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## Introduction

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|                  |                        |
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| 1  | 2                                          | (3)                          | 4               | 5                                                                                                                                  | (6)                                                                      | 7                                                  |
|----|--------------------------------------------|------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------|
| MB | Clause No./ Subclause No./Annex (e.g. 3.1) | Paragraph/ Figure/Table/Note | Type of comment | Comment (justification for change) by the MB                                                                                       | Proposed change by the MB                                                | Secretariat observations on each comment submitted |
|    | 3.1                                        | Definition 1                 | ed              | Definition is ambiguous and needs clarifying.                                                                                      | Amend to read '...so that the mains connector to which no connection...' |                                                    |
|    | 6.4                                        | Paragraph 2                  | te              | The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK. | Delete reference to UV photometer.                                       |                                                    |



# DRAFT International Standard

## ISO/DIS 22532

### Health informatics — Identification of medicinal products — Core vocabulary (terms and definitions) for the IDMP Standards

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ISO/TC 215

Secretariat: **ANSI**

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This document is circulated as received from the committee secretariat.

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| Contents          |                            | Page |
|-------------------|----------------------------|------|
| Foreword.....     |                            | iv   |
| Introduction..... |                            | v    |
| 1                 | Scope.....                 | 1    |
| 2                 | Normative references.....  | 1    |
| 3                 | Terms and definitions..... | 1    |
| 3.1               | Definitions.....           | 1    |
| Bibliography..... |                            | 30   |

## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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This document was prepared by Technical Committee ISO/TC 215, Health Informatics.

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 <<link>>.

## Introduction

The series of “Identification of Medicinal Products” (IDMP) 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 IDMP core definitions.

IDMP core definitions are these which are used in at least three of the IDMP series of standards and technical specifications. The need to group core definitions in one single international standard helps keep the alignment of core definitions over the time and simplifies the work of all interested parties (standards developers and implementers) since the core definitions are available in one single place.

If a term can designate more than one concept (homonymy), usually different concepts in different contexts, the context for the given definition should be stated in conformance with the ISO/IEC Directives, part 2, 16.5.6. In that case the context should precede 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.

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# Health informatics — Identification of medicinal products — Core vocabulary (terms and definitions) for the IDMP Standards

## 1 Scope

This document provides the comprehensive list of terms and definitions (“core definitions”) used in the IDMP standards and their related standards and technical specifications.

The purpose is to provide a single reference to the core definitions in each of the IDMP standards and related normative documents, as well as in technical reports.

## 2 Normative references

There are no normative references in this document.

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

### 3.1 Definitions

#### 3.1.1

##### **adjuvant**

component that potentiates the immune response to an antigen and/or modulates it towards the desired immune response

#### 3.1.2

##### **administrable dose form**

pharmaceutical administrable dose form

pharmaceutical dose form for administration to the patient

Note 1 to entry: Transformation of the manufactured items and their corresponding manufactured dose forms may 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]

- ("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")

### 3.1.3 allergen

substance used as ingredient or in a device capable of stimulating a type-I hypersensitivity and allergic reaction

Note 1 to entry: The active allergens are structurally diverse substance 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.

- ("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")

### 3.1.4 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: Over the last decade, co-crystals have gained considerable attention as alternative solid-state forms in drug development. By making co-crystals of pharmaceutically interesting substances, their solid state properties such as solubility, hygroscopicity and stability may be improved as well as manufacturing behaviour (e.g., compaction, flowability, filterability, etc.). The salt formation is already widely used for this purpose, but with co-crystal formation this can now be achieved also for substances that lack the possibility of salt formation. A principal tool is the hydrogen bond, which is responsible for the majority of directed intermolecular interactions in molecular solids. Co-crystals are multi-component crystals based on hydrogen bonding interactions without the transfer of hydrogen ions to form salts; this is an important feature, since bronsted acid-base chemistry is not a requirement for the formation of a co-crystal.

- ("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")

### 3.1.5 combined pharmaceutical dose form

single term used to describe two or more manufactured items that are intended to be combined in a specific way to produce a single pharmaceutical product

EXAMPLE The term "powder and solvent for solution for injection" articulates a combined pharmaceutical dose form wherein the medicinal product comprises a powder and a solvent, both intended for solution for injection. Once combined, these items produce an injectable solution.

Note 1 to entry: This term encompasses detailed information regarding each item's manufactured dose form as well as the final administrable dose form of the compounded pharmaceutical product. In accordance with the standards outlined in ISO 11239<sup>[1]</sup> and ISO/TS 20440,<sup>[2]</sup> the combined pharmaceutical dose form is characterized by a distinctive term and a corresponding term identifier, 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: includes information on the manufactured dose form of each manufactured item and the administrable dose form of the pharmaceutical product

- ("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")

### 3.1.6

#### **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 unless proper credentials and the informations 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

- ("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")

Note 2 to entry: In certain jurisdictions there is a distinct difference between on one hand confidentiality = safety and accuracy of information and on the other hand confidentiality = privacy of information.

### 3.1.7

#### **constituent**

substance present within a specified substance or mixture

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, vehicles, active markers or signature substances, parent substances or single substances mixed together to form a multi-substance material.

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.

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.

- ("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")

### 3.1.8

#### **constituent (to delete)**

substance present within a specified substance or mixture

**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, vehicles, active markers or signature substances, parent substances or single substances mixed together to form a multi-substance material.

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.

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.

- ("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")