International Standard

ISO 22532

Health informatics — Identification of medicinal products — Core vocabulary

Informatique de santé — Identification des produits destinés à des fins médicinales — Vocabulaire de base

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Contents

Page

Foreword

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The documents on the identification of medicinal products (IDMP) developed by the ISO/TC 215 consists in five international standards and four technical specifications. When these documents were developed, a special attention was given to use identical terms and definitions; in the meantime, successive revision of these documents has shown that it becomes challenging to keep terms and definition perfectly aligned. Further, in the meantime, new technical specifications have been developed or are in development, which will inherit and refer to the IDMP core definitions and therefore remove the risk of misalignment.

IDMP core definitions are used in at least three of the ISO standards and technical specifications on IDMP. The need to group core definitions in one single International Standard helps keep the alignment of core definitions over time and simplifies the work of all interested parties (standards developers and implementers).

If a term can designate more than one concept (homonymy), usually different concepts in different contexts, the context for the given definition is stated in conformance with the ISO/IEC Directives, Part 2, 16.5.6. In that case, the context ("domain") precedes the definition text enclosed between angle parentheses (<context>). This indicates that the same term may occur in another context with another definition, designating another concept, in the same document or in another document.

Each term has its own defining triples (ontology), which provides the hook for computer understanding of each definition.

Health informatics — Identification of medicinal products — Core vocabulary

1 Scope

This document defines the terms used in the ISO standards on the identification of medicinal products (IDMP) and their related technical specifications.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

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

3.1
adjuvant
component that potentiates either the immune response to an antigen or modulates it towards the desired immune response, or both

3.2
administrable dose form
pharmaceutical administrable dose form
pharmaceutical dose form (3.37) for administration to the patient

Note 1 to entry: Transformation of the *manufactured items* (3.19) and their corresponding *manufactured dose forms* (3.18) can be necessary before administration.

Note 2 to entry: The administrable dose form is identical to the manufactured dose form in cases where no transformation of the manufactured item is necessary (i.e. where the manufactured item is equal to the *pharmaceutical product* (3.38)).

Note 3 to entry: semantic triples (Ontology):

— ("administrable dose form", "is a type of", "pharmaceutical dose form")

— ("administrable dose form", "is for", "administration to the patient")

— ("administrable dose form", "is equal to", "manufactured dose form ", "when", "no transformation")

3.3
allergen
substance (3.56) used as *ingredient* (3.13) or in a device capable of stimulating a type-I hypersensitivity and allergic reaction

Note 1 to entry: The active allergens are *structurally diverse substances* (3.55) derived from biological matrices. In several instances, if the allergenic protein responsible for the allergenic response has been isolated and characterised in the majority of patients, then the substance is classified as protein.

Note 2 to entry: semantic triples (Ontology):

— ("allergen", "is a type of", "material")

— ("allergen", "used as", "ingredient or in a device")

— ("allergen", "capable of", "stimulating a type-I hypersensitivity")

— ("allergen", "capable of", "stimulating an allergic reaction")

— ("allergen", "is derived from", "biological matrices")

— ("allergen", "is classified as", "protein")

3.4
co-crystals
homogenous (single phase) crystalline structures made up of two or more components in a definite stoichiometric ratio where the arrangement in the crystal lattice is not based on ionic bonds

Note 1 to entry: semantic triples (Ontology):

— ("co-crystals", "are", "homogenous crystalline structures")

— ("co-crystals", "made up of", "two or more components in a definite stoichiometric ratio")

— ("co-crystals", "arrangement in the crystal lattice", "not based on ionic bonds")

— ("co-crystals", "are used as", "alternative solid-state forms in drug development")

— ("co-crystals", "can improve", "solid state properties (such as solubility, hygroscopicity and stability)")

— ("solid state properties", "includes", "solubility, hygroscopicity and stability")

— ("co-crystals", "can improve", "manufacturing behaviour (e.g. compaction, flowability, filterability, etc.)")

— ("manufacturing behaviour", "includes", "compaction, flowability, filterability, etc.")

— ("co-crystals", "are based on", "hydrogen bonding interactions without the transfer of hydrogen ions to form salts")

3.5
combined pharmaceutical dose form
dose form consisting of two or more *manufactured items* (3.19) that are intended to be combined in a specific way to produce a single *pharmaceutical product* (3.38)

EXAMPLE The term “powder and solvent for solution for injection” articulates a combined pharmaceutical dose form wherein the *medicinal product* (3.27) comprises a powder and a solvent, both intended for solution for injection. Once combined, these items produce an *administrable dose form* (3.2): “solution for injection”.

Note 1 to entry: This term encompasses detailed information regarding each item’s *manufactured dose form* (3.18) as well as the final administrable dose form of the compounded pharmaceutical product. In accordance with the standards outlined in ISO 11239 and ISO/TS 20440, the combined pharmaceutical dose form is characterized by a distinctive term and a corresponding term *identifier* (3.12), each of which is expressed by a “display name” and a “code” within an XML structure. This combined form is identified and coded within the established terminology framework, reflecting the comprehensive nature of the product. In essence, the combined pharmaceutical dose form is an integral term utilized in the identification and classification of complex medicinal products that are composed of multiple components, which, when combined as directed, result in a final pharmaceutical product ready for administration to the patient.

