

Standard Terms

Introduction and Guidance for Use

Version 2.1.3 – 16 November 2018

GENERAL PRINCIPLES AND INSTRUCTIONS FOR USE OF THE LISTS OF STANDARD TERMS

The lists of Standard Terms were initially drawn up by the European Pharmacopoeia (Ph. Eur.) Commission further to a request of the EU Commission, for use in marketing authorisation applications (MAAs), labelling (including the summary of product characteristics (SmPC)), and electronic communications. The first list was published as a special edition of *Pharmeuropa* in October 1996. The European Directorate for the Quality of Medicines & HealthCare (EDQM), a Directorate of the Council of Europe based in Strasbourg, France, is responsible for continuing this work.

Standard Terms have the double purpose of bringing information to the patient/user/prescriber and distinguishing medicinal products having the same trade-name. Because of the labelling purposes it is imperative that any Standard Term is constructed with a view to the patient and the prescriber. It conveys essential information on the properties and uses of the particular medicinal products. To avoid a proliferation of over-complicated terms, complete information cannot always be included in a Standard Term, and should instead appear elsewhere in the labelling, in particular the package leaflet and SmPC.

Since 2017 the scope of the Standard Terms database has also widened to allow the inclusion of certain additional terms that are not intended for use in MAAs, but are used for related purposes such as adverse event reporting (pharmacovigilance) and clinical trials. At the same time, in an effort to encourage greater global harmonisation of electronic communications, applications for terms to describe concepts that are not used in European Pharmacopoeia Commission member states but are used in other regions are also now accepted for consideration.

The Standard Terms database is only available online via the EDQM website (<https://standardterms.edqm.eu>).

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1. INTRODUCTION

1.1. Standard Terms overview

The lists of Standard Terms were initially drawn up by the European Pharmacopoeia (Ph. Eur.) Commission further to the request of the EU Commission for use in marketing authorisation applications (MAAs), labelling (including the summary of product characteristics (SmPC) and patient information leaflet (PIL)), and electronic communications. Standard Terms have the double purpose of bringing information to the patient/user/prescriber and distinguishing medicinal products having the same trade-name. In 2016 the Ph. Eur. Commission agreed to widen the scope of the Terms of Reference for the Standard Terms Working Party (ST WP) in order to allow the consideration of terms for additional specialised uses, such as investigational studies and adverse event reporting for pharmacovigilance, with such terms being appropriately tagged to allow them to be distinguished from the ‘traditional’ Standard Terms intended for the uses described above. This change in scope was implemented in 2017 with the inclusion of the first terms intended for use solely in adverse event reporting.

Standard Terms are used to define certain elements of a medicinal product, including the **Pharmaceutical dose form** (i.e. the dosage form), **Route or method of administration**, and certain important **Packaging** items such as the **Container**, **Closure** and **Administration device**.

Also included are combinations terms, which are used to describe two or more elements that are packaged together, such as the **Combined pharmaceutical dose form** (two or more manufactured items that are combined to create a single administrable pharmaceutical product), **Combined term** (where a container is specified alongside the pharmaceutical dose form) and **Combination pack** (where two or more pharmaceutical dose forms are packaged together but are administered as independent pharmaceutical products).

Patient-friendly terms are generally shorter Standard Terms that, where justified and authorised by the competent authority, may be used on certain labels where space is limited.

Units of presentation are Standard Terms that can be used when expressing strength or quantity in relation to a single unit, such as a particular type of pharmaceutical dose form or container.

Standard Terms are available in 34 languages: Albanian, Bosnian, Bulgarian, Chinese, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Icelandic, Italian, Kazakh, Latvian, Lithuanian, Macedonian, Maltese, Norwegian, Polish, Portuguese, Romanian, Russian, Serbian, Slovak, Slovene, Spanish, Swedish, Turkish and Ukrainian.

New terms are created in English after consultation within the ST WP and, where appropriate, adoption by the Ph. Eur. Commission (see Section 6.1). Translations are provided by the relevant national authorities on an ongoing basis; this work by the national authorities constitutes a significant contribution to Standard Terms, and is greatly appreciated by the EDQM. Any mappings between Standard Terms and terms from external databases are provided and maintained by the owners of those external databases.

1.2. Standard Terms database developments since 2014

The Standard Terms database was completely overhauled in 2014 to allow a greater flexibility in searching, viewing and editing terms. It contains all of the information from the previous version of the database, but significant additional information has also been included. Much of this is as a result of the implementation of the International Standard ISO 11239:2012^{*} and its accompanying implementation guide ISO/TS 20440:2016[†], an integral part of the Identification of Medicinal Products (IDMP) project, whose aim is to provide a harmonised system that can be used throughout the world for identifying medicinal products. The initial driver for IDMP was pharmacovigilance, but during its development it was realised that the project would be ideal for a much wider range of uses in the regulation of medicinal products.

The most noticeable change in the Standard Terms database is the way in which Pharmaceutical dose forms are presented: these are now organised in a hierarchy according to their state of matter and basic dose form, and additional characteristics have also been associated with each term: release characteristics, transformation, intended site of administration, method of administration.

Another feature that has changed, and which is presented slightly differently compared to the original database, is the set of lists of combined terms. These are now divided into Combined pharmaceutical dose forms, Combined terms, and Combination packs.

Routes and methods of administration are largely unchanged, while Containers, Closures and Administration devices are now classed as separate lists under the Packaging category. A new controlled vocabulary, Units of presentation, was added as part of the 2016 revision in order to provide all of the terms required for ISO 11239:2012.

More comprehensive links between terms are now included, partly owing to the reorganisation of combined terms.

Users can view the history of a selected term in a selected language, and summary sheets for individual terms.

National authority translators can submit new or revised translations directly from the database, and additional functionalities allow for missing translations to be displayed and organised in a more user-friendly manner.

Authorised owners of external databases can introduce their own terms as Mapped terms, and link each of their terms to one or more Standard Terms. This is in order to provide guidance to any users wishing to identify possible equivalent terms in cases where controlled vocabularies other than Standard Terms are used (e.g. in regions outside Europe), in an effort to help with the global harmonisation of these controlled vocabularies.

^{*} ISO 11239:2012, *Health informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

[†] ISO/TS 20440 :2016, *Health informatics – Identification of medicinal products – Implementation guide for ISO 11239 data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

Application programming interfaces (APIs, also known as web services) allow authorised users to access and download data from the Standard Terms database directly to their own system. These specialised functions are described in separate documentation available from within the Standard Terms database itself.

In 2017 a tagging system was introduced in order to handle the widened scope of the Standard Terms database, while allowing users to see the data that is appropriate to their requirements. The widening of the scope allows for the inclusion of terms that are intended for use only in special situations (such as adverse event reports or investigational studies), and that would not be considered appropriate for a marketing authorisation application. By selecting the appropriate tags, the user can filter the terms in order to retrieve, for example, just the 'traditional' Standard Terms for labelling, MAAs etc., or just the terms that are used for specific purposes such as adverse event reports, or to retrieve all possible terms. By default, only the 'traditional' Standard Terms are displayed; in order to see any additional specialised terms when browsing or searching the database, the user must specifically request them to be shown by using the filtering tool. This is in order to avoid specialised terms being mistaken for 'traditional' Standard Terms. Further information can be found in Section 4.4.

2. DEFINITIONS

The following terms are used throughout this document and in the Standard Terms database. Many of the definitions given below are also used in ISO 11239:2012.

2.1. Administrable dose form

Pharmaceutical dose form for administration to the patient, after any necessary transformation of the manufactured dose form has been carried out.

EXAMPLES: Solution for injection; tablet; hard-capsule powder for inhalation.

NOTE: 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).

2.2. Administration method

General method by which a pharmaceutical product is intended to be administered to the patient.

EXAMPLES: Application; inhalation; injection.

NOTE: The administration method is a general term that is used to group related pharmaceutical dose form concepts, and is not intended to describe a precise method or route of administration.

2.3. Basic dose form

Generalised version of the pharmaceutical dose form, used to group together related pharmaceutical dose forms.

