

Certification of Substances Division

Title:	Clarification concerning the assessment of stability data within the Certification procedure
Reference Document:	PA/PH/CEP (11) 47

According to current regulatory requirements¹, defining a re-test period for an active substance described in the European Pharmacopoeia is not mandatory: the manufacturer of a medicinal product may test the active substance immediately prior to manufacture of the finished product and confirm the former complies with its specification.

Therefore, assessing the re-test period for active substances is an optional feature of the Certification procedure, which is done at the request of the applicant / CEP holder.

The EDQM hereby wishes to clarify to CEP users (manufacturers of medicinal products as well as national competent authorities), CEP holders and applicants for a CEP that the stability data presented under section 3.2.S.7 of the dossier are only assessed when the company requests a re-test period. In this case, the approved re-test period is mentioned on the CEP when granted.

If no re-test period is mentioned on a CEP, stability data have not been assessed; they may be included in the marketing authorisation application for the finished product, for assessment of the re-test period by the relevant national competent authority. Alternatively, in the absence of an approved re-test period, the manufacturer of the finished product may still opt to test compliance of the substance immediately prior to use.

¹*Guideline on stability testing: stability testing of existing active substances and related finished products CPMP/QWP/122/02, rev 1 corr*