

Certification of Substances Division

AMM/CB

PUBLIC DOCUMENT

(Level 1)

English only/Anglais seulement

PA/PH/CEP (08) 60

Strasbourg, November 2008

Certification of suitability to Monographs of the European Pharmacopoeia

Clarification on the acceptability of CEP applications for sterile grade material

Scope: This document addresses the conditions for acceptability of applications for certificate of suitability to the monographs of the European Pharmacopoeia materials for which the sub-title sterile is requested. This document should be read in conjunction with 'Content of the dossier for chemical purity and microbiological quality' (PA/PH/ CEP (04) 1 4R) and with 'Certificates of suitability for sterile active substances' (PA/PH/Exp. CEP/T (06) 13, 1R).

The possibility to apply for a certificate of suitability for a sterile grade material has existed for the last 10 years. It was never the intention, however, for the procedure to cover applications which describe only the sterilisation operations required to obtain the sterile substance. Following a request from the European Licensing Authorities it has therefore been decided to issue clarification in this direction.

An application for a sterile grade material can only be accepted if the sterilisation step is considered an integral part of manufacture of the material as performed by the manufacturer. This means for example that an application is not acceptable where a crude or non-sterile substance is purchased from an external supplier and subjected to purification and/or salt formation before sterilisation, since the sterilisation step is not considered to be an integral part of manufacture. Similarly an application is not acceptable where a crude or non-sterile substance is transferred to an external manufacturer for purification and/or salt formation before sterilisation, since the sterilisation step is not considered to be an integral part of manufacture.

Certificates, which have already been issued for sterile grade material where this requirement is not met will continue to be valid, if maintained up to date by the certificate holder. Any new application which does not satisfy this requirement that the sterilisation operation is an integral part of manufacture carried out by the manufacturer will not be accepted.