

Certification of Substances Division

NV/CB

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PA/PH/CEP (11) 70

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Certification of suitability to Monographs of the European Pharmacopoeia

Communication with EDQM Certification Division

The aim of this document is to provide information to the applicants for certificates of suitability (CEP) on how to obtain information on the Certification procedure, as well as to clarify the existing ways to communicate with the EDQM Certification Division (DCEP). It also details how to send information to DCEP for the submission of applications, to request information and the ways used by the DCEP to communicate with companies.

1. How to find information relating to the Certification procedure?

1.1. Website

For many years the EDQM has developed a website in order to give information on its activities, to provide policies for CEP application submissions and to inform applicants on recent updates. It also provides information on the EDQM inspection programme. The website also provides access to the documents that need to be completed for any submission.

The pages dedicated to Certification are divided into 7 different topics within the EDQM website (www.edqm.eu):

- News and general information, including actions on CEPs (suspensions and withdrawals).
- Legal status and background of the Certification Procedure.
- Mission and organisation of the Certification procedure.
- The 'New applications' page details how to prepare and submit a new application, depending on the relevant category (chemical, TSE, herbal drug or herbal drug preparation, sterile). A link to the application form in force is also provided.
- The 'Revision and renewals' page details how to prepare and submit any changes to dossiers, depending on the current classification of revisions. A link to the corresponding application forms in force is also provided.
- The EDQM Inspection programme.
- 'Technical Advice & One-to-One Meetings': a dedicated page on the communication tools proposed by the DCEP team for oral communication during technical meetings, EDQM training and other conferences.

1.2. Database

From the EDQM web homepage and from almost all Certification pages, applicants can have access to the Certification Database by clicking on the corresponding buttons or, directly, using the following link https://extranet.edqm.eu/publications/recherches_CEP.shtml



This database, updated daily, contains the list of certificates granted, including their status. The search tool allows a search to be undertaken by: Name of substance, Holder of the certificate, Certificate number, Monograph number or Status of the certificate (VALID, WITHDRAWN BY HOLDER, EXPIRED, SUSPENDED, WITHDRAWN BY EDQM).

The screenshot shows the 'Search Database online' interface for 'Certification'. It includes a list of search criteria and a search form. The search form has a dropdown for 'Substance Name', a dropdown for 'that' (set to 'Contains'), a text input field, and a 'TSE Only' checkbox. There are 'Search' and 'Clear' buttons.

Search Database online | Certification

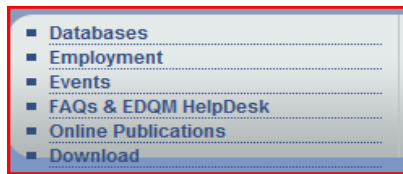
- Dear User: The presentation of our list of certificates granted has been up-dated. Please use the search tool to find the information you need. You can search by:
 - Name of the certified substance or
 - Holder of the certificate or
 - Certificate number or
 - Monograph number or
 - Status of the certificate
- If you select "is exactly", the entry that matches exactly your search term will be returned if it exists. To search for a certificate number using 'is exactly' the complete reference must be entered eg 'RO-CEP 1999-024-Rev 01'.
- The list includes the status of the last revision of the certificate:
 - the valid certificates are identified by status of VALID
 - the certificates withdrawn at the request of the applicant (production stopped, site closed etc.) which includes the certificates not renewed after the 5-year validity period (expired certificates) are identified by status of WITHDRAW BY HOLDER.
 - the certificates not renewed after the 5-year validity period (expired certificates) are identified by status of EXPIRED
 - the certificates suspended for a defined period (for GMP deficiencies) are identified by status of SUSPENDED
 - the certificates withdrawn by EDQM (for GMP deficiencies or insufficient information no longer in line with regulatory requirements) are identified by status of WITHDRAWN BY EDQM.

Search a that TSE Only

1.3. FAQs.

The DCEP has generated a selection of Frequently Asked Questions (FAQs) that can be found either:

- on the EDQM homepage of the website



- from any DCEP pages of the website (menu on left of screen).
- at the following address: http://www.edqm.eu/en/page_630.php?rubrique=31

The search can be performed using key words.

The screenshot shows a search interface with the title 'TOPICS : 07- CERTIFICATION OF PHARMACEUTICAL SUBSTANCES'. It lists four topics: 01- GENERAL INFORMATION, 02- REVISIONS/ RENEWALS, 03- INSPECTIONS, and 04- GENERAL MATTERS RELATED TO CERTIFICATION. There is a search input field and a 'Search' button.

TOPICS : 07- CERTIFICATION OF PHARMACEUTICAL SUBSTANCES

- [01- GENERAL INFORMATION](#)
- [02- REVISIONS/ RENEWALS](#)
- [03- INSPECTIONS](#)
- [04- GENERAL MATTERS RELATED TO CERTIFICATION](#)

In case answers to questions are not found after having read the FAQs, a link is proposed at the end of each FAQ to allow companies to send the question via the HelpDesk (see Chapter 2.2 of this document).

