European Directorate for the Quality of Medicines & HealthCare

Council of Europe

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

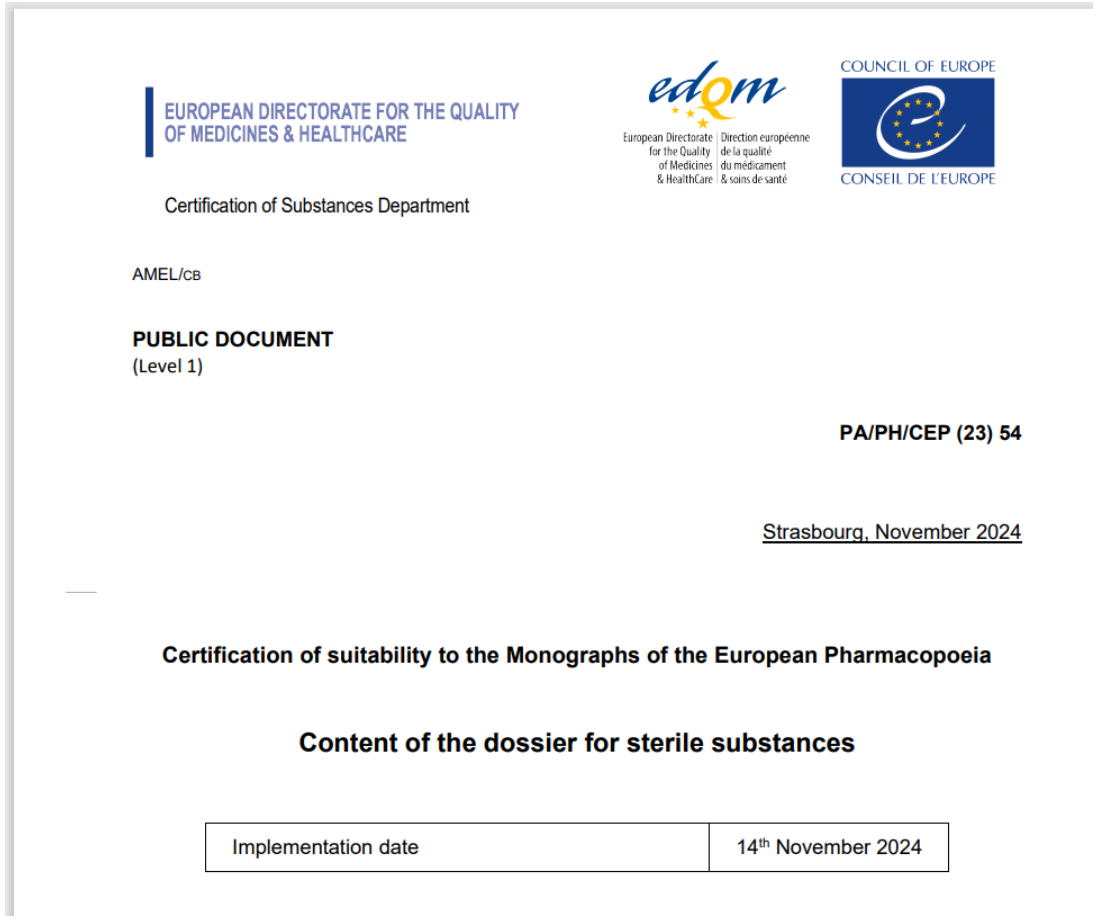
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Update of EDQM policy on sterile substances

Andrea MELLONI, Certification of Substances Department

4 June 2025, CEP webinar

Update of EDQM policy on sterile substances



EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

AMEL/CB

PUBLIC DOCUMENT
(Level 1)

PA/PH/CEP (23) 54

Strasbourg, November 2024

Certification of suitability to the Monographs of the European Pharmacopoeia

Content of the dossier for sterile substances

Implementation date	14th November 2024

- "Content of the dossier for sterile substances" PA/PH/CEP (23) 54
- Implemented from November 2024
- Available on EDQM website

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Update of EDQM policy on sterile substances

This guideline should be read in conjunction with:

- EDQM policy “Content of the dossier for chemical purity and microbiological quality”,
- EMA Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container (EMA/CHMP/CVMP/QWP/850374),
- Ph. Eur., chapters 5.1.1 *Methods of preparation of sterile products* and 5.1.2. *Biological indicators and related microbial preparations used in the manufacture of sterile products*,
- Annex 1 of EudraLex Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use.

Update of EDQM policy on sterile substances

It should be noted that sterilisation of the active substance is generally regarded by the licensing authorities as part of finished product manufacture.

Therefore, data on the sterilisation process of the active substance (including validation data) should be shared with the Marketing Authorisation applicant/holder for inclusion in the marketing authorisation application for the finished product submitted to the relevant licensing authority(ies).

What is new? What has changed?

The acceptability of CEP applications for sterile active substances is applicable to the manufacturing processes where sterilisation operations required to obtain the sterile material are performed either at the active substance manufacturing site or at a different site.

Normally, the holder should be substance manufacturer. Cases where the crude substance is purchased from a manufacturer who is not part of the same group as the site of sterilisation/holder are strongly discouraged.

The CEP holder is responsible for the manufacturing steps to obtain the active substance and its sterilisation, and full documentation should be provided in the CEP application.

Examples

Site A	Intermediate 1
	Intermediate 2
Site B (Holder)	Intermediate 3
	Prednisolone acetate
Site C	Sterile filtration
	Prednisolone acetate, sterile

API

Examples

Site A	Intermediate 1
	Intermediate 2
Site B (Holder)	Intermediate 3
	Budesonide
Site C	Gamma radiation
	Budesonide, sterile

API

Examples

Site A	Intermediate 1
	Intermediate 2
Site B	Intermediate 3
	Vancomycin
Site C (Holder)	Sterile filtration & salification
	Vancomycin HCl , sterile

API

Examples

Site A

Intermediate 1

Intermediate 2

Site B

Intermediate 3

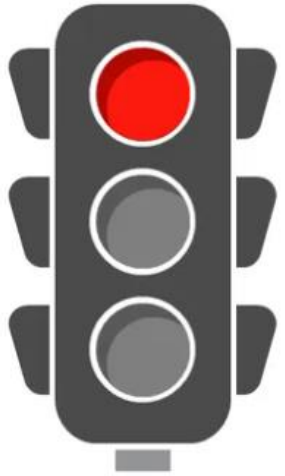
Ampicillin sodium

API

Site C (Holder)

Sterile filtration

Ampicillin sodium, sterile



More information

www.edqm.eu

https://go.edqm.eu/Newsletter

Follow us on

edqm

@edqm_news

EDQMCouncilofEurope

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE