European Directorate for the Quality of Medicines & Healthcare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

**Certification of Substances Division**

AMM/CB

**PUBLIC DOCUMENT**
(Level 1)

*English/Chinese*

**PA/PH/CEP/(08)60**

Strassbourg, November 2008

# Certification of suitability to Monographs of the European Pharmacopoeia
# 欧洲药典适应性证书

# Clarification on the acceptability of CEP applications for sterile grade material
# 无菌级CEP证书申请受理说明

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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).

范围：本文说明副标题有无菌级字样的欧洲药典适应性证书申请的受理条件。本文应与“化学物质和有微生物质量要求的文件内容规定(PA/PH/ CEP (04) 1 4R)”以及“无菌活性物质适应性证书(PA/PH/Exp. CEP/T (06) 13, 1R)”一同使用

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.

过去10年来一直可以申请无菌级CEP证书。但是，CEP程序历来就不适用只描述无菌操作的申请资料。根据欧洲上市许可证签发部门的意见和请求，我们决定特此进行如下澄清和说明。

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.

灭菌工序必须是生产厂生产全过程中一个必不可少的工序，我们方可受理申请。举例来说，如果工厂外购粗品或非无菌成品，自己在灭菌之前再进行精制或/和成盐，这种申请是不会受理的，因为灭菌工序不是生产过程中必不可少的环节。同样，如果粗品或非无菌成品送到外部生产厂在灭菌之前进行精制和/或成盐，我们也不会受理此项申请，因为灭菌工序不是生产过程中必不可少的环节。

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.

已经签发的无菌级CEP证书，若不符合这个条件，但CEP证书持有人若进行更新，将继续有效；所有新申请中，如果灭菌工序不是生产厂生产过程中必不可少的工序，EDQM将不再受理。