EXAMPLES: Capsule; tablet; powder; solution.

2.4. Closure

Item used to close a container for the purpose of the correct storage and (where appropriate) use of the product.

EXAMPLES: Cap; child-resistant closure; screw-cap.

NOTE 1: A closure may have an administration device incorporated into it.

NOTE 2: A closure may be an integral part of an immediate container.

2.5. Combination pack

Single term to describe two or more medicinal products that are packaged together and marketed under a single licence, and which are intended to be administered independently, as separate pharmaceutical products.

EXAMPLE: Cream + pessary.

NOTE: The medicinal products are separated by a plus symbol in order to distinguish combination packs from combined pharmaceutical dose forms.

2.6. Combined term

Single term to describe a pharmaceutical dose form (or combined pharmaceutical dose form) and an item of packaging, either for the purpose of distinguishing between marketed products that differ only in the container or administration device, or where the item of packaging has special characteristics that are relevant to the use of the medicinal product.

EXAMPLE: Solution for injection in pre-filled syringe.

NOTE: For certain products in Europe a combined term is always used on the labelling to emphasise the container, e.g. preparations in pre-filled syringes or pens, pressurised inhalations, single-dose eye preparations.

2.7. Combined pharmaceutical dose form

Single term to describe two or more manufactured items that are intended to be combined in a specific way to produce a single pharmaceutical product, and which includes information on the manufactured dose form of each manufactured item and the administrable dose form of the pharmaceutical product.

EXAMPLE: Powder and solvent for solution for injection.

NOTE: In the above example, the medicinal product contains two manufactured items: (i) a powder for solution for injection, and (ii) a solvent; the pharmaceutical product that is prepared from the two manufactured items is a solution for injection; the combined pharmaceutical dose form for the medicinal product is therefore 'powder and solvent for solution for injection'.

2.8. Container

Item of packaging that is part of a medicinal product and is used for storage, identification and/or transport of the components of the medicinal product.

EXAMPLES: Ampoule; bottle; box.

NOTE: 'Container' is a general concept that groups together the concepts of immediate container, intermediate packaging and outer packaging.

2.9. Dosage form

Pharmaceutical dose form.

NOTE: 'Dosage form' and 'Pharmaceutical dose form' are synonyms. 'Dosage form' is the term used in the European Pharmacopoeia, and there is no intention to change this. 'Dosage form' was previously used in Standard Terms, but the term 'Pharmaceutical dose form' is now used in order to harmonise with the vocabulary that is used across the Identification of Medicinal Products project.

2.10. Intended site

General body site at which a pharmaceutical product is intended to be administered.

EXAMPLES: Auricular; ocular; oral.

NOTE: The intended site is a general term that is used to group related pharmaceutical dose form concepts, and is not intended to describe a precise site or route of administration.

2.11. Manufactured dose form

Pharmaceutical dose form of a manufactured item as manufactured and, where applicable, before transformation into the pharmaceutical product.

EXAMPLE: Powder for solution for injection.

NOTE: The manufactured dose form is identical to the administrable 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).

2.12. Manufactured item

Qualitative and quantitative composition of a product as contained in the packaging of the medicinal product.

NOTE 1: A medicinal product may contain one or more manufactured items.

NOTE 2: In many instances, the manufactured item is equal to the pharmaceutical product. However, there are instances where the manufactured item(s) must undergo a transformation before being administered to the patient (as the pharmaceutical product) and the two are not equal.

NOTE 3: The manufactured item is not in direct contact with the outer packaging except where the outer packaging also serves as the immediate container.

2.13. Mapped term

Term from an external terminology resource that is provided with a link to one or more Standard Terms, in order to help users identify equivalent concepts from different terminology systems.

NOTE 1: Mapped terms are not Standard Terms, and have not been assessed by the Standard Terms Working Party. They are provided and maintained by the owners of the external terminology resource from which they originate, and are not the responsibility of the EDQM.

NOTE 2: Links between Mapped terms and Standard Terms are provided as guidance only, and are not a guarantee of equivalence of concepts. In many cases, owing to differences in granularity of different terminology systems, links will be provided to more than one term.

NOTE 3: Any queries concerning Mapped terms themselves should be directed to the owners of the external terminology resource from which they originate.

2.14. Medicinal product

Any substance or combination of substances, which may be administered to human beings or animals for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions.

NOTE: A medicinal product may consist of one or more manufactured items and one or more pharmaceutical products.

2.15. Patient-friendly term

Generally shortened term that may be used for labelling only, in case of space limitation, where justified and authorised.

EXAMPLES: Cutaneous spray; injection.

2.16. Pharmaceutical dose form

Physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient.

NOTE 1: 'Pharmaceutical dose form' and 'Dosage form' are synonyms.

NOTE 2: 'Pharmaceutical dose form' can refer to the administrable dose form or the manufactured dose form, depending on the product that it is describing.

2.17. Pharmaceutical form

A pharmaceutical dose form, a combined pharmaceutical dose form or a combined term.

NOTE: In the assessment of marketing authorisation applications in Europe, pharmaceutical forms that differ only with respect to the container/administration device may not always be considered as different pharmaceutical forms.

2.18. Pharmaceutical product

Qualitative and quantitative composition of a medicinal product in the dose form authorised for administration by a medicines regulatory agency and as represented with any corresponding regulated product information.

NOTE 1: A medicinal product may contain one or more pharmaceutical products.

NOTE 2: In many instances, the pharmaceutical product is equal to the manufactured item. However, there are instances where the manufactured item(s) must undergo a transformation before being administered to the patient (as the pharmaceutical product) and the two are not equal.

2.19. Release characteristics

Description of the timing by which an active ingredient is made available in the body after administration of the pharmaceutical product, in comparison with a conventional, direct release of the active ingredient.

EXAMPLES: Delayed; prolonged; conventional.

2.20. Route of administration

Path by which the pharmaceutical product is taken into or makes contact with the body.

EXAMPLES: Intravenous use; oral use; ocular use; oromucosal use.

2.21. State of matter

Physical condition describing the molecular form of a product.

EXAMPLES: Gas; liquid; semi-solid; solid.

NOTE: State of matter is used to group basic dose forms according to their physical properties.

2.22. Transformation

Procedure that is carried out in order to convert a manufactured item that requires such a procedure into a pharmaceutical product, i.e. from its manufactured dose form to its administrable dose form.

EXAMPLES: Dilution; dispersion; dissolution.

NOTE: A transformation is not required when the manufactured item is equal to the pharmaceutical product.

2.23. Unit of presentation

Qualitative term describing the discrete countable entity in which a pharmaceutical product or manufactured item is presented, in cases where strength or quantity is expressed referring to one instance of this countable entity.

EXAMPLE 1: To describe strength: "Contains 100 mg per tablet" ('tablet' is the unit of presentation).

EXAMPLE 2: To describe quantity: "Contains 100 mL per bottle" ('bottle' is the unit of presentation).

NOTE: A unit of presentation will often have the same name as a concept in another controlled vocabulary list, such as a basic dose form or a container, but the two concepts are not equivalent, and each has its own definition and identifier.

3. CONTROLLED VOCABULARIES

The following section outlines the different Standard Terms vocabularies, including their function and how they are presented in the database.

The scope of Standard Terms has been widened from the ‘traditional’ terms that are intended for use in MAAs, labelling, etc., to include additional terms that are intended only for certain specialised uses, such as adverse event reporting or clinical trials. Such terms are included in the lists of controlled vocabularies described below, but are tagged in order to distinguish them from the ‘traditional’ Standard Terms, and to allow them to be included or excluded in results depending on the requirements of the user. The descriptions of the controlled vocabularies below are therefore aimed at the ‘traditional’ Standard Terms. For further information on these additional specialised terms and the tagging system in the database, see Section 4.4.