Note 2 to entry: The combined pharmaceutical dose form includes information on the manufactured dose form of each manufactured item and the administrable dose form of the pharmaceutical product,

Note 3 to entry: semantic triples (Ontology):

— ("combined pharmaceutical dose form", "is composed of", "two or more manufactured items")

— ("combined pharmaceutical dose form", "is intended to", "produce a single pharmaceutical product")

— ("combined pharmaceutical dose form", "includes information on", "the manufactured dose form of each manufactured item")

— ("combined pharmaceutical dose form", "includes information on", "the administrable dose form of the pharmaceutical product")

— ("combined pharmaceutical dose form", "is characterized by", "a distinctive term and a corresponding term identifier")

— ("combined pharmaceutical dose form", "is expressed by", "a "display name" and a "code" within an XML structure")

— ("combined pharmaceutical dose form", "is utilized in", "the identification and classification of complex medicinal products")

— ("combined pharmaceutical dose form", "results in", "a final pharmaceutical product ready for administration to the patient")

3.6
confidentiality
<medicinal products> safety and privacy of a piece of information or an entity

EXAMPLE Content of the information can be trusted by the reader. The authorized reader can trust that no unauthorised persons can access the information. This means that the information can contain enterprise secrets which are not available to unauthorised persons, personal information cannot be accessed without proper credentials and the information can always be trusted.

Note 1 to entry: Confidentiality is a property especially of information which means that the information is available only to authorized persons.

Note 2 to entry: In certain *jurisdictions* (3.16) there is a distinct difference between confidentiality intended as safety and accuracy of information and confidentiality intended as privacy of information.

Note 3 to entry: semantic triples (Ontology):

— ("confidentiality", "is related to", "safety and privacy", "of", "a piece of information")

— ("confidentiality", "implies", "available only to authorised persons")

— ("confidentiality", "ensures", "no unauthorised persons can access the information")

— ("confidentiality", "protects", "enterprise secrets")

— ("confidentiality", "protects", "personal information cannot be accessed unless proper credentials")

3.7
constituent
substance present within a *specified substance* (3.49) or *mixture* (3.30)

EXAMPLE The substance triamcinolone acetonide is the parent (constituent) substance of the specified substance group 1 substance, triamcinolone acetonide, micronized.

Note 1 to entry: Constituents can be impurities, degradants, *extraction solvents* (3.11), *vehicles* (3.58), active markers or signature substances, parent substances or single substances mixed together to form a *multi-substance material* (3.34).

Note 2 to entry: Constituents shall have an associated role and amount at the specified substance group 1 information model. Constituent specifications shall be used to describe components as well as limits on impurities or related substances for a given *material* (3.24).

Note 3 to entry: Constituent component is part of a mixture belonging to a homologous group of individual components, described as parent substances for the manufacture of an allergenic extract.

Note 4 to entry: semantic triples (Ontology):

— ("constituent", "is", "a substance")

— ("constituent", "can be present within", " specified substance")

— ("constituent", "can be present within", "mixture")

— ("constituent", "may have", "an amount")

— ("constituent", "shall have", "an associated role")

— ("constituent", "can have role of", "impurities")

— ("constituent", "can have role of", "degradants")

— ("constituent", "can have role of", "extraction solvents")

— ("constituent", "can have role of", "vehicles")

— ("constituent", "can have role of", "active markers")

— ("constituent", "can have role of", "signature substances")

— ("constituent", "can be part of", "a multi-substance material")

— ("constituent", "is part of", "a mixture belonging to a homologous group of individual components")

— ("constituent", "can be", "impurities, degradants, extraction solvents, vehicles, active markers or signature substances, parent substances or single substances mixed together to form a multi-substance material")

3.8
controlled vocabulary
controlled terminology
finite set of predetermined values that constitute the exclusive permissible options for a given data item

Note 1 to entry: These values ensure consistency and standardization in data representation and can manifest as codes, textual descriptions, or numeric designations.

Note 2 to entry: The set of values is restricted in scope to facilitate data accuracy, interoperability, and conformance with established data standards.

Note 3 to entry: Controlled vocabularies may encompass a taxonomy that organizes terms hierarchically or relationally, and any subset of terms within such a taxonomy may be referred to as a sub-vocabulary.

Note 4 to entry: When relevant, the definition and concept of controlled vocabulary are adapted to external glossary such as from the CDISC (Clinical Data Interchange Standards Consortium) clinical research glossary, ensuring alignment with clinical research data standards and practices.

