General information on Substances for pharmaceutical use

General and scope

- What does ‘CEP’ mean?
- (NEW 22/03/24) 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?
- (NEW - 28/03/24) 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?
- 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 manufacture an active substance using a fermentation process that uses materials of fish origin, including peptones?
- What should we do if we manufacture an active substance using a fermentation process that uses peptones that are not of fish origin?
- What should we do if we manufacture an active substance that does not use a fermentation process but does use a material of fish origin?
- 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?

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?

E-submission

- How can I submit an application or documents to the EDQM in electronic format?

Fees