

Certification of Substances Department

FML/CB

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Certification of suitability to the Monographs of the European Pharmacopoeia

User guide for Certification On-Line database

1. Background

In September 2023, the European Directorate for the Quality of Medicines & Healthcare (EDQM) updated the Certification On-Line Database following the implementation of the CEP 2.0.

The tabulated data now include additional columns showing SPOR/OMS ORG and LOC-ID information for the holder where this is available*, as well as the renewal date for the CEP (where not yet renewed) and the closure date of the last procedure. Users are also able to view and print a tabulated history of a selected CEP**, that provides information on the revision history, date, type of revision, and the outcome.

This user guide is intended to assist users who access the Certification On-Line database and to optimise their user experience.

Note : The data presented in the database is for CEPs only and is therefore not a directory of manufacturers of active substances.

* In the EDQM internal databases.

** History of procedures is available for procedures opened as of 1 January 2020.

2. Glossary

CEP(s)	Certificate(s) of Suitability to the Monographs of the European Pharmacopoeia.
TSE	Transmissible Spongiform Encephalopathy
SPOR OMS	Substances, products, organisations and referential, Organisation Management Services. A central dictionary of organisation data, managed by EMA, which includes organisation and location codes for organisations and locations
ORG-ID	Organisation Identification Code (SPOR OMS data)
LOC-ID	Location Identification Code (SPOR OMS data)
ISO	International Organisation for Standardization

3. Search options for the Database

The database is accessible from the EDQM website www.edqm.eu, either from the [Certification of Suitability page](#), or from the [Databases choice](#) under "Useful Information" at the bottom of the EDQM webpages.

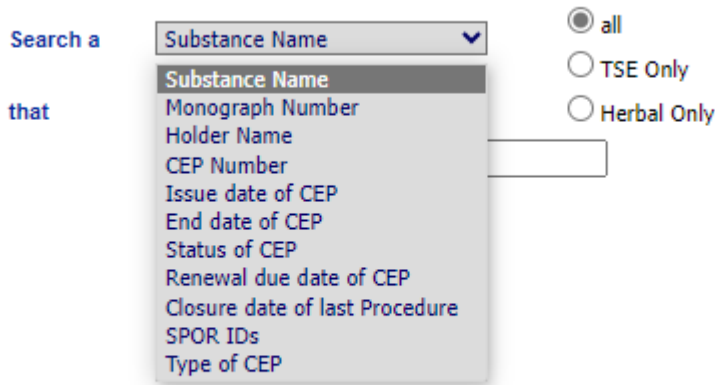
It can also be accessed directly at the following link.:

https://extranet.edqm.eu/publications/recherches_CEP.shtml

When the database is selected, the landing page includes a search pane, with a dropdown menu for the options to be searched, and some radio buttons to be selected.

The default search option on this landing page is Substance Name. Other choices are available from the dropdown menu.

The radio buttons allow the search results to be restricted to TSE or herbal CEPs only.



Note: When you select a choice from the dropdown menu, some text may be displayed above the search options which provide advice on how to search for this specific option.

The search conditions for the choices from the dropdown menu depend on whether the data for this option is available as text or dates.

Text

For text, the options are “Contains” or “Is exactly”. The option “Contains” is proposed as the default when one of the text search options is selected as this is the recommended condition to use.

If “Is exactly” is selected the text entered must match exactly, including spaces, hyphens etc. to the content of a column, and therefore it is not recommended.

Dates

For dates, the options are “Is equal to”, “Is before”, “Is after”, or “Is between”. There is a calendar icon beside the field(s) to enter the required date values and this can be used to select the dates, but if you wish to, these can be entered manually in format DD/MM/YYYY.

If using the condition “is between” then the earliest date should be entered in the first field and the later date in the second field. If this is not done, then the search will be unsuccessful.

4. Information available in the Certification On-Line database

4.1 Initial result table

The following columns are available in the database:

Monograph Number	Substance	Type CEP	Certificate (CEP) Holder	Holder SPOR ORG-ID SPOR LOC-ID	Certificate (CEP) Number	Issue Date CEP	Status CEP	Renewal due	End date CEP	Closure Date of last Procedure
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Monograph Number

Searching of this column requires use of the search option “Monograph number”.

This column contains the monograph number for the substance covered by the CEP, where there is a monograph for the substance in the European Pharmacopoeia, with a hyperlink to the entry in the EDQM Knowledge Database for this monograph.

There is no entry in this column if the CEP is a TSE CEP for a substance for which there is no monograph in the European Pharmacopoeia.

Substance

Searching of this column requires use of the search option “Substance Name”, but both text for the substance name and the subtitle can be entered into the search value field. It is recommended to use the search condition “Contains” as if you do not, you may not get the expected results.

