European Directorate for the Quality of Medicines & HealthCare

Certification of Substances Division

PPR/CB

PUBLIC DOCUMENT
(Level 1)

English only/Anglais seulement

PA/PH/Exp. CEP/T (04) 27, 5R

Strasbourg, April 2009

Certification of suitability to Monographs of the European Pharmacopoeia

TECHNICAL ADVICE TO APPLICANTS AND HOLDERS OF CERTIFICATES OF SUITABILITY (CEP)

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TECHNICAL ADVICE TO APPLICANTS AND HOLDERS OF CERTIFICATES OF SUITABILITY (CEP)

To answer several requests from applicants and holders of Certificates of Suitability, EDQM has launched a new procedure for technical advice.

The technical advice procedure is intended to applicants who would like to clarify the requirements for demonstrating the suitability of the monograph for their substance prior to the submission of an application for a new CEP or for its subsequent revision or renewal. Applicants can also request technical advice also during the assessment procedure. The procedure is voluntary and applicable to substances covered by the scope of the CEP Scheme. The procedure is expected to simplify the workflow of all involved parties during the assessment, mainly by reducing the need for additional information after the submission of the application, and shorten the total time for obtaining a CEP.

The procedure is intended to cover technical questions on the content of an application or relative to the planning of applications for complex and multiple changes.

The meetings must be booked in advance. They can take place at the premises of the EDQM or can be held by teleconference. They are organised once a week.

In order to request for technical advice the applicants should send the form ('technical advice meeting form' available on our website) duly filled in, together with their questions and a charge of 1000 Euros. Questions should be phrased clearly and accompanied with the necessary supplementary information. The request should be sent preferably one month before the chosen date to cep@edqm.eu or
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Certification of Substances Division,
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The use of the procedure does not replace submission or assessment of a CEP application or granting of a CEP. It does not address items within the scope of the advice procedures for medicinal products nor does it relieve the applicant for CEP from his legal responsibilities.