3.1. Pharmaceutical dose form

3.1.1. Pharmaceutical dose form: function

The pharmaceutical dose form is used to describe the manufactured item (i.e. the item as presented in the packaging by the manufacturer) or the pharmaceutical product (i.e. the item as intended to be administered to the patient, after any necessary transformation has been carried out). When used to describe the manufactured item, it may be referred to as the manufactured dose form; when describing the pharmaceutical product, it may be referred to as the administrable dose form. See Figure 1.



Figure 1 – Relationship between manufactured item and pharmaceutical product, and the use of pharmaceutical dose forms as the manufactured dose form and the administrable dose form

The Standard Terms database does not explicitly distinguish between manufactured dose forms and administrable dose forms other than by use of the tagging system (see Section 4.4.2). However, for a term representing a manufactured dose form such as ‘Powder for solution for injection’, the words ‘for solution for injection’ indicate that a reconstitution is required, and that the resulting administrable dose form is ‘Solution for injection’.

3.1.2. Pharmaceutical dose form: database hierarchy

Each pharmaceutical dose form term is arranged in the database according to its state of matter followed by its basic dose form. This arrangement allows terms to be searched for and grouped according to the physical form in which they are presented. Further searching functionalities are provided by the attribution of 4 additional types of characteristic: release characteristics, transformation, intended site, and administration method. See Figure 2. The controlled vocabularies used for these characteristics may be downloaded from the Standard Terms database under the ‘News and Information / Guidance and change requests’ section.

The lists are used internally in the database to organise and characterise the pharmaceutical dose forms; the terms in those lists are not Standard Terms, and are only used for organisational and search purposes within the database.

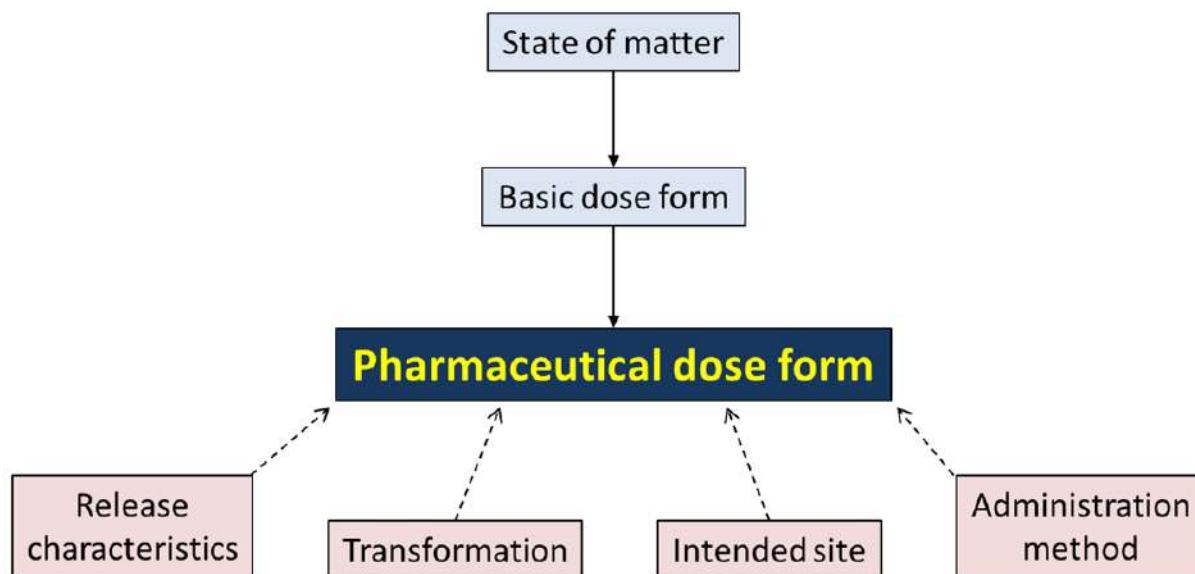


Figure 2 – Hierarchy of the pharmaceutical dose form, arranged according to the state of matter and basic dose form, and further characterised by release characteristics, transformation, intended site, and administration method

3.2. Combined pharmaceutical dose form

3.2.1. Combined pharmaceutical dose form: function

The combined pharmaceutical dose form is used to combine two or more pharmaceutical dose forms into a single term, in order to describe a medicinal product that consists of two or more manufactured items that are intended to be combined to produce a single pharmaceutical product for administration to the patient. See Figure 3.

It is not used to combine pharmaceutical dose forms with other classes of term such as containers or administration devices (see instead combined terms in Section 3.3).

It is not used to combine pharmaceutical dose forms that are packaged together but administered separately rather than being combined to produce a single pharmaceutical product (see instead combination packs in Section 3.6).

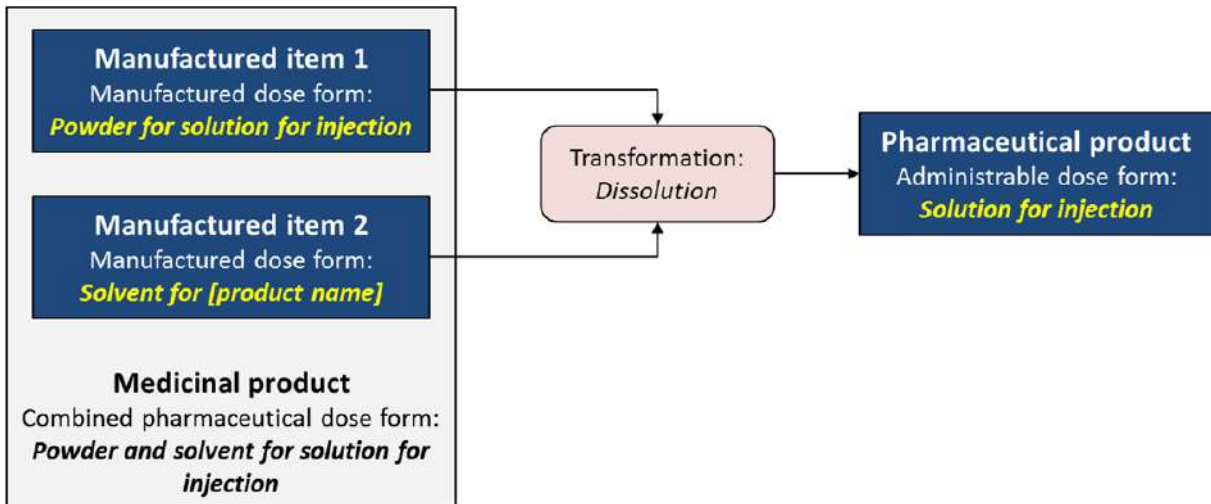


Figure 3 – Relationship between manufactured items and pharmaceutical product, manufactured dose form, administrable dose form, and combined pharmaceutical dose form

3.2.2. Combined pharmaceutical dose form: links to other terms

Unlike a pharmaceutical dose form, a combined pharmaceutical dose form has no hierarchy and other related characteristics, since it is built up from manufactured dose forms that are themselves pharmaceutical dose forms with hierarchies and characteristics. Instead, the combined pharmaceutical dose form has links to the pharmaceutical dose forms (manufactured and/or administrable dose forms) with which it is associated.

3.3. Combined term

3.3.1. Combined term: function

The combined term is used to combine one or more pharmaceutical dose forms and one or more items of packaging (usually a container or an administration device) into a single term. See Figure 4.