This column contains the name of the substance for which the CEP is granted. The substance name is the same as the monograph name for those substances with a monograph in the European Pharmacopoeia. For substances which do not have a monograph in the European Pharmacopoeia (for TSE CEPs) then the name will be that proposed by the applicant and accepted by EDQM.

In addition to the substance name, this column also includes the subtitle applied on the CEP if there is one. Subtitles are proposed by applicants and accepted by EDQM.

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Type CEP

The entries in this column reflect the type of CEP and therefore the choices are Chemical, TSE, Chemical and TSE (which are sometimes referred to as “double” CEPs) and Herbal.

Searching of this column requires use of the search option “Type of CEP”. Care should be taken when searching, as for example, searching with “contains” TSE will lead to results for both TSE and “Chemical and TSE” CEPs being displayed, whilst “is exactly” will result in only TSE CEPs being displayed, and will not display the “Chemical and TSE” CEPs.

Certificate (CEP) Holder

Searching of this column requires use of the search option “Holder Name”, but both text for the holder name and the location (see below) can be entered into the search value field. It is recommended to use the search condition “Contains” as if you do not, you may not get the expected results.

The information included in this column about the location of the holder of a CEP is limited to the county or state and the country code (ISO 2-digit code).

Holder SPOR ORG-ID SPOR LOC-ID

The SPOR OMS information on holders is being gradually introduced onto CEPs and published on the Certification On-Line database. For technical reasons, the SPOR OMS data may not be present in the tabulated data for each CEP which has the same holder, and the data may be present in the tabulated data on the website but not present on the most recent version of the CEP.

Searching of data in this column requires use of the option “SPOR IDs, and if present will return the SPOR ORG ID and SPOR LOC ID as recorded in EDQM databases.

Certificate (CEP) number

Searching of this column requires use of the option “CEP Number” and it is recommended to search using “Contains” and the CEP root number (e.g., CEP YYYY-XXX).

CEP numbers are displayed for the most recently issued version of a CEP and these may either be of two formats depending on when the CEP was issued.

For CEPs issued from 1st September 2023, the format of a CEP number is CEP YYYY-XXX Rev XX.

For CEPs issued before 1st September 2023, the format of a CEP number is RXX-CEP YYYY-XXX Rev XX.

The changes introduced in September 2024, included the addition of tabulated, downloadable data for the history of procedures (regulatory activities) for a CEP dossier where the status of the most recent CEP is VALID, SUSPENDED BY HOLDER, SUSPENDED BY EDQM – GMP NON-COMPLIANCE or SUSPENDED BY EDQM – FAILURE TO CEP PROCEDURE

For those CEPs with other status (e.g., status of EXPIRED, WITHDRAWN BY HOLDER, WITHDRAWN BY EDQM – GMP NON-COMPLIANCE, WITHDRAWN BY EDQM – FAILURE TO CEP PROCEDURE), the history of procedures is not available.

A CEP which has a history table will have a hyperlink on the CEP number:

[New Search](#)

Monograph Number	Substance	Type CEP	Certificate (CEP) Holder	Holder SPOR ORG-ID SPOR LOC-ID	Certificate (CEP) Number	Issue Date CEP	Status CEP	Renewal due	End date CEP	Closure Date of last Procedure
718	Glibenclamide	Chemical	SRI KRISHNA PHARMACEUTICALS LIMITED Hyderabad IN	100015104 100023787	R1-CEP 2000-289 - Rev 09	02/08/2023	Valid			02/08/2023

A CEP with no history table will not have a hyperlink on the CEP number.

Monograph Number	Substance	Type CEP	Certificate (CEP) Holder	Holder SPOR ORG-ID SPOR LOC-ID	Certificate (CEP) Number	Issue Date CEP	Status CEP	Renewal due	End date CEP	Closure Date of last Procedure
748	Vinblastine Sulfate	Chemical	Eli Lilly SA County Cork IE		R1-CEP 1992-005 - Rev 00	15/12/1999	Withdrawn by Holder		20/12/2004	20/12/2004

To access the history table, click on the hyperlink. There is more information in section [4.2](#).

Note : This history of procedures includes only those procedures which have been completed and which started after 1st January 2020.

Issue Date CEP

Searches can be made as described earlier under date format using the option “Issue date of CEP”.

The issue date of the last revision of the certificate is displayed with the format DD/MM/YYYY.

Status CEP

Searches can be made using the option “Status of CEP”.

