

Certification of Substances Division

NV/CB

PUBLIC DOCUMENT

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PA/PH/CEP (11)31

Strasbourg, May 2011

Certification of suitability to Monographs of the European Pharmacopoeia

MONTHLY REPORT PUBLICATION April 2011

New applications for CEP

	Month (current)	Cumulated/year
Nr of applications received		
Chemical	29	134
Others (TSE, double, herbal)	0	2
Total	29	136
Nr of treated applications	32	109
Nr of CEPs granted	48	133

Actual time vs. deadlines (day)	+ 5
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(+) means delay

Revisions (including notifications and renewals) of CEP applications

	Month (current)	Cumulated/year
Nr of applications received		
Chemical (incl sister files)	94	381
Others (TSE, double, herbal)	6	28
Total	100	409
Nr of treated applications	118	445
Nr of CEPs granted	108	402

Actual time vs. deadlines (day)	in time
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(+) means delay

Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
Nr of answers received		
Chemical	64	217
Others (TSE, double, herbal)	2	7
Total	66	224
Total treated applications	90	263

Actual time vs. deadlines (\pm day)	in time
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(+) means delay

Inspections:

	Month (current)	Cumulated/year
Nr of inspections	0	7
Place		
Asia	0	6
EEA	0	0
Other places	0	1

Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
Nr of CEPs suspended	4	5
Nr of CEPs expired	0	2
Nr of CEPs withdrawn by EDQM	0	9
Nr of CEPs withdrawn by holder	5	12

Other activities

	Month (current)	Cumulated/year
Technical Advice meetings	2	6

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

- GPS/DUNS information to be mentioned in the application forms (New applications / Revisions)
- Refusal of information from third parties in reply to EDQM's request for information
- Update of monographs regarding limit for unspecified impurities
- CEP Suspensions: Following inspection of the manufacturing site(s):
 - 12/04/11 : Naltrexone hydrochloride CEP 2008-167
 - 12/04/11 : Buprenorphine CEP 2007-065
 - 12/04/11 : Fentanyl CEP 2005-164
 - 12/04/11 : Buprenorphine hydrochloride CEP 2001-278