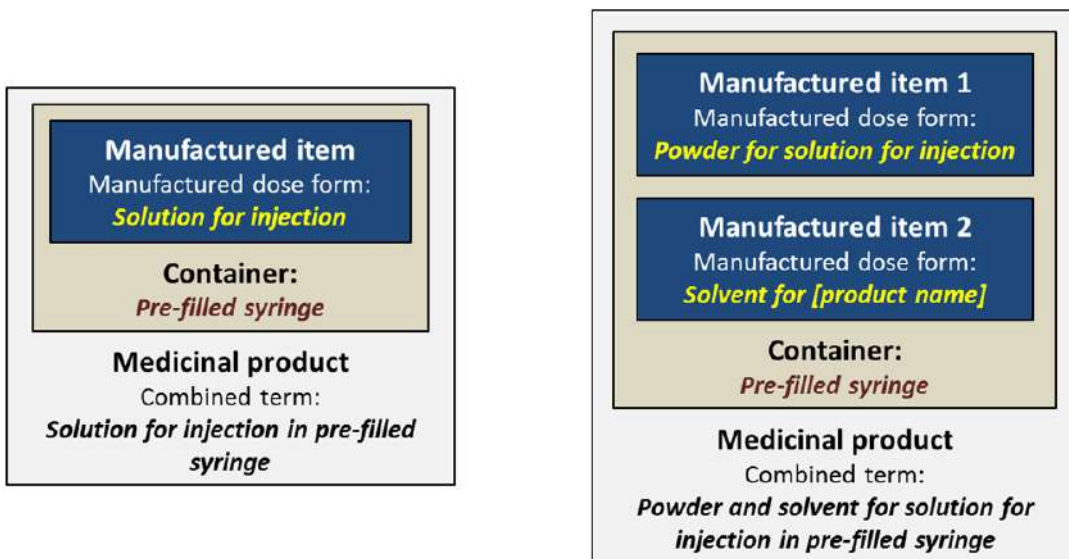


Figure 4 – Two products described using combined terms, one with a single manufactured item (left) and the other with two manufactured items (right), in both cases presented in a pre-filled syringe

3.3.2. Combined term: links to other terms

Similar to a combined pharmaceutical dose form, a combined term is built up from the manufactured dose form(s) and item(s) of packaging. It has links to the manufactured dose form(s), administrable dose form, combined dose form, and packaging item(s) with which it is associated.

3.4. Route or method of administration

The route of administration indicates the part of the body on which, through which or into which the medicinal product is to be introduced. The method of administration is used mostly in the veterinary field to indicate the way the medicinal product is to be administered to the animals.

The routes and methods of administration terms appear in a simple flat list, with no hierarchy and generally no links to other terms, since they can be considered as independent terms.

3.5. Packaging

The packaging terms appear in a very simple hierarchy, in which the terms are arranged according to their type: administration device, closure, or container. Certain of the terms have links to those combined terms in which the packaging item appears.

3.6. Combination pack

3.6.1. Combination pack: function

The combination pack is used to combine two or more pharmaceutical dose forms (or combined pharmaceutical dose forms, or combined terms) to describe products that are packaged together but are administered separately as independent pharmaceutical products. The plus symbol (+) is used in order to avoid any confusion with combined pharmaceutical dose forms. Some regions may not use combination packs. See Figure 5.

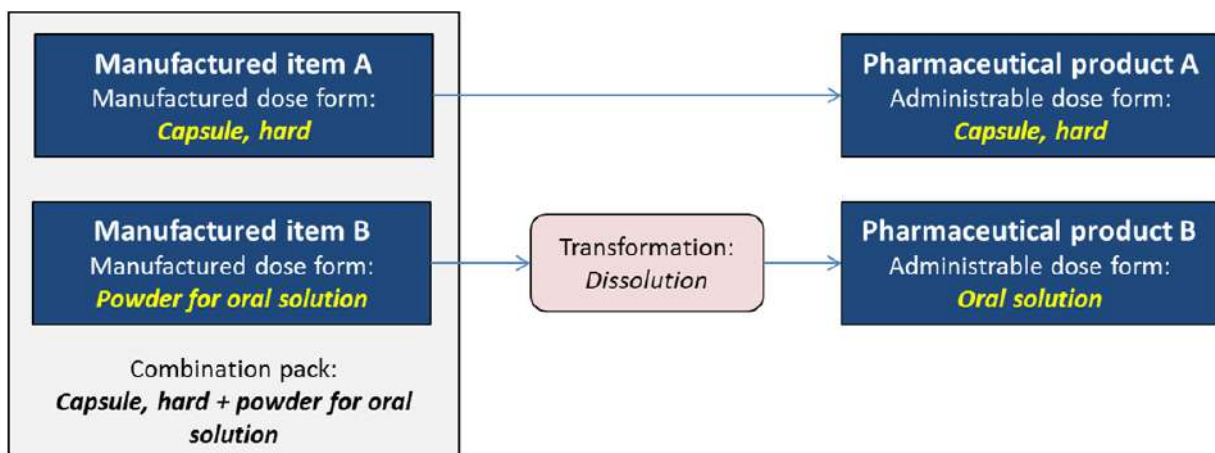


Figure 5 – Combination pack consisting of two manufactured items, resulting in two independent pharmaceutical products to be administered separately

3.6.2. Combination pack: links to other terms

Similar to a combined pharmaceutical dose form, a combination pack is built up from the manufactured dose forms, combined pharmaceutical dose forms or combined terms that describe

the products in the package. It may have links to the manufactured dose form(s), administrable dose forms, combined pharmaceutical dose forms, combined dose forms, and packaging item(s) with which it is associated.

3.7. Patient-friendly term

3.7.1. Patient-friendly term: function

The patient-friendly term is used, in those jurisdictions where it is permitted and in those circumstances where it is justified, to represent a full Standard Term on a label where there is insufficient space to use the full term. Elsewhere in the product information the full term is used.

3.7.2. Patient-friendly term: links to other terms

The patient-friendly term is linked to other terms that it might be appropriate to represent, where authorised. These are usually pharmaceutical dose forms, but the links are not necessarily exhaustive.

3.8. Unit of presentation

Units of presentation are used when it is necessary to describe strength or quantity in terms of a countable entity, rather than a unit of measurement. For example, the strength of a solution can be expressed as a concentration using standard units of measurement, such as “0.5 mg/mL” or “5 mg per 100 mL”. However, the strength of a modified-release tablet is expressed in terms of each tablet, for example “10 mg per tablet”, and units of presentation (in this case ‘tablet’) are used in such situations. Similarly, where the quantity of product in a pre-filled syringe needs to be expressed, for example “10 mL per syringe”, a unit of presentation (‘syringe’) is also used.

While a unit of presentation will often share the same name as another concept such as a basic dose form or container, it is important that a separate list of terms is maintained for units of presentation. This is because they are used in a different way, and have their own definitions and identifiers.

The units of presentation terms appear in a simple flat list, with no hierarchy and generally no links to other terms, since they can be considered as independent terms.

4. NAVIGATING THE STANDARD TERMS DATABASE

4.1. Recommended software and hardware systems

The Standard Terms database is accessed via a web browser, but not all versions of all browsers will necessarily be compatible with all functions of the database. The latest versions of Firefox, Safari, Chrome and Internet Explorer are recommended. Full functionality is available when browsing on a desktop/laptop computer; some functionality might be lacking when browsing on smaller devices such as tablets and smart phones.

4.2. Landing page and logging in

The database is accessed via the website <https://standardterms.edqm.eu>. On the landing page, the login menu (top right) allows the user to log in with their e-mail address and password to enter the main website and database. New users will first need to create an account with the EDQM's HelpDesk Publications Registration tool at <https://www.edqm.eu/register> (or log in to an existing account), where they can then register for free access to the Standard Terms database and will subsequently be sent an individual password to access the Standard Terms database. This password is specific to the Standard Terms database, and will not be the same as any passwords that are used for other EDQM websites and databases such as Register.

4.3. Database user interface

After logging in, the user will see the main database interface. The initial page provides a summary of pertinent information relating to the database, including general information on the use of the database, a list of any open requests, a list of any recent decisions of the Ph. Eur. Commission, a list of the changes that have been made since 2004, and a list of the most recent translations to be added to the database.

At the top of the page is the menu bar, which includes a number of buttons that are used to navigate around the database and take advantage of the various tools that are available (see Figure 6).



Figure 6 – Menu bar buttons

4.3.1. News and Information

The News and Information button allows the user to navigate to a specific section of the information that is presented on the initial page. The individual sections are described below.

4.3.1.1. Guidance and change requests

This section contains links to the latest versions of the Introduction and guidance for use document (with a separate version specific for national authorities, translators and mappers), the Change request form (available in the preferred DOCX format, but also in DOC format for those unable to use DOCX), and the list of Internal controlled vocabularies for pharmaceutical dose forms.

