

CERTIFICATION OF SUBSTANCES FOR PHARMACEUTICAL USE

CEP 2.0

- SPOR OMS Organisation & Location IDs
 - Where can I get or modify a SPOR OMS Organisation & Location ID?
 - Do intermediate manufacturers need to apply for a SPOR OMS Organisation & Location ID?
 - Will my CEP 2.0 be revised if I submit a change in the address of a manufacturing site?
 - Will my hybrid CEP be revised if I submit a change in the address of a manufacturing site?
 - (NEW! 01/04/25) Can I use an address for a CEP dossier that is different to the one in the SPOR OMS?
- Revisions/renewals
 - Where can I find the due date for the renewal of my Certificate of Suitability (CEP)?
 - If the changes I want to introduce do not affect the content of my CEP, do I need to submit a revision of my dossier?
 - Do I need to submit an updated holder's commitment when submitting a request for revision?
 - For an upcoming renewal, do the CEP 2.0 requirements have to have been implemented before submitting a renewal application or will this be requested during the assessment process?
 - Will CEPs 2.0 be renewed?
 - Will the CEP be revised if a monograph revision only affects the specifications for impurities?
- Public database
 - Can I download my CEP from the public database?
- Old CEP, hybrid CEP and CEP 2.0
 - What are the differences between old CEP, hybrid CEP and CEP 2.0?
 - How can a CEP holder apply to switch from old CEP to CEP 2.0?
- CEP 2.0 and content of the application
 - What are the requirements for the quality of water used in the last steps of the synthesis and reported on the CEP 2.0?
 - How can I get confirmation that a specific grade (e.g. micronised, milled, etc.) described in my CEP dossier is approved by the EDQM?
 - How can we provide two distinct sections (3.2.S.4.2) in our eCTD* sequences?
 - CEP 2.0 requires maximum daily dose (MDD), route of administration and treatment duration to be provided in S.1.3. However, these characteristics do not apply to active ingredients. What should I do?
 - Is it possible to apply for a re-test period when only 3 months of accelerated/long-term stability studies are available at the time of the original submission?
 - What will be the procedure for deleting non-approved information from the dossier?
- Letter of access – Declaration of access box
 - Can a letter of access be withdrawn? Will a letter of withdrawal template be made available for the CEP procedure?
 - Is the letter of access template accepted in non-EU member states?
- Sister file
 - Is it possible to have an old CEP for the parent file and a CEP 2.0 for the sister file?

General information on Substances for pharmaceutical use

- General and scope
 - What does 'CEP' mean?
 - How to use a CEP?
 - Is CEP mandatory for marketing a substance in EU countries?
 - How should the certificate coding be interpreted?
 - How do I know if I have the latest valid version of a CEP?
 - Can I get a copy of a certificate from the EDQM?
 - Does the Certification procedure apply to herbal drugs and herbal drug preparations?
 - How long does it take to obtain a certificate of suitability?
 - Which countries accept certificates of suitability?
 - Is a certificate of suitability equivalent to a GMP certificate?
 - Is it possible to apply for a CEP for biological substances?
 - How can I withdraw my CEP?
 - What does "P0X" or "PXX" mean as an extension to the CEP number on EDQM CEP communication letters (Re: CEP 202X-XXX-P0X or PXX / Substance name)?
- Quality Overall Summary (QOS)
 - How should the Quality Overall Summary (QOS) be prepared?
 - What does the QOS consist of?
 - Who has to write the QOS? Can the expert be a person from the manufacturing company?
- Application dossier
 - Are alternative methods accepted?
 - Are analytical procedures appended to a CEP considered equivalent to a European Pharmacopoeia monograph method?
 - Can some tests be omitted?
 - Should all tests referred to in a CEP be performed for routine analysis/batch release?
 - Is a certificate of suitability equivalent to a certificate of analysis?
 - How should I deal with different grades of the same substance?
 - How should I deal with recovery of materials in a dossier?
 - Does skip testing need to be declared in CEP application dossier?
 - What should we do if we use peptones in the manufacture of an active substance?
 - Is it possible to apply for a Chemical CEP with reference to a specific polymorphic form when no statement on polymorphism is included in the corresponding individual Ph. Eur. monograph?
 - In our CEP application, is it possible to claim that the quality of our substance complies with a specific degree of hydration when degree of hydration is not defined in the corresponding individual Ph. Eur. monograph?

- In the revised Ph. Eur. monograph, a degree of hydration has been either removed from / clarified in the title of the substance. Will EDQM issue a new certificate of suitability to reflect this?
- Sterile substances
 - Is it possible to apply for CEPs for sterile substances?
 - Which GMPs should apply to the sterilisation step of a substance?
- TSE
 - Which types of material require a TSE risk assessment?
 - I am applying for a "double" CEP, where should I include the TSE information in the application if this is not covered by a CEP?
- E-submission
 - How can I submit an application or documents to the EDQM in electronic format?
- Fees

Revisions/ Renewals

- When should the applicant request a renewal?
- When is a CEP revised?
- How do I submit a grouped notification or grouped transfer of holdership?

Inspections

- Under what circumstances are EDQM inspections performed?

General matters related to certification

- I would like to submit an idea/feedback to improve the quality of your service.
- I would like to contact EDQM about general matters related to Certification of Suitability, but my item is not in the FAQs.