European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Certification of Substances Division

NV/CB

PUBLIC DOCUMENT
English only/Anglais seulement

PA/PH/CEP (11) 78

Strasbourg, November 2011

Certification of suitability to Monographs of the European Pharmacopoeia

MONTHLY REPORT PUBLICATION
October 2011

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New applications for CEP

	Month (current)	Cumulated/year
Nr of applications received		
Chemical	**28**	**310**
Others (TSE, double, herbal)	**3**	**16**
Total	**31**	**326**
Nr of treated applications (chemical)	**33**	**297**
Nr of CEPs granted (all)	**29**	**283**

Actual time vs. deadlines (day)	**+ 3**

(+) means delay

Revisions (including notifications and renewals) of CEP applications

	Month (current)	Cumulated/year
Nr of applications received		
Chemical (incl sister files)	**105**	**952**
Others (TSE, double, herbal)	**5**	**68**
Total	**110**	**1020**
Nr of treated applications (chemical)	**133**	**1137**
Nr of CEPs granted (all)	**102**	**970**

Actual time vs. deadlines (day)	**+ 1**

(+) means delay

Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
Nr of answers received		
Chemical	**55**	**552**
Others (TSE, double, herbal)	**5**	**37**
Total	**60**	**589**
Total treated applications (chemical)	**58**	**626**

Actual time vs. deadlines (± day)	**+ 11**

(+) means delay

Inspections:

	Month (current)	Cumulated/year
Nr of inspections	**3**	**18**
Place		
Asia	**2**	**14**
EEA	**1**	**2**
Other places	**0**	**2**

Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
Nr of CEPs suspended	**3**	**9**
Nr of CEPs expired	**0**	**5**
Nr of CEPs withdrawn by EDQM	**0**	**13**
Nr of CEPs withdrawn by holder	**2**	**27**

Other activities

	Month (current)	Cumulated/year
Technical Advice meetings	**1**	**12**

Information published on our Website (www.edqm.eu)

- Updated list of assessors
- CEPs suspension following the inspection of the manufacturing site(s):
    - 06/10/11 Oxytetracycline Dihydrate CEP 2002-211
    - 06/10/11 Oxytetracycline Hydrochloride CEP 2002-070
    - 06/10/11 Oxytetracycline Hydrochloride CEP 2001-125