Also provided is a link to the HelpDesk system on the EDQM website.

Finally, this section lists the conditions of use for anyone wishing to reproduce any information from the Standard Terms database, for example in their own database systems, on a website or in another publication.

4.3.1.2. Status definitions

This section defines the meaning of the various statuses that can be assigned to a Standard Term.

- **Current:** the Standard Term is approved for use.
- **Deprecated:** the Standard Term is no longer approved for use; it is not physically removed from the database and is maintained to cover legacy data.
- **Rejected:** the proposed term has been rejected during evaluation and is not approved for use as a Standard Term; terms that have been rejected are not systematically included in the database; those that are included as rejected terms are provided for information in order to avoid the submission of new requests for similar terms.
- **Pending:** the proposed term is being evaluated; it is not considered a current Standard Term and is not approved for use. *(This status is rarely used, and was created for practical purposes when the database was completely reorganised in 2014.)*

4.3.1.3. Technical information

This section provides technical information that might be of interest to certain users. It includes the international standards that the database structure is based upon, and a list of object identifiers (OIDs) that may be used in electronic communications and systems to identify the entire contents of the Standards Terms database or a single controlled vocabulary.

4.3.1.4. Open requests

This section lists the internal request number and name of any change requests that have been sent to the ST WP and are still open.

4.3.1.5. Recent decisions of the European Pharmacopoeia Commission

This section lists the latest decisions that have been taken by the Ph. Eur. Commission when Standard Terms have been sent to them for adoption. Only proposals for changes that are considered to be of particular significance or to be entirely new concepts (for example a new route of administration) are sent to the Ph. Eur. Commission for adoption.

4.3.1.6. Revision history

This section provides a list of the changes that have been made to the content of the Standard Terms database since it was first published online in 2004. New or revised terms are indicated here, as well as significant changes to the structure of the database itself. Individual translations are not mentioned.

4.3.1.7. Last 100 translations

This section contains a list of the last translations to be added to the database, and is updated automatically.

4.3.1.8. Help API

This section only appears once a user has requested and been granted access to the application programme interface (API, or web services) that are made available to users (see Section 4.3.4.2). It contains the technical API Documentation that is needed by users to set up web services in order to retrieve information directly from the Standard Terms database and integrate it into their own systems. It is assumed that anyone requesting API services has the necessary IT knowledge to implement them according to the documentation.

4.3.2. Browse

This is perhaps the primary way that many users will access the content of the database in order to browse through all of the available terms. It provides direct links to the different classes of terms, which can then be browsed in order to locate the specific desired term.

Pharmaceutical dose forms are arranged in two ways: according to their intended site of administration, and according to their state of matter followed by their basic dose form. When arranged by intended site, a pharmaceutical dose form that is associated with more than one intended site will appear under each of those headings.

Combined pharmaceutical dose forms, combined terms, routes of administration, combination packs and units of presentation are arranged in individual lists without any further hierarchy.

Packaging terms are arranged according to their category of administration device, closure or container.

Patient-friendly terms are arranged according to their intended site of administration.

Mapped terms are arranged according to the external terminology resource from which they originate.

When browsing Standard Terms, users will have the option to broaden or narrow the results according their specific needs by using the 'Filter by tags' functionality. Before using this functionality, it is imperative that users familiarise themselves with the principles described in Section 4.4.

4.3.3. Search

There are a number of search tools that allow a user to find one or more terms in a variety of ways. Since pharmaceutical dose forms are the terms with the most additional information for grouping and characterising them, there is in addition a specific section providing extra tools for finding the appropriate pharmaceutical dose form(s).

4.3.3.1. All concepts by name

This tool allows the user to search for a string of characters within the names of all terms, in all languages, and among all versions. Filters can be applied to limit the search to a specific language, a specific status or a specific domain, and to search only the most recent version of each term. The user can also choose whether to search either Standard Terms or Mapped terms, or both. In addition, by selecting the global search option, the user can extend the search to include the definition and comment sections, although these are only provided in English for Standard Terms, and the search will also be limited to the last versions of terms only.

When searching concepts by name, users will have the option to broaden or narrow the results according to their specific needs by using the 'Filter by tags' functionality. Before using this functionality, it is imperative that users familiarise themselves with the principles described in Section 4.4.

4.3.3.2. All concepts by code or substring

This tool allows the user to perform a real-time search in the names of all concepts in a chosen language; a single concept class can also be specified. As characters are typed, the real-time search displays the terms that contain that string of characters anywhere in their name, and allows a specific term to be located quickly.

Alternatively, the 5- or 8-digit code (for patient-friendly and full terms respectively) can also be used to search for a term.

The terms that may appear in these search results include those that are not 'traditional' Standard Terms (i.e. do not carry the 'ST' tag). Users should familiarise themselves with the principles described in Section 4.4 to ensure that the term they have identified is appropriate for their intended use.

4.3.3.3. Pharmaceutical dose forms by characteristics

This tool allows the user to search for pharmaceutical dose forms according to the six characteristics that are used to arrange and characterise them: state of matter, basic dose form, release characteristics, transformation, intended site, and administration method. Each characteristic has a drop-down list, so the user can choose to display all terms that have a particular characteristic, or all terms that share multiple characteristics.

For example, selecting 'State of matter: Liquid', 'Transformation: No transformation' and 'Intended site: Cutaneous/transdermal' will generate a list all of the pharmaceutical dose forms that are liquid, do not require transformation before administration, and are intended for cutaneous/transdermal administration.

It also performs a real-time check of possible results, so that each time a characteristic is selected, the other options are automatically restricted to those characteristics that are compatible with the existing selection(s). For example, if 'Solid' is selected for the state of matter, the possible pharmaceutical dose forms are restricted to those classed as solids; as a result, 'Solution' can no longer be selected as the basic dose form.

When searching pharmaceutical dose forms by characteristics, users will have the option to broaden or narrow the results according to their specific needs by using the 'Filter by tags' functionality. Before using this functionality, it is imperative that users familiarise themselves with the principles described in Section 4.4.

4.3.4. Welcome menu

To the right of the menu bar is the 'Welcome [User]' button. From here it is possible to access the user Profile page or log out of the database.

4.3.4.1. Profile - General information

The user's general information is managed by the EDQM HelpDesk and Publication Registration system (Register). A link is provided to the Register website, where the user can change their EDQM profile.

4.3.4.2. Profile - Web Services

The Profile page also allows the user to request access to web services (also known as application programming interfaces, or APIs). Conditions of use are displayed, and users must agree with them before requesting access to web services. Once a request for access has been validated, a new menu item 'Help API' appears under the News and Information menu (see Section 4.3.1.8), containing documentation describing how the APIs are used. It is expected that any user requesting access to web services already has sufficient technological expertise in the field in order to use the API documentation provided.

4.4. Tags and 'traditional' and 'non-traditional' Standard Terms

The tagging functionality was introduced into the Standard Terms database in order to allow the inclusion of terms that are similar in nature to the 'traditional' Standard Terms, but that are not intended for use in the same way. It also allows for a term to be labelled as having a specific property. This section describes the purpose of 'non-traditional' terms and how the tags can be used. It is very important that anyone using the 'Filter by tags' functionality is familiar with its purpose and how it works, to ensure that they retrieve the intended results.

4.4.1. 'Traditional' and 'non-traditional' Standard Terms

Standard Terms were originally created for use in marketing authorisation applications (MAAs) and labelling (including SmPCs and PILs), in order to provide information to the prescriber, patient and other health-care professionals. Terms that are created for these purposes can be considered as 'traditional' Standard Terms, since they are intended for the original, principal purpose. Since then, the terms of reference of the Standard Terms Working Party have been broadened in order to allow Standard Terms to be used for other related purposes, such as adverse event reporting (pharmacovigilance). In order to be able to provide the complete list of terms necessary for such purposes, it was recognised that certain additional terms would be needed, and that those terms would not necessarily be appropriate for use in MAAs, labelling, etc. Such terms can be considered as 'non-traditional' Standard Terms.

