identifying the herbal medicaments (3.2) that is composed of HB-SNMs (4.4) [B], additional characterizing categories (A.2.3.3) are required, but they are equivalent to characterizing categories (A.2.3.3) already specified in Clause 5.2.

Semantic links (A.2.2.3) among them are specified in Clause 6.3, except redundancies.

The outline of the relations among mentioned above is illustrated in a concept diagram (B.3.2.12) in Figure 2.

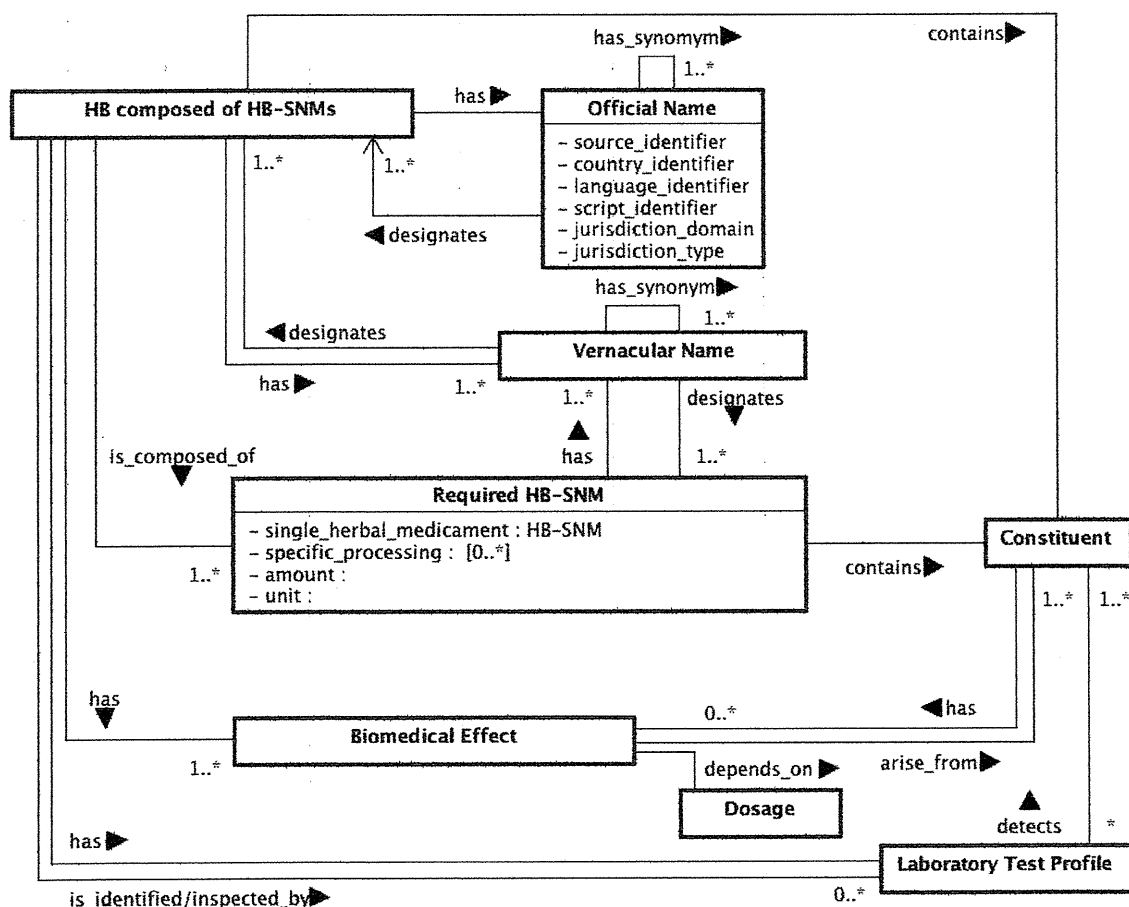


Figure 2 — Characterizing categories for herbal medicaments composed of HB-SNMs

6.2 Characterizing Categories (except redundancies)

6.2.1 List of main categories

Almost all characterizing categories (A.2.3.3) used for expression of herbal medicament (3.2) composed of HB-SNMs (4.4) [B] are same as HB-SNM (4.3) [A] except Required HB-SNM (6.2.2).

