EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE

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Certification of suitability to the Monographs of the European Pharmacopoeia

Guidance on requesting reliance-based assessment of CEP applications

Implementation date	01 March 2026

Purpose

This guideline provides information on how applicants may request reliance-based assessment for new applications for certificates of suitability (CEP) and on eligibility.

Scope

As outlined by the WHO, reliance-based assessment is recognised as good regulatory practice (GRP), which when implemented effectively can result in consistent regulatory processes, sound regulatory decision-making, increased efficiency and better public health outcomes.

This guideline is intended to define cases where the EDQM considers that reliance-based assessment may be possible in the context of the CEP procedure for a new application for chemical purity. The Reliance process is based on the existence of an approved ASMF/DMF, or of a related CEP application, and allows applicants to benefit from expedited and harmonised assessment based on prior regulatory approval within the European Union, EEA, Switzerland, the UK, Australia, Canada, or WHO prequalification programme.

CEP applicants are advised that reliance-based assessments conducted by EDQM are still subject to the same regulatory diligence as any standard CEP application. Indeed, quality guidelines and EDQM policies may have evolved since the approval of a file via which reliance is claimed. No matter what information was submitted in the previously approved dossier, the CEP application is expected to conform with EDQM requirements (e.g. Content of the dossier for chemical purity and microbiological quality), with the Ph. Eur. monograph the dossier submitted refers to and to applicable regulatory guidelines/policies (e.g. ICH Q11 and ICH M7). As such the extent of reliance in the context of the CEP procedure remains at the discretion of the EDQM.

Sterile and TSE CEP applications are currently considered outside the scope of this guideline.

Conditions

The cases detailed below are considered by the EDQM to be eligible for reliance-based assessment. Applications for reliance-based assessment should be made as per any standard new CEP application, using the same application form, however, additional case specific requirements detailed below must also be met.

Approved ASMF/DMF

CEP applications where an ASMF/DMF has already been assessed and accepted within the European Union, EEA, Switzerland, the UK, Australia, or Canada **after October 2012** may be considered eligible for reliance-based assessment by EDQM when the manufacturing process which is described is the same. CEP holders wishing to avail of this option should

In module 1:

a) Clearly request to have their application treated via Reliance-based assessment in the **Cover letter** of their submission.
b) Appropriately update section "*3. History of the Substance*" of the **application form**. Failure to provide the correct ASMF/DMF number may result in ineligibility for reliance-based assessment.
c) In requesting reliance-based assessment it is expected that the dossier be identical to that accepted in the ASMF/DMF. In exceptional, well justified, cases EDQM may accept minor updates to the dossier relative to the ASMF/DMF. Such updates such be clearly identified by means of a suitable **comparative table** which should be appended to the application form.
Note to applicant: where changes are considered by EDQM to result in a different synthetic strategy, then reliance-based assessment is not considered as possible, and the application will be treated in accordance with the regular flow and timelines for new applications.

In module 3:

d) If available, provide any assessment reports received from the approving authority in the context of the ASMF/DMF in **section 3.2.R**.
Note to applicant: *Should the assessment reports not be provided, EDQM will attempt to liaise with the relevant authority to retrieve them directly. If this is unsuccessful then reliance-based assessment is not considered as possible, and the application will be treated in accordance with the regular flow and timelines for new applications.*

Use of a CEP in a CEP application

CEP applications which involve the use of another valid CEP to describe an intermediate as outlined in the associated EDQM guideline Use of a CEP to describe a material used in an application. Prospective CEP applicants wishing to avail of this option should

a) Clearly request to have their application treated via Reliance-based assessment in the **Cover letter** of their submission. The details of the CEP which is included in the submission should be clearly indicated.
b) Ensure their application is in compliance with the requirements of the aforementioned guideline.

Timetable and fees

The flow and timeline for treatment of a new CEP application which is accepted for **Reliance based assessment** are aligned with those of a "sister file" application as described in Annex II of the EDQM guideline on the Stepwise process to get a CEP/having a change approved.

Initial evaluation by EDQM:	46 working days.
Deadline for response by applicant:	30 calendar days.
Subsequent evaluation by EDQM:	23 working days.

The acceptance of an application for Reliance-based assessment will be confirmed by EDQM in the official acknowledgement of receipt. CEP applications which are not accepted for reliance-based assessment will be treated in accordance with the standard flow and timelines for a new application outlined in the above mentioned EDQM guideline.

The fee for reliance-based assessment of a CEP application is the same as for a standard new CEP application.

References

List of referenced guidelines

PA/PH/CEP (04) 1	Content of the dossier for CEP applications for chemical purity and microbiological quality of substances for pharmaceutical use.
PA/PH/CEP (14) 06	Use of a CEP to describe a material used in an application for another CEP.
PA/PH/CEP (24) 51	Stepwise process to get a CEP/having a change approved.