

Certification of Substances Division

NV/CB

PUBLIC DOCUMENT

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PA/PH/CEP (12) 02

Strasbourg, January 2012

Certification of suitability to Monographs of the European Pharmacopoeia

MONTHLY REPORT PUBLICATION December 2011

New applications for CEP

	Month (current)	Cumulated/year
Nr of applications received		
Chemical	32	349
Others (TSE, double, herbal)	5	23
Total	37	372
Nr of treated applications (chemical)	27	358
Nr of CEPs granted (all)	32	340

Actual time vs. deadlines (day)	in time
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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)	91	1113
Others (TSE, double, herbal)	1	73
Total	92	1186
Nr of treated applications (chemical)	94	1345
Nr of CEPs granted (all)	82	1147

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	36	646
Others (TSE, double, herbal)	3	49
Total	39	695
Total treated applications (chemical)	69	765

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

Inspections:

	Month (current)	Cumulated/year
Nr of inspections	3	22
Place		
Asia	3	18
EEA	0	2
Other places	0	2

Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
Nr of CEPs suspended	7	18
Nr of CEPs expired	2	8
Nr of CEPs withdrawn by EDQM	1	14
Nr of CEPs withdrawn by holder	1	33

Other activities

	Month (current)	Cumulated/year
Technical Advice meetings	3	15

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

- CEPs suspension following the inspection of the manufacturing site(s):
 - 20/12/11 Azathioprine CEP 2001-341
 - 20/12/11 Ticlopidine Hydrochloride CEP 2003-066
 - 20/12/11 Haloperidol CEP 2003-206
 - 20/12/11 Risperidone CEP 2004-135
 - 20/12/11 Diphenoxylate Hydrochloride CEP 2005-084
 - 20/12/11 Nifuroxazide CEP 2006-074
- CEPs suspension due to a failure to comply with a declaration of willingness to be inspected and/or to operate according to EU GMP (e.g. refusal, of inspection, reconstruction/restoration of site(s), to achieve GMP level, and temporary closure):
 - 20/12/11 Troxerutin CEP 2006-153