4.4.2. Tags

In order to provide continuity for the majority of users of Standard Terms, it was decided that a tagging system would be introduced in order to allow ‘non-traditional’ terms to be distinguished from ‘traditional’ terms, and that the default setting for browsing and searching the database would be to show only the ‘traditional’ Standard Terms. Anyone wishing to see the new ‘non-traditional’ Standard Terms would need actively to request their inclusion in any browsing or search results.

The ‘Filter by tags’ functionality was introduced to the browse and search pages in order to allow the user to define the types of term to be displayed in any results. As mentioned above, by default the filters are set to display only the ‘traditional’ Standard Terms; this means that users wishing to view the ‘traditional’ Standard Terms do not need to use the ‘Filter by tags’ functionality at all. For example, the ‘traditional’ Standard Terms carry the tag ‘ST’, while terms that are intended for use only in adverse event reporting and not as a ‘traditional’ Standard Term carry the ‘AER’ tag, and not the ‘ST’ tag. Terms carrying the ‘AER’ tag would only be displayed if the ‘Filter by tags’ settings were specifically adjusted by the user in order to include them.

In addition to the ‘traditional’ and ‘non-traditional’ Standard Terms, certain classes of Standard Term can be divided into one or more subtypes, while remaining part of the same class. Such differences can also be represented by the use of tags. For example, pharmaceutical dose forms are used to describe both the manufactured item (i.e. the item as presented in the packaging by the manufacturer) and the pharmaceutical product (i.e. the item as intended to be administered to the patient, after any necessary transformation has been carried out) (see Section 3.1). Only certain pharmaceutical dose forms can be used to describe an administrable pharmaceutical product, and these can be distinguished by the application of an appropriate tag (‘AdmDF’). The use of such a tag is independent of the presence of any other tags, and indeed more than one tag may be applied to a given term. For example, a ‘traditional’ pharmaceutical dose form that can be used to describe an administrable pharmaceutical product would carry both ‘ST’ and ‘AdmDF’ tags.

4.4.2.1. Filter by tags

The ‘Filter by tags’ function can be used to alter the results that are displayed when browsing or searching the Standard Terms database. It is opened by clicking on the ‘Filter by tags’ bar. By default, only the ‘ST’ tag appears in the ‘Any of these tags’ field, in order that the ‘traditional’ Standard Terms are always displayed by default. The default settings can be retrieved at any time by clicking on the ‘Default’ button when on a ‘Browse’ page, or the ‘Reset’ button on a ‘Search’ page. Clicking in one of the fields will call up a drop-down list containing the various available tags; a description of each tag can be seen under ‘Information about available tags’ (see Figure 7).

Filter by tags

Any of these tags	ST x
All of these tags	Select tags (and)
None of these tags	Select tags (not)

Filter
Clear
Default

Information about available tags

ST
 A filter tag to indicate a 'traditional' Standard Term that may be used in marketing authorisation applications, SmPCs etc. in Europe, according to the original intended use of Standard Terms. Non-current terms (e.g. deprecated, rejected) also carry this tag, but that simply means that they were requested for the use described above, and they remain either not recommended or rejected.

AdmDF
 A filter tag to indicate that a pharmaceutical dose form can be used as an administrable dose form, i.e. it can be used to represent the pharmaceutical dose form of the pharmaceutical product at the point of administration to the patient. A pharmaceutical dose form that always requires some sort of transformation (e.g. dissolution) prior to administration is not an administrable dose form.

AER
 A filter tag to indicate that a term has a specialist use in adverse event reporting, and is not considered a 'traditional' Standard Term. Such terms are not for use in marketing authorisation applications, SmPCs, etc.

Figure 7 - Filter by tags functionality on a Browse page

Selecting tags in the 'Any of these tags' field will mean that all terms that carry one or more of those tags will appear in the results.

Selecting tags in the 'All of these tags' field will mean that only terms that carry all of those tags will appear in the results.

Selecting tags in the 'None of these tags' field will mean that any terms that carry any of those tags will be excluded from the results.

Combinations of these fields can also be used, for example to return all terms that carry the 'ST' tag except those that also carry the 'AdmDF' tag, by selecting 'ST' in the 'Any of these tags' field and 'AdmDF' in the 'None of these tags' field.

5. HOW INFORMATION ON A TERM IS PRESENTED

5.1. List of results

Whenever an action results in the creation of one or more returned results (e.g. by browsing terms or performing a search), a list of terms is displayed, immediately providing a small amount of pertinent information on each term: the status, the term name, any tags, and the domain (see Figure 8). The results are always displayed in English, unless another language has been specified for a search, in which case the term itself is displayed in the selected language, alongside a label indicating the language.

At the top of the list is the number of results, followed by an export link.

Routes and Methods of Administration

List of routes and methods of administration.

IMPORTANT NOTICE: The 'Filter by tags' section should not be used without first carefully reading the relevant sections of the Introduction and Guidance for Use document. By default, the filters are set to display only the 'traditional' Standard Terms.

Filter by tags

Results: 100 [export](#)

Current	Auricular use	ST	Human and Veterinary
Current	Beak dipping	ST	Veterinary only
Current	Buccal use	ST	Human and Veterinary
Current	Cutaneous use	ST	Human and Veterinary
Current	Dental use	ST	Human and Veterinary
Current	Dipping	ST	Veterinary only
Current	Endocervical use	ST	Human and Veterinary

Figure 8 – List of results displayed when browsing Routes and Methods of Administration

5.1.1. Export results

Clicking on the export link will create an HTML file containing the expanded code (consisting of a 3-letter code indicating the class of term followed by the 5- or 8-digit concept code), status, term and domain of all of the results displayed. This file can be opened in a browser for simple viewing of the results, or in a spreadsheet program (e.g. Excel) where the results can be manipulated as required by the user.

5.2. Detailed information

Clicking on a term in the list of results will expand the term to display a number of tabs, each of which contains more detailed information on the term (see Figure 9). The possible tabs are Details, Characteristics, Translations, Linked terms, Mappings and Summary sheets; however, not all terms will display all tabs; for example, only pharmaceutical dose forms have the characteristics tab, and only terms with links or mappings to other terms have the Linked terms or Mappings tabs.

Furthermore, Mapped terms are not constructed in the same way as Standard Terms, and just have Details and Versions tabs containing adapted information.

The screenshot shows the 'Details' tab selected for the term 'Solution for injection'. The interface includes a header with 'Current', 'Solution for injection', 'ST', 'AdmDF', and 'Human and Veterinary'. Below the header are tabs for 'DETAILS', 'CHARACTERISTICS', 'TRANSLATIONS', 'LINKED TERMS', and 'SUMMARY SHEETS'. The 'DETAILS' tab is active, displaying the following information:

Concept Code	11201000
Term	Solution for injection
Definition	Liquid sterile single-dose or multidose preparation consisting of a solution intended for administration by injection.
Comment	For infusions, see 'Solution for infusion'.
Concept Class	PDF
Ph. Eur. Monograph	0520
Domain	Human and Veterinary
Concept Status	Current
Version Number	2
Version creation date	2016-03-30 06:28:27
Modification made	Definition harmonised.
Language	English
Expanded code	PDF-11201000-EN-GB
Concept Creation Date	2006-03-14 00:00:00

Figure 9 – Detailed information of a term displaying the different possible tabs ('Details' tab selected)

5.2.1. Details

The Details tab is where the most important information is visible, such as the code, definition, Ph. Eur. monograph number, domain, status, and versioning details (see Figure 9).

5.2.2. Characteristics

The Characteristics tab only appears for pharmaceutical dose forms, and displays the state of matter, basic dose form, release characteristics, transformation, intended site and administration method (see Figure 10).