2. How to communicate with DCEP?

2.1. Helpdesk (http://www.edqm.eu/site/FAQ_Helpdesk-521.html)

Applicants have to register before using the helpdesk via <https://www.edqm.eu/register/>

The HelpDesk is a support service provided by the EDQM to respond to user and customer questions on a variety of topics. It provides a central point of contact and, as a result, facilitates communication with the EDQM. It allows the EDQM to improve its response rate and ensure that consistent replies are provided to questions, and it helps the EDQM to regularly update the list of Frequently Asked Questions (FAQs) published on its website.

The HelpDesk is to be used for all general questions not related to an already submitted application, and when answers are not found in the FAQs.

To access the HelpDesk, click on “[FAQs & EDQM HelpDesk](#)” which appears on every web page (menu on left of screen) or go directly to the HelpDesk web page.

To send a question and access the relevant question form, the applicant must first select the topic and the FAQ that most closely relates to the question. The topic selected also guides to whom the question will be transferred. Therefore, if the topic and FAQs are incorrectly selected, the response provided might be insufficient or delayed and there may be a need to re-submit the question in order to receive a comprehensive response. It is therefore recommended to choose the topic and the FAQs very carefully.

Applicants should be aware that answers provided through the HelpDesk remain of a general nature. The answers should not be considered as binding for a future dossier submission. The aim of the HelpDesk is not to replace Technical Advice meetings.

The deadline for providing an answer is set at 7 working days.

2.2. Technical Advice meetings

In order to guide applicants, DCEP has put in place Technical Advice meetings (<http://www.edqm.eu/en/Technical-Advice-One-to-One-Meetings-160.html>). These meetings are intended to answer applicants' questions relating to the Certification procedure or for specific questions on an application already, or planned to be, submitted.

Questions can be of a scientific nature, on matters concerning the content of an application, on the submission of a revision application with complex or multiple changes or on inspection matters.

Please note that, in some instances, if an applicant requests a Technical Advice meeting due to a DCEP request for additional information, DCEP may instead decide to send clarifications to the applicant via email.

Requests for Technical Advice using the application form downloaded from the corresponding web page must be sent via the email address given in the form. An acknowledgement of receipt is sent within 5 working days after receipt of the request.

3. How to communicate with DCEP for the submission of documentation?

There are several ways in which to submit documents related to a CEP application or linked to EDQM inspections, which are presented below:

3.1. Dropbox

The Certification Division has put in place a secure Internet-based Deposit Box (called “Dropbox”) for exchanging documents (*e.g.* applications, technical documents, e-QOS, replies to official letters, data related to inspections, *etc.*).

This tool should be used in place of e-mail communications. The Dropbox only allows one file or folder to be sent at any given time. If an e-CTD structure or several files need to be submitted, these should be zipped together before being posted in the Dropbox.

To put documents in the Dropbox, access codes should be requested from the EDQM by e-mail, as described on the CEP application form. These access codes will be sent to applicants, together with instructions for use.

The files will be posted in a secure server, and the Certification Division will be informed of receipt by e-mail. Please note that no reply is sent through the Dropbox.

If Dropbox access codes are no longer valid, new codes should be requested via the email (refer to 3.2.).

3.2. Email

An e-mail address is communicated to applicants after a submission has been received; this email address may be used to send a single letter or for any kind of communication, provided it is related to a specific application or inspection. This email address should not be used for general questions (instead, refer to 2.1. HelpDesk).

For a targeted response, the subject of the email should preferably be written as follows:

For CEP applications:

EDQM CEP XXXX-XXX Code

where ‘XXXX-XXX’ corresponds to the CEP application number

and ‘Code’ is either Ndos (new application), Rev (Revision/Renewal) or Misc (miscellaneous).

For inspections:

EDQM INS XXXX-XXX

where ‘XXXX-XXX’ corresponds to the inspection number.

When answering a DCEP email, applicants are requested not to change the email subject title.

The maximum permitted size of any email attachment is 5Mb.

Applicants are reminded not to send emails asking about the status of their application(s) before the deadline mentioned in the acknowledgement of receipt letter sent by the EDQM.

DCEP endeavours to answer e-mail requests within 3 working days.

4. Format of the documentation

Companies are encouraged to submit electronic versions of their applications/documents. The requirements for e-submissions are available in the current version of the EDQM guideline [PA/PH/CEP \(09\) 109](#), which is available on the website. For inspections, specific instructions are given in correspondence from the EDQM.

The postal address to which hard-copy documents should be sent is:
Certification of Substances Division,
European Directorate for the Quality of Medicines & HealthCare (EDQM),
Council of Europe,
7 allée Kastner - CS 30026,
F-67081 Strasbourg (FRANCE).

5. Communication sent by DCEP for CEP applications and EDQM inspections

Letters sent by DCEP informing applicants about the final outcome of a procedure (after evaluation or inspection), as well as warning letters, actions taken on CEPs, inspection reports, *etc.*, are all sent in hard-copy format by courier service. All other communication is only sent electronically, generally by email.