The status of the last revision of the certificate is displayed:

- valid certificates are identified by status of VALID,
- certificates withdrawn at the request of the CEP Holder are identified by status of WITHDRAWN BY HOLDER,
- certificates not renewed after the 5-year validity period are identified by status of EXPIRED,
- certificates suspended for a defined period at the request of the CEP Holder are identified by status of SUSPENDED BY HOLDER,

certificates suspended for a defined period by EDQM are identified by status and a reason for the suspension, the available values are:

SUSPENDED BY EDQM – GMP NON-COMPLIANCE,

SUSPENDED BY EDQM – FAILURE TO CEP PROCEDURE (for issues linked to the maintenance of CEPs)

certificates withdrawn by EDQM are identified by status and a reason for the suspension, the available values are:

WITHDRAWN BY EDQM – GMP NON-COMPLIANCE

WITHDRAWN BY EDQM – FAILURE TO CEP PROCEDURE (for issues linked to the maintenance of CEPs).

Renewal Due

Searches can be made using the option “Renewal due date of CEP”.

If a CEP has not yet been renewed, the date by which the CEP should be renewed is displayed in this column in the format DD/MM/YYYY.

CEPs which have already been renewed have no renewal due date displayed.

CEPs which ceased to be valid before the CEP was renewed have no renewal due date displayed in the database.

CEPs which are suspended before the CEP was renewed will have the renewal due date displayed in the database.

Dates are in format DD/MM/YYYY.

It is important to note that for CEPs issued from 1st September 2023, the renewal due date is no longer visible on a CEP, and it can only be found in this database.

End Date CEP

Searches can be made using the option End date of CEP”.

The end date of the last revision of the certificate where these certificates are no longer valid is displayed in red and the Dates are in the format DD/MM/YYYY.

CEPs with status valid therefore have no end date.


Closure Date of Last Procedure

Searches can be made using the option “Closure Date of Last Procedure”.

In this column, the completion date of the last Procedure (regulatory activity) for this CEP dossier is displayed. This may not be the same as the issue date of the current latest CEP.

4.2 History of Procedures

When there is a history of procedures available for the CEP, there will be a hyperlink on the CEP number and if clicked on, the table of history of procedures for the CEP is opened:

Monograph Number	Substance	Type CEP	Certificate (CEP) Holder	Holder SPOR ORG-ID SPOR LOC-ID	Certificate (CEP) Number	Issue Date CEP	Status CEP	Renewal due	End date CEP	Closure Date of last Procedure
558	Propranolol hydrochloride	Chemical	IPCA Laboratories Limited Mumbai IN	100011695 100018690	R1-CEP 2002-026 - Rev.05	03/08/2023	Valid			03/08/2023
		Procedure Type	Outcome		Closure Date of Procedure					
		Notification	CEP granted		03/08/2023					
		Minor revision	CEP granted		22/05/2023					
		Minor revision	Accepted - CEP remains valid		15/07/2022					
		Minor revision	CEP granted		21/09/2021					
		Minor revision	Accepted - CEP remains valid		01/04/2021					
		Minor revision	Accepted - CEP remains valid		13/03/2020					

As can be seen above, the columns in the procedure history include:

Procedure Type

Information is displayed on the type of procedure which are: New application, Notification, Grouped notification, Minor revision, Major revision, Renewal, Monograph revision, Transfer of holdership and Administrative procedure.

Outcome

The outcome is for the procedure is displayed which can be Accepted - CEP remains valid, CEP granted, Rejected or Abandoned.

Closure date

The closure date of the procedure is the date at which the procedure was closed, and the outcome was confirmed.

Download

The table can be downloaded by selection of the download icon



The download will include:

- an upper table with details of the CEP concerned (the information from the columns in the initial results table presented in tabular format)

- a lower table with the procedure history.

An example is provided in Annex 1.

Annex 1 : Download of details of CEP



Certification of Substances Department

Monograph Number	568
Substance	Propranolol hydrochloride
Certificate (CEP) Holder	IPCA LABORATORIES LIMITED Mumbai IN
Holder SPOR ORG-ID	100011685
SPOR LOC-ID	100018680
Certificate (CEP) Number	CEP 2002-026 - Rev 06
Issue Date CEP	06/12/2023
Status CEP	Valid
Renewal due	
End date CEP	
Closure Date of last Procedure	06/12/2023
Type CEP	Chemical

Procedure Type	Outcome	Closure Date of Procedure
Minor revision	CEP granted	06/12/2023
Notification	CEP granted	03/08/2023
Minor revision	CEP granted	22/05/2023
Minor revision	Accepted - CEP remains valid	15/07/2022
Minor revision	CEP granted	21/09/2021
Minor revision	Accepted - CEP remains valid	01/04/2021
Minor revision	Accepted - CEP remains valid	13/03/2020