

Certification of Substances Department

AHE/SPC

**PUBLIC DOCUMENT**

(Level 1)

*(English only/Anglais seulement)*

**PA/PH/CEP (26) 05**

Strasbourg, March 2026

**Certification of suitability to the Monographs of the European Pharmacopoeia**

**Guidance on requesting fast-track assessment of CEP applications,  
revisions and renewals**

Implementation date	01 March 2026
---------------------	---------------

## Purpose

This guideline provides details on how prospective CEP applicants and holders may request consideration for fast-track assessment for new applications, revisions, or renewals of certificates of suitability (CEP) by the EDQM and eligibility.

## Scope

Medicine shortages can significantly affect patient care worldwide, and their causes are often multifactorial. Regulatory authorities in Europe and globally are increasingly working together to reduce the impact of such shortages. The unavailability of active substances is one contributing factor in Europe. To help mitigate this risk, the EDQM has introduced fast-track assessment procedures for eligible new CEP applications, revisions and renewals. This guideline is intended to define the instances where the EDQM considers that fast-track assessment may be possible in the context of the CEP procedure.

CEP applicants are advised that fast-track assessments conducted by EDQM are still subject to the same regulatory diligence and rigor as any standard CEP application. Indeed, the CEP application is expected to conform fully 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).

In the context of the CEP procedure the acceptance of new applications, revisions and renewals for fast-track assessment remains fully at the discretion of the EDQM.

## Conditions

The following CEP applications, revisions and renewals are **eligible for consideration** for fast tracked assessment by the EDQM.

- a) Instances where the European Medicines Agency (EMA) or any National Competent Authority (NCA) has engaged with the EDQM to express their support for fast-track assessment to address an active substance (or excipient) related shortage in Europe.
- b) Substances for which the EMA has reported an ongoing active substance related shortage within the “EMA shortages catalogue” available on their website.

The EDQM may also, on a **case-by-case basis**, consider requests for fast-track assessment for new applications, revisions and renewals where the prospective CEP holder can:

- a) Clearly demonstrate—based on criticality, therapeutic indication, and availability of the active substance—that fast-track assessment would deliver significant benefit to patients; and/or
- b) Clearly demonstrate that a fast-track assessment of the CEP application aligns with the objectives of the EU Critical Medicines Act.

*Note: Requests for fast-track assessment based solely on commercial grounds will not be accepted.*

## Timelines

The expected timeline for new applications accepted for fast-track 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 expected timeline for revisions or renewals accepted for fast-track assessment are aligned with those of a minor revision described in Annex III of the EDQM policy on the [Stepwise process to get a CEP/having a change approved](#).

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

### **Submission of a request for fast-track assessment**

Requests for fast-track assessment of new CEP applications, revisions, or renewals should be submitted in the same manner as standard CEP applications, using same **application form**. In all cases, the **cover letter** must explicitly state that fast-track assessment is being requested. The cover letter must also present a compelling justification for the request, based on the eligibility cases described above. Where applicable, any supporting correspondence from the EMA or a national competent authority (NCA) endorsing fast-track assessment may also be included as an annex to the cover letter.

The acceptance of a request for fast tracked assessment will be confirmed by the EDQM in the acknowledgement of receipt. CEP applications/revisions/renewals which are not accepted for fast tracked assessment will be treated in accordance with the regular flows and timeline outlined in the EDQM policy on the [Stepwise process to get a CEP/having a change approved](#).

The fee for fast-track 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 (24) 51 Stepwise process to get a CEP/having a change approved.