

Certification of Substances Division

SHE/CB

PUBLIC DOCUMENT

(LEVEL 1)

English only/Anglais seulement

PA/PH/CEP (12) 112

Strasbourg, December 2012

Certification of suitability to Monographs of the European Pharmacopoeia

Definition section of Ph. Eur. Monographs and CEPs

ENGLISH

According to the European Pharmacopoeia, any statements included under the heading "Definition" of the monograph constitute an official definition of the substance which is the subject of the monograph.

In these cases, any substance, for which the mode of preparation is not in line with the requirements of the Definition Section of the related monograph, falls outside the scope of the procedure for Certification of Suitability to the Monograph of the European Pharmacopoeia.

The EDQM will therefore no longer accept (effective 2 January 2013) any new application for CEPs for which the mode of preparation of the substance is not in line with the requirements of the Definition Section of the related monograph.

For example, if the Definition Section of the monograph states "Semi-synthetic product derived from a fermentation product" and the substance in question is manufactured by a purely synthetic process then a new application for a CEP will not be accepted.

Existing CEPs and on-going applications are not affected by this decision.