European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Certification of Substances Division

VLA/CB

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Certification of suitability to Monographs of the European Pharmacopoeia

MONTHLY REPORT PUBLICATION
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New applications for CEP

	Month (current)	Cumulated/year
Nr of applications received		
Chemical	**33**	**193**
Others (TSE, double, herbal)	**0**	**10**
Total	**33**	**203**
Nr of treated applications (chemical)	**30**	**149**
Nr of CEPs granted (all)	**24**	**129**

Actual time vs. deadlines (day)	**-10**

(+) means delay

Revisions (including notifications and renewals) of CEP applications

	Month (current)	Cumulated/year
Nr of applications received		
Chemical (incl sister files)	**117**	**586**
Others (TSE, double, herbal)	**8**	**53**
Total	**125**	**639**
Nr of treated applications (chemical)	**118**	**736**
Nr of CEPs granted (all)	**73**	**505**

Actual time vs. deadlines (day)	**-12**

(+) means delay

Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
Nr of answers received		
Chemical	**61**	**324**
Others (TSE, double, herbal)	**11**	**33**
Total	**72**	**357**
Total treated applications (chemical)	**68**	**375**

Actual time vs. deadlines (± day)	**-4**

(+) means delay

Inspections

	Month (current)	Cumulated/year
Nr of inspections	**4**	**18**
Place		
Asia	**4**	**15**
EEA	**0**	**1**
Other places	**0**	**2**

Suspended/Withdrawn CEPs

	Month (current)	Cumulated/year
Nr of CEPs suspended	**5**	**20**
Nr of CEPs expired	**3**	**6**
Nr of CEPs withdrawn by EDQM	**2**	**13**
Nr of CEPs withdrawn by holder	**5**	**18**

Other activities

	Month (current)	Cumulated/year
Technical Advice meetings	**0**	**4**

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

- Revision of EDQM Policy Document "Terms of Reference" - PA/PH/CEP (01) 1, 9R
- List of Certification assessors (updated 04/06/12)
- CEPs suspensions following inspection of the manufacturing site(s):
  - 27/03/2012 Pilocarpine hydrochloride CEP 1997-034
  - 27/03/2012 Pilocarpine nitrate CEP 2002-202