- Official Name
- Vernacular Name
- Required HB-SNM
- Constituent
- Biomedical Effect
- Laboratory Test Profile

6.2.2 Required HB-SNM

necessary HB-SNM (4.3) [A] for composing a herbal medicament (3.2) composed of HB-SNMs (4.4) [B], i.e. a formula composed of HB-SNMs (4.4)

NOTE 1 **required HB-SNM** (6.2.2) **characterizing category** (A.2.3.3) that are valid for representation of a herbal medicament (3.2) includes: { HB-SNM (4.3) }, { specifying certain processing }, { amount }, { unit }.

NOTE 2 The representation of **required HB-SNM** (6.2.2) is defined in Cause 5 as HB-SNM (4.3) [A] in this Technical Specification.

NOTE 3 **values** (3.19) for the subordinate **characterizing categories** (A.2.3.3) of **required HB-SNM** (6.2.2) are described in some references listed in bibliography [47,49,51-52] but not limited to them.

NOTE 4 **required HB-SNM** (6.2.2) contains **constituent** (5.2.10) and has **biomedical effect** (5.2.12) by itself. Further expression is described in the previous Cause 5.

6.3 Semantic Links (except redundancies)

6.3.1 List of main semantic links

semantic links (A.2.2.3) used for expression of HB-SNM (4.3) [A] are also used for expression of herbal medicament (3.2) composed of HB-SNMs (4.4) [B], except those are only used for expression of the relations to HB-SNM (4.3) [A], **source** (5.2.7), and **source** (5.2.7) related **characterizing categories** (A.2.3.3).

semantic links (A.2.2.3) of **isComposedOfRequiredHB-SNM** (6.3.2), designatesHBcomposedOfHB-SNMs and designatesRequiredHB-SNM newly appear in the expression of herbal medicament (3.2) composed of HB-SNMs (4.4) [B]. However, the second and the third are essentially same as designatesHB.

- hasOfficialName
- hasVernacularName
- designatesHB (i.e. designatesHBcomposedOfHB-SNMs and designatesRequiredHB-SNM)
- isComposedOfRequiredHB-SNM
- containsConstituent
- hasBiomedicalEffect
- arisesFromConstituent
- detectsConstituent
- hasLaboratoryTestProfile

- isIdentifiedByLaboratoryTestProfile
- isInspectedByLaboratoryTestProfile

6.3.2 isComposedOfRequiredHB-SNM

semantic link (A.2.2.3) between the herbal medicament (3.2) composed of HB-SNMs (4.4) [B] and **required HB-SNM** (6.2.2) of which herbal medicament (3.2) composed of HB-SNMs (4.4) [B] is composed

NOTE 1 **required HB-SNM** (6.2.2) shall be qualified with: { HB-SNM (4.3) }, { specifying certain processing }, { amount }, { unit }.

NOTE 2 Every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

7 Conformance

7.1 Conformance principles

To be conformant with EN 12264:2005 [3] and ISO 17115:2007 [4], any categorial structure for representation of herbal medicaments in a terminological system shall be provided the followings:

- **categories** that organise 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**) authorised 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**.

7.2 Goal of the terminological system for which the categorial structure is set

The goal of each herbal medicaments terminology used in terminological system(s) of health, healthcare and biomedical science shall be defined by the users and make statement on situations and applications for which the categorial structure is intended and the limits of use.

EXAMPLE controlled vocabulary, comparison with another terminological system for coding, some kinds of official document, monograph for domain experts, product for clinicians, textbook for education

7.3 List of minimal domain constraint

The list shall contain the different semantic links clause 5.3 or 6.3, and the different categories from specified clause 5.2 or 6.2, that are valid and necessary for the intended goal of setting categorial structures in a terminological system for representation of herbal medicaments.