The screenshot shows the 'Characteristics' tab selected for the term 'Solution for injection'. The interface includes a header with 'Current', 'Solution for injection', 'ST', 'AdmDF', and 'Human and Veterinary'. Below the header are tabs for 'DETAILS', 'CHARACTERISTICS', 'TRANSLATIONS', 'LINKED TERMS', and 'SUMMARY SHEETS'. The 'CHARACTERISTICS' tab is active, displaying the following information:

State of matter	Liquid
Basic dose form	Solution
Administration method	Injection
Intended site	Parenteral
Release characteristics	Conventional
Transformation	No transformation

Figure 10 – Characteristics of the pharmaceutical dose form

5.2.3. Translations

The Translations tab provides all of the translations for the term in each of the available languages (see Figure 11). For each language, the latest version is displayed, followed by the version date and the version number. If a user has translator rights for a language, then a symbol representing a globe is also visible alongside the version number (see Section 6.3.2).

Also available under this tab is a history of the versions for each language. Clicking on the booklet symbol to the right of the version number will generate a PDF file displaying the available information for each version of the chosen language.

Current		Solution for injection	ST	AdminDf	Human and Veterinary
DETAILS	CHARACTERISTICS	TRANSLATIONS	LINKED TERMS	SUMMARY SHEETS	
English	Solution for injection	2016-03-30	2		
French	Solution injectable	2006-03-14	1		
Italian	Soluzione iniettabile	2006-03-14	1		
Spanish	Solución inyectable	2006-03-14	1		
Portuguese	Solução Injetável	2014-03-10	2		
Romanian	Soluție injectabilă	2006-03-14	1		
German	Injektionslösung	2006-03-14	1		
Dutch	Oplossing voor injectie	2006-03-14	1		

Figure 11 – Current translations of the term

5.2.4. Linked terms

The Linked terms tab lists all of the associated terms according to the class of term (see Figure 12). Each term is in the form of a hyperlink that will open a new window containing the selected term.

The Linked terms tab is a useful way to navigate to a combined pharmaceutical dose form, combined term or combination pack, based on the pharmaceutical dose form (manufactured or administrable dose form). It also provides links to Patient-friendly terms.

Current		Solution for injection	ST	AdminDf	Human and Veterinary
DETAILS	CHARACTERISTICS	TRANSLATIONS	LINKED TERMS	SUMMARY SHEETS	
Combined pharmaceutical dose form					
<ul style="list-style-type: none"> Concentrate and solvent for solution for injection Concentrate and solvent for solution for injection/infusion Lyophilisate and solvent for solution for injection Powder and solution for solution for injection Powder and solvent for solution for injection Powder and solvent for solution for injection/infusion Powder and solvent for solution for injection/skin-prick test 					
Combined term					
<ul style="list-style-type: none"> Powder and solvent for solution for injection in cartridge Powder and solvent for solution for injection in pre-filled pen Powder and solvent for solution for injection in pre-filled syringe Solution for injection in administration system Solution for injection in cartridge Solution for injection in dose-dispenser cartridge Solution for injection in needle-free injector Solution for injection in pre-filled injector Solution for injection in pre-filled pen Solution for injection in pre-filled syringe Solution for injection/infusion in pre-filled syringe 					
Patient-friendly term					
<ul style="list-style-type: none"> Injection 					

Figure 12 – Links to associated terms

5.2.5. Mappings

The Mappings tab contains links to all of the external terms in the mapped terms list that have been associated with the Standard Term (see Figure 13). Each term is in the form of a hyperlink that will open a new window containing the selected mapped term.

For each mapped term, the latest version is displayed, followed by the version date and the version number. Also available is a history of the versions for each mapped term; clicking on the booklet

symbol to the right of the version number will generate a PDF file displaying the available information for each version of the chosen mapped term.



Figure 13 – Links to Mapped terms

5.2.6. Summary sheets

The Summary sheets tab contains links to PDF documents that contain the information that is found in the previous tabs (see Figure 14). A sheet containing the Details and Translations information, and a sheet containing all of the information, are available. Clicking on the links will generate a PDF containing the requested information.



Figure 14 – Links to information summary sheets for the term

6. ADDITION OR REVISION OF STANDARD TERMS

The following section outlines the procedure that is followed in order to request a change to the Standard Terms database, whether it is for the addition of a new term, or the revision or suppression of an existing term. It also outlines the editorial guidelines that the Standard Terms Working Party use when assessing the suitability of any request, which can be useful in helping a potential applicant to decide whether or not a change request might be appropriate. Finally, it outlines how a nominated translator can provide translations in their assigned language for any term, and how an authorised mapper can add mapped terms from their external terminology resource.

6.1. Procedure for the addition or revision of a Standard Term

Only national authorities of the member states, the European Medicines Agency (EMA), the EU Commission, or selected national or regional competent authorities (e.g. competent authority members of The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)) can submit a change request. This is in order to avoid the creation of unnecessary requests, since these competent authorities have an overview of the terms that are already in use to describe medicinal products, and are responsible for ensuring that the correct terms are used to describe a medicinal product. Below is the procedure that is followed.

- i. The competent authority sends the completed request form to the EDQM. The request form can be found on the Standard Terms website (<https://standardterms.edqm.eu>).
- ii. Within one week, the EDQM sends the proposal to the Standard Terms Working Party of the European Pharmacopoeia Commission.
- iii. The members of the Standard Terms Working Party examine the proposal, and provide comments via the EDQM's commenting system. An initial commenting period of two weeks is set, although this may be extended if necessary, for example if there are unresolved issues remaining. For certain periods of the year, a longer initial commenting period of 4 weeks is set in order to allow for likely absences of experts and closures (e.g. during summer and winter holidays). If necessary a meeting is arranged to discuss any issues.
- iv. The Standard Terms Working Party gives an opinion together, if necessary proposing a new term and definition. The opinion is sent to the authority that submitted the request, for confirmation or, if necessary, further discussion. If a proposed term is considered to be an entirely new concept, it is sent for adoption to the European Pharmacopoeia Commission, whereby the member states' competent authorities are asked to comment within 1 month. Any disagreement with the proposal must be justified. If the new term is considered to be a reformulation of existing current terms or elements thereof, rather than an entirely new concept, then the term can be added directly to the database without requiring further consultation with the European Pharmacopoeia Commission.
- v. The opinion of Group of Experts No. 12 of the European Pharmacopoeia Commission may be sought so that, where necessary, it can make a proposal on the revision of the corresponding monograph or on the elaboration of a new monograph.
- vi. Taking into account any comments received and the advice of the Standard Terms Working Party, the European Pharmacopoeia Commission adopts (by correspondence) the new Standard Term(s) or the modification of a Standard Term so that the change can be introduced into the list of Standard Terms. It authorises, if necessary, the revision of the corresponding monograph or elaboration of a new monograph. A new or modified Standard

Term is introduced into the list of Standard Terms and is then translated into the various languages by the national authorities. For those terms that are considered by the Standard Terms Working Party not to be entirely new concepts, the European Pharmacopoeia Commission has granted permission for the Standard Terms Working Party to adopt the changes without further consultation with the European Pharmacopoeia Commission.

- vii. In case the request for a new Standard Term is made for a licence application, the request mentions the date of the receipt of the valid application so that an approved Standard Term is provided within 120 days. The EDQM is duly informed of the result of the assessment of the licence application before publishing the new Standard Term.

6.2. Editorial rules

Standard Terms are created in accordance with a number of guiding principles and assumptions. These act as editorial rules when requests for new terms or revisions are assessed by the Standard Terms Working Party, and can also act as a guide to a potential applicant to help them assess whether a change request is warranted.

