### 3.2.R.3 Certificate(s) of suitability with respect the Ph.Eur. (CEPs)

A valid EU certificate of suitability (CEP) may be submitted if available.

The CEP certifies the suitability of the relevant Ph. Eur. monograph to control the quality of the API produced by the manufacturer specified in the CEP. The Ph. Eur. must be used for API specifications and procedures if a CEP is submitted.

Please ensure that the CEP is accompanied by any annexes mentioned in the CEP. Any additional requirements indicated in the CEP and the methods described in the annexes are officially part of the API specification. Also ensure that the declaration of access is completed.

If a CEP is submitted, detailed description of the methods of synthesis and analysis of the API are not required.

Impurities and residual solvents listed in the CEP should be included in the API specifications (3.2.S.4.1).

It is the responsibility of the applicant to be aware of changes in the status of CEPs that are used for their products and to notify Council accordingly. It is also the responsibility of the applicant to ensure that the revised CEP is obtained from the CEP holder when applicable and to submit such updated CEP. If the CEP is withdrawn or suspended for whatever reason a DMF or APIF should be submitted within six months, in accordance with 3.2.S.

The validity of the CEP can be verified under “Certification” at:

http://www.edqm.eu/site/Databases-10.html

In addition: a) Any information required for the APIF but not addressed in the CEP must be submitted, e.g. physico-chemical properties [3.2.S.1.3 above].

b) If the retest period is not reflected in the CEP, stability data generated according to the Stability guideline and/or supporting literature to demonstrate the API stabilityshould be submitted. (Module 3.2.S.7)

c) Certificates of Analysis (CoAs) from the API manufacturer relating to at least two batches should be included. (Module 3.2.S.4.4)