7.4 Conformity to this Technical Specification

A categorial structure for a terminology representing herbal medicaments claiming conformance to this Technical Specification shall provide the information described in clause 7.1, 7.2, and 7.3, and shall be conformant to the following minimum rules:

- a herbal medicament made of single natural material [**A**] shall consist of **origin** (5.2.4), **processing** (5.2.8), **constituent** (5.2.10) and **biomedical effect** (5.2.12), with related **characterizing categories** (A.2.3.3) if necessary for detailed description in order to achieve the intended goal.
- a herbal medicament composed of the herbal medicaments made of single natural material [**B**] shall consist of **required HB-SNM** (6.2.3), **constituent** (5.2.10) and **biomedical effect** (5.2.12), with related **characterizing categories** (A.2.3.3) if necessary for detailed description in order to achieve the intended goal.

Annex A (normative)

Selected definitions from ISO 17115:2007

The following terms and definitions are selected from ISO 17115:2007. They are included here as background to the key terms and definitions in Clause 3 of this Technical Specification. The numbering in this Annex reflects the numbering in ISO 17115:2007, for consistency.

A.1 Specialization

A.2.1.1

specialize

form a more **specific concept** (B.3.2.16) [by constraining the **extension** (B.3.2.8) of a more **generic concept** (B.3.2.15)]

EXAMPLE 1 Infection that hasCause Bacteria can be specialized to Infection that hasCause.

EXAMPLE 2 Pneumococcus Hepatitis can be specialized to NonA-NonB-hepatitis.

NOTE 1 To specialize is to increase the intension and decrease the extension of a concept. The more **specific concept** (B.3.2.16) has a larger **intension** (B.3.2.9), but a smaller extension than the **general concept** (B.3.2.3). Specialization and generalization can be achieved in many ways, including replacing a semantic link with a more specific semantic link (and vice versa for generalization).

NOTE 2 The more specific concept has a broader intension, but a narrower extension than the generic concept.

NOTE 3 Ways to specialize concepts include

- adding one or more **composite characteristics** (A2.2.1),
- replacing the **characterizing concept** (A2.2.2) in one or more **characteristics** (B.3.2.4) with a more **specific concept** (B.3.2.16), and
- forming an intersection of two concepts (where the intersection is a specialization of both the "parents").

NOTE 4 The opposite is **generalize** (2.1.2).

A.2.1.2

generalize

form a more **generic concept** (B.3.2.15) [that represents a superset of the **extension(s)** (B.3.2.8) of one or more **specific concepts** (B.3.2.16)]

EXAMPLE Infection that hasCause Pneumococcus can be generalized to Infection that hasCause Bacterium.

NOTE 1 To generalize is to decrease the **intension** (B.3.2.9) and increase the extension of a concept. Specialization and generalization can be achieved in many ways, including replacing a semantic link with a less specific semantic link (and vice versa for specialization).

NOTE 2 This can be done by removing one or more **characteristics** (B.3.2.4) or by replacing the **characterizing concept** (A2.2.2) in one or more characteristics with a more generic concept.

NOTE 3 The opposite is **specialize** (A2.1.1).

A.2.1.3

level of specialization

property of a **concept** (B.3.2.1) reflecting the number of and detail of **characteristics** (B.3.2.4) in its **intension** (B.3.2.9)

NOTE A **specific concept** (B.3.2.16) has a high level of specialization and a fine granularity; a **generic concept** (B.3.2.15) has low level of specialization and coarse granularity.

A.2.1.4**generic concept****category**

concept (B.3.2.1) in a **generic relation** (B.3.2.21) having the narrower **intension** (B.3.2.9) [and the wider **extension** (B.3.2.8)]

A.2 Formal representation of characteristics**A.2.2.1****composite characteristic****qualifier**

representation of a **characteristic** (B.3.2.4)

EXAMPLE hasCause Bacteria; Location = LeftUpperLobeOfLung

NOTE 1 Typically expressed by a **semantic link** (A.2.2.3) and a **characterizing concept** (A.2.2.2)

NOTE 2 Can be compared to an attribute-value pair in a **compositional system** (A.2.5.2)

NOTE 3 A qualifier often denotes **characteristics** with a small simple **characterizing generic concept** (A.2.3.3), such as laterality (left or right), or severity (low, moderate, high).