- i. Terminology is used consistently throughout the list of terms.
- ii. Each term is as short as possible, commensurate with providing the necessary information to inform the patient, prescriber or user.
- iii. The creation of unnecessary terms is avoided.
- iv. Terms are generally provided in the singular form, but the plural form may be used where appropriate, for example, 'Tablets', 'Solutions for sealant'.
- v. Terms are sometimes (but not always) written using a word order that allows related terms to be grouped together alphabetically; for example, 'Capsule, hard' and 'Capsule, soft'. While these remain the official Standard Terms, where such terms are used as part of a sentence it is acceptable to change the order of the words to ensure that a more natural phrase is formed; for example '...hard capsule...' and '...soft capsule...'.
- vi. Each pharmaceutical dose form term conveys at least two elements of information, including the physical manifestation and an indication of the intended route or method of administration. In some cases, established usage allows a single word to convey more than one element of information; for example, the term 'Tablet', unless otherwise qualified, denotes a product for oral use, i.e. to be swallowed. This also applies to patient-friendly terms.
- vii. Where a medicinal product can be used in more than one way, the focus should be on what is considered to be the primary use, in order to avoid the proliferation of unnecessary terms. For example, the term 'Oral solution' is sufficient to describe a product that can be used as an oral, gastric or gastrointestinal solution.
- viii. Where it is not possible to identify a primary use, a single term might indicate two or more uses, separated by a slash ('/'), for example: 'Gargle/mouthwash', 'Chewable/dispersible tablet'. The elements are placed in alphabetical order, although terms created before June 2009 did not necessarily follow this order, and therefore some anomalies exist. Strong justification must be provided for any term that indicates more than two uses.
- ix. Certain combinations of uses are not allowed for safety reasons, for example where the different uses have different microbiological requirements. Separate marketing authorisations (MAs) are usually required for such products, but where one does exist under a single MA, the term with the strictest requirements is to be used, with any other permitted

uses described in the product information. For example, ‘Solution for injection’ rather than ‘Solution for injection/rectal use’.

- x. In the case of a powder that is dissolved in a small amount of solvent before it is diluted in a larger volume to be infused and this dilution is mandatory for safety reasons, the term ‘concentrate’ should appear in the pharmaceutical form (e.g. ‘Powder for concentrate for solution for infusion’). If the powder that is dissolved in a small amount of solvent can either be administered as such or be further diluted before administration (i.e. there is no safety issue), there is no need to use the term ‘concentrate’ (e.g. ‘Powder for solution for infusion’).
- xi. The term ‘modified-release’ is not usually sufficiently precise for describing a particular product. A more specific term such as ‘prolonged-release’ or ‘gastro-resistant’ should be used, wherever applicable.
- xii. Combined terms are necessary where certain special containers, closures or administration devices are required for the correct administration of the medicinal product (the closure or administration device may be an integral part of the immediate container). This applies to pre-filled syringes, pre-filled pens, pressurised preparations for inhalation and single-dose eye preparations.
- xiii. Combined terms are sometimes required to differentiate between marketed products that share the same trade name and differ only in their immediate container; for example, ‘Oral suspension’ and ‘Oral suspension in sachet’. This approach is not necessary where the medicinal products are authorised on the same licence and the container does not impact on the use of the product; for example, ‘Solution for infusion’ is sufficient to cover a medicinal product that is available in both a bag and a bottle, where both presentations are on the same MA; separate terms are not necessary.
- xiv. Combined pharmaceutical dose forms are constructed by placing the active elements (i.e. those containing active ingredient(s)) first, followed by the inactive elements; for example ‘Suspension and solvent for suspension for injection’ (not ‘Solvent and suspension for suspension for injection’). Where multiple active elements are involved, alphabetical order (in English) is followed; for example ‘Powder and solution for solution for injection’ (not ‘Solution and powder for solution for injection’).
- xv. Combination packs may be created where a member state, the EMA or the EU Commission considers that a single product-specific term is required to describe a combination pack, in which case such a term may be created by combining existing terms (e.g. pharmaceutical dose forms, combined pharmaceutical dose forms). Each component of a combination pack is described using its full term, appears in alphabetical order (in English), and is separated by a plus symbol (+). For example: ‘Granules + powder for oral solution’ (N.B. compare this with the combined pharmaceutical dose form ‘Granules and powder for oral solution’, which results in the single administrable product ‘Oral solution’).

6.3. Translations

Users with translator rights have access to additional features, namely a button at the top of the page to display missing translations, and an additional button next to their assigned language(s) under the Translations tab for each term.

6.3.1. Missing translations

The Missing translations button is only available to users who have translator rights for one or more languages (see Figure 15). It provides an overview of the terms that are missing a translation in their assigned translation language, and allows the translator to filter the terms by class and status. Selecting only the language will display all terms that are missing a translation in that language, regardless of class of term or status.



Figure 15 – Menu bar buttons for users with translator rights

6.3.2. Submitting a new translation

A new translation can be submitted for any term by a translator in their assigned language, via the Translations tab under the term (see Section 5.2.3). A globe symbol appears on the right hand side of the assigned language, next to the version number if one exists. Clicking on this globe symbol will open a field in which a new translation can be typed.

Once submitted, the translation is sent to the Standard Terms database administrator for validation. In the meantime, a lock symbol replaces the globe symbol, indicating that a translation is awaiting validation. Until the term is accepted or rejected by the administrator, no new translation can be submitted for that term in that language.

6.4. Mapped terms

Users with mapper rights have access to additional features, namely a Mappings menu button at the top of the page to add and manage mapped terms (see Figure 16).

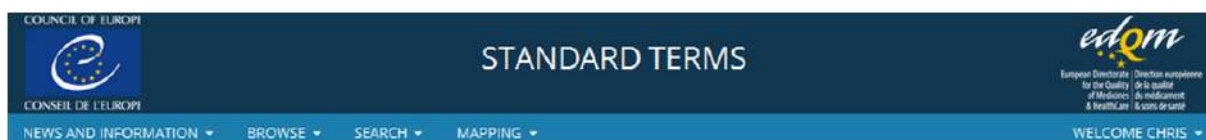


Figure 16 – Menu bar buttons for users with mapper rights

6.4.1. Adding a new mapped term

The Add Mapping option under the Mapping menu allows an authorised user to submit data on a term that appears in their own external terminology resource, and link it to one or more Standard Terms.

The following mandatory information must be provided to identify the external term: language, region and source of the external term (these are all pre-defined for the mapper), and the term in the specified language.

The following optional information may be provided to describe the external term in more detail: domain, status, definition, comment, regional identifier, hyperlink to the term, and synonym indicator.

The mapper can then choose one or more Standard Terms to which the external term is mapped. Although this field is not mandatory, it is only intended to be left empty while the appropriate Standard Terms are identified for the mapping.

Once submitted, the mapped term is sent to the Standard Terms database administrator for validation.

6.4.2. Editing mapped terms

The Manage Mapping option under the Mapping menu allows an authorised user to edit data on a mapped term from their own external terminology resource that has already been added to the database. All of the terms for which the mapper has authorisation appear in the list, and a search function allows a specific term to be found. By clicking on the edit icon, the mapper will be taken to the editing page where all of the fields used to define the mapped term can be modified.

Once submitted, the revised mapped term is sent to the Standard Terms database administrator for validation, and until it has been validated or rejected, the mapped term disappears from the Manage Mapping list. The original version of the mapped term remains visible to users of the database.

Annex 1 – DOCUMENT HISTORY

Contained in this annex is a summary of the changes made in each version of this document.

Date	Version	Summary of revision
14/11/14	1.0.0	Document first published.
16/12/14	1.1.0	Section 6.2-vii revised. Figure 13 added. 'Annex 2 - Document history' section created.
19/01/15	1.2.0	Sections 1.1 and 6.2-x revised. Sections 6.2-xiii and 6.2-xiv added.
25/11/15	1.3.0	Section 6.2-v inserted; subsequent subsections increased in value by i. Section 3.1.2, Section 6.2-vi and Annex 1 revised.
31/03/16	2.0.0	Document revised to take account of new features in Standard Terms database (Units of presentation, Mapped terms, APIs).
21/08/17	2.1.0	Document revised to take account of new tagging features in Standard Terms database and the expanded scope of terms that can be covered. Previous Annex 1 deleted and its contents incorporated into the main text.
04/01/18	2.1.1	Improved resolution of figures.
05/06/18	2.1.2	Added EU-CoE co-funding logo on front page.
26/11/18	2.1.3	Consolidated into single edition.