

Certificate of Suitability (CEP)



What is CEP?

CEP or Certificate of Suitability to the monographs of the European Pharmacopoeia (also known as Certificate of Suitability) is a certificate given by EDQM to confirm that pharmaceutical substances or active pharmaceutical ingredients (API) are produced according to the monographs of the EP and meets the requirements of EU directives for medicine.



What changes with CEP application are approaching in 2020?

CEP application was and still is accepted in different formats like PDF or Nees. From 1st January, 2020 CEP will be accepted only in eCTD format. This mandate applies to notifications, revisions, renewals & new applications. Exceptions may apply to TSE only submissions.



How do I submit CEP in eCTD?

It's a fairly complex process. CEP in eCTD has 3 Modules with different documents attached to the submission. eCTD also has a specific folder structure, XML backbone & many other details that need to be filled by the requirements. Luckily Cunesoft's cune-eCTD software is built for easy submissions. Documents when uploaded drops directly in the right folder, the software automatically creates an eCTD tree, and with validation tool you can see what is missing or needs to be changed in your submission.



Does Cunesoft also help me to transform my paper CEP to eCTD?

YES! Paper, Nees, whatever format you have – we will help you to transform it to eCTD CEP!



In what language can I submit my CEP?

CEP submission needs to be submitted in one of two official languages of Council of Europe – English or French (preferably English). If you had previous CEP submissions that were not in one of those two languages, translation won't be necessary. Exceptions might apply.



Do I need Module 3 for my submission?

If you had previous CEP submissions – Module 3 is necessary, as it holds all the information from your previous submissions.



How do I produce technically valid CEP?

Ideally you would have software that has an embedded eCTD Validator. It will help you to learn what is missing in your submission. If there is still something unclear – our Client Success team would be happy to help you!