A.2.2.2**characterizing concept**

concept (B.3.2.1) that is referenced by a **semantic link** (A.2.2.3) in a **composite characteristic** (A.2.2.1)

EXAMPLES "Bacterium" in the construct "Disease that hasCause Bacterium"; "Yellow" in the construct "SkinLesion that hasColor Yellow".

A.2.2.3**semantic link**

formal representation of a directed **associative relation** (B.3.2.23) or **partitive relation** (B.3.2.22) between two **concepts** (B.3.2.1),

EXAMPLES hasLocation (with inverse isLocationOf); isCauseOf (with inverse hasCause)

NOTE 1 This includes all relations except the **generic relation** (B.3.2.21).

NOTE 2 A semantic link always has an inverse, i.e. another semantic link with the opposite direction.

NOTE 3 A semantic link can be part of a **composite characteristic** (A.2.2.1) where it describes the role of the **characterizing concept** (A.2.2.2). Similarly, it defines the role of a **characterizing generic concept** (A.2.3.3) in a sanctioned **characteristic** (B.3.2.4).

A.3 Sanctioned specialization**A.2.3.1****sanctioned characteristic**

formal representation of a **type of characteristic** (B.3.2.5)

EXAMPLE 1 performedUsing <INSTRUMENT>; hasLocation <BodyPartOrImplantedDevice>.

EXAMPLE 2 "CauseOfInflammation canBe set{ bacteria, virus, parasite, autoimmune, chemical, physical }", where "canBe" is the **semantic link** (A.2.2.3), and "set{ bacteria, virus, parasite, autoimmune, chemical, physical }" is the **characterizing generic concept** (A.2.3.3)

NOTE A sanctioned characteristic is typically made up of a combination of a semantic link and a characterizing generic concept, and can be used in **domain constraints** (A.2.3.2).

A.2.3.2

domain constraint

sanction rule prescribing the set of **sanctioned characteristics** (A.2.3.1) that are valid to **specialize** (A.2.1.1) a **concept** (B.3.2.1) in a certain **subject field** (B.3.1.2)

EXAMPLE "Infection possibly hasLocation SkeletalStructure" describes that an infection in a certain context can be located in a structure that is a kind of skeletal structure

NOTE 1 The rule describes the set of sanctioned **characteristics** (B.3.2.4) by combining the **semantic link** (A.2.2.3) and the **characterizing generic concept** (A.2.3.3) it links to, possibly by enumeration of the concepts in the characterizing generic concept

NOTE 2 Different levels of sanctioning are possible (e.g. conceivable, sensible, normal, usuallyInTheContextOf, necessary).

A.2.3.3

characterizing generic concept

characterizing category

value domain

formal category (A.2.5.3) whose specialisation by a **domain constraint** (A.2.3.2) is allowed to be used as **characterizing concept** (A.2.2.2) in a particular context

EXAMPLE <INFECTIOUS_ORGANISM> = {bacterium, virus, parasite}, in the context of "Infection that hasCause INFECTIOUS_ORGANISM".

NOTE The context includes a **superordinate concept** (B.3.2.13) and a **semantic link** (A.2.2.3)

A.4 Formal concept representation

A.2.4.1

compositional concept representation

intensional definition (B.3.3.2) of a **concept** (B.3.2.1) using as **delimiting characteristics** (B.3.2.7) one or more **composite characteristics** (A.2.2.1)

NOTE This allows inference and subsumption within a **compositional system** (A.2.5.2). It is usually expressed in a formalism, such as description logic.

A.2.4.2

axiomatic concept representation

axiom concept representation present in a **formal system** (A.2.5.1) without a **formal definition** (A.2.4.3)

EXAMPLES Liver; Incision act; Pain

NOTE This often represents a "natural kind" from the perspective of a particular terminology system; i.e. something that "just exists". It may have a definition or description outside the system but by choice, this is not represented in the system.

A.2.4.3

formal definition

definition within a **formal system** (A.2.5.1)

NOTE This can be done by a **compositional concept representation** (A.2.4.1) or a formal **extensional definition** (B.3.3.3)

NOTE It is usually automatically processable and governed by explicit rules