Note 5 to entry: semantic triples (Ontology):

— ("controlled vocabulary", "is", "a finite set of predetermined values")

— ("controlled vocabulary", "constitutes", "the exclusive permissible options", "for", "a given data item")

— ("controlled vocabulary", "ensures", "consistency")

— ("controlled vocabulary", "ensures", "standardization")

— ("controlled vocabulary", "support", "data representation")

— ("controlled vocabulary", "can manifest as", "codes")

— ("controlled vocabulary", "can manifest as", "textual descriptions")

— ("controlled vocabulary", "can manifest as", "numeric designations")

— ("controlled vocabulary", "is restricted in scope to facilitate", "data accuracy, interoperability, and conformance with established data standards")

— ("controlled vocabulary", "is restricted in scope to facilitate", "interoperability")

— ("controlled vocabulary", "is restricted in scope to facilitate", " compliance", "with", "established data standards")

— ("controlled vocabulary", "may encompass", "a taxonomy")

— ("controlled vocabulary", "may refer to", "a sub-vocabulary")

— ("sub-vocabulary", "is part of", "taxonomy")

— ("controlled vocabulary", "is adapted to", "external glossary")

— ("CDISC clinical research glossary", "is", "an external glossary")

— ("controlled vocabulary", "provides", "controlled term")

— ("controlled term", "has", "term identifier")

3.9
country
<medicinal products> recognized territorial entity

Note 1 to entry: The designation of a country is critical in regulatory contexts to ensure clarity and uniformity in the identification of *jurisdictions* (3.16) pertaining to pharmaceutical and clinical activities.

Note 2 to entry: For the purposes of international harmonization, the ISO 3166-1 alpha-2 code elements serve as the standardized nomenclature for the representation of countries and significant geographic areas.

Note 3 to entry: In certain instances, the code “EU” is used to represent the European Union within the ISO 3166-1 framework. While the European Union is not a country, this designation is reserved to signify the collective member states in contexts where unified regulatory or marketing authorisation is applicable.

Note 4 to entry: A country is designated using the two-letter codes as defined by the ISO 3166-1 alpha-2 standard.

Note 5 to entry: Information about the *medicinal product* (3.27) may be marketing authorisation, *measurement points* (3.25), medicinal product applicability, or clinical trial authorisation, is specified.

Note 6 to entry: semantic triples (Ontology):

— ("country", "is", "a recognized territorial entity")

— ("country", "is used to characterize", "medicinal product")

— ("country", "is used to characterize", "marketing authorization")

— ("country", "is used to characterize", "clinical trial authorization")

— ("country", "is used to characterize", "measurement points")

— ("country", "is used to characterize", "medicinal product applicability")

— ("country", "is critical in", "regulatory contexts")

— ("country", "is represented by", "the ISO 3166-1 alpha-2 code elements")

— ("the ISO 3166-1 alpha-2 code elements", "are used for", "the purposes of international harmonization")

3.10
critical process parameter
process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality

Note 1 to entry: A *manufacturing* (3.20) parameter is considered “critical” and necessary for the production of *substance* (3.56) or *specified substance* (3.49), e.g. inclusion of chromatographic step for removal or reduction of impurities, viruses, etc.

Note 2 to entry: The critical process is tied to the production method type.

Note 3 to entry: Adapted from Reference [12].

Note 4 to entry: semantic triples (Ontology):

— ("critical process parameter", "is", "a process parameter")

— ("critical process parameter", "has", "a variability")

— ("critical process parameter variability", "has", "an impact on a critical quality attribute")

— ("critical process parameter", "should be", "monitored or controlled")

— ("critical process parameter", "is linked to", "production process")

— ("critical process parameter monitoring or controlling", "ensure", " the desired quality")

— ("critical process parameter", "is tied to", "the production method type")

— ("critical process parameter", "is defined in accordance with", "the ICH Q8 guideline")

3.11
extraction solvent
solvent which is used for the extraction process

Note 1 to entry: semantic triples (Ontology):

— ("extraction solvent", "is a type of", "solvent")

— ("extraction solvent", "is used for", "the extraction process")

3.12
identifier
descriptor adequate to represent an entity uniquely in a specific context, ensuring its distinction from other entities

Note 1 to entry: In the realm of *medicinal products* (3.27), an identifier consists of a set of identifying characteristics that, when combined, unambiguously distinguish a medicinal product, *pharmaceutical product* (3.38), substance, *specified substance* (3.49), *route of administration* (3.47), *pharmaceutical dose form* (3.37), or any other element necessitating unique recognition.

Note 2 to entry: Identifiers may be represented through various forms such as alphanumeric codes, global unique identifiers (GUID) or universally unique identifier (UUID), or other internationally accepted coding systems. When applied to organizations or locations, an international system for unique identifiers may be utilized in accordance with regional regulatory requirements.

Note 3 to entry: The purpose of an identifier is to provide clarity and precision in the tracking, regulation, and management of entities within the pharmaceutical environment, as established by recognized standards.

Note 4 to entry: semantic triples (Ontology):

— ("identifier", "is", "a descriptor")

— ("identifier", "is characterized", "one entity or record")

— ("identifier", "is bound to", "a specific context")

— ("identifier", "ensures", "distinct identification")

— ("identifier", "characterizes", "medicinal product")

— ("identifier", "characterizes", "pharmaceutical product")

— ("identifier", "characterizes", "substance")

— ("identifier", "characterizes", "specified substance")