

**Certification of Substances Division**

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

**Note for applicants: Procedure for validation of new applications  
申请人须知：新CEP申请验收程序**

**2008年06月 - 施特拉斯堡**

This document presents the measures taken for the validation of new applications for a CEP that were put in place in 2007, and also the results obtained.

本文讨论2007年生效的新CEP证书申请文件受理方法，以及2007年的受理情况。

## **1. Procedure for validation of new applications:**

### **新申请的受理程序**

All applications are screened at reception to check whether they are acceptable and can be validated.

所有申请文件在收文时均会浏览一遍，检查是否可以受理和验收。

The main criteria that are checked for completeness are:

文件完整性检查的主要原则是:

- administrative information: the application form and all the declarations filled in, the signed quality overall summary and the technical dossier in CTD format are present.

管理信息: 申请表格内容以及所有声明信, 签字的质量总结以及CTD格式的技术文件。

- the dossier contains all the relevant sections of the CTD as described in the relevant document "Content of the dossier" (PA/PH/CEP 04 1 4R, or PA/PH/CEP (06) 2).

申报文件必须包括CTD各相关章节 ( 要求详见“申报文件内容”(PA/PH/CEP 04 1 4R, 或PA/PH/CEP (06) 2)。

The evaluation clock can start only once the application has been validated. Otherwise, it is blocked and a deficiency letter is sent to the applicant together with a deadline for providing the missing documentation.

只有在文件得到验收后，评审时间表方可启动。否则，文件会被搁置，并向申请人发送缺陷信，同时规定提供缺失文件的期限。

The clock will start only if the required information is received in time. Failing to provide the missing information will result in the definite closure of the procedure without reimbursement of the fees.

只有及时收到缺失文件后，评审时间表方可启动。若不能按时提供资料，肯定会关闭评审程序，费用概不退回。

## 2. How to avoid a blockage of the application at receipt:

### 如何避免申请在首次递交时被搁置

38% of the applications received in 2007 have been blocked at receipt. The requirements and the corresponding information which should be submitted for a new chemical application are listed below.

2007年收到的申请中，有38%在首次递交时被搁置。化学物质进行首次申请时，要求的所需资料如下：

- in the case a complex starting material is declared, its route of synthesis should be described and its specifications suitably defined. This has been the first reason for blocking an application in 2007 (45% of the blocked applications)

若使用复杂的起始物质，必须描述其合成途径、规定合适的质量标准。这是2007年申请搁置中的首要缺陷（45%）

- in case of an active substance, the company should provide a declaration that the manufacture of the substance takes place in accordance with the dossier presented and according to Good Manufacturing Practice for Active Substances used as Starting Materials as published in the Rules governing Medicinal Products in the European Union, Volume 4, EU Guidelines to Good Manufacturing practice for Human and Veterinary use, Part II, and Annex 1 in case of sterile substances, (10% of the blocked applications in 2007)

若为活性物质，公司必须提供声明：生产与文件一致；生产符合EU药品管理法第4卷登载的活性起始物质质量管理规范、人用与兽用药生产质量管理规范第II部（EU GMP，如果是无菌物质，还必须符合附录I要求。（10%）

- the dossier should contain information showing that all solvents used during synthesis have been either properly removed or suitably limited in the specification of the final substance. The methods used to demonstrate the absence of residual solvents should be properly described and validated. (9% of the blocked applications in 2007)

文件必须说明合成生产中使用所有溶剂的信息：必须说明溶剂已经适当除去或在成品中建立适当限量。残留溶剂的检验方法必须适当描述并经过验证（9%）

- all the potential impurities of the process with their origin should be listed, correspondence with the transparency statement of the monograph should be established and individual impurity results should be provided. (8.5% of the blocked applications in 2007)

必须列出该生产过程中可能产生的所有杂质，并与药典杂质清单对照，必须提供单个杂质的检验结果（8.5%）

- the company should refer to the current European Pharmacopoeia monograph (6.5% of the blocked applications in 2007)

公司必须执行现行欧洲药典(6.5%)

- if the substance is claimed to be sterile, the applicant should provide a description and the complete validation data for the sterilisation process.

无菌物质，必须提供无菌工艺描述、以及完整的验证资料。

- if a Class I solvent is used, a proper justification for doing so and suitable control of this solvent should be made,

若使用了1类溶剂，必须证明使用的合理性，必须建立适当的控制。

- in case there is a non-specific TLC method in the European Pharmacopoeia monograph, the applicant should propose an alternative quantitative method.

若欧洲药典只有非专属性的TLC方法，申请人必须提出另一种更能定量检测的方法。

The attention of the applicants is drawn to these points in order for them to submit applications complying with requirements and not to delay the process.

希望申请人注意以上几点，从而按要求申请资料，不影响申请进程。