

Certification of Substances Division

NV/CB

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Certification of suitability to Monographs of the European Pharmacopoeia

MONTHLY REPORT PUBLICATION October 2011

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
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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)	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
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(+) 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 (\pm day)	+ 11
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(+) 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Suspended/Withdrawn CEPs: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Nr of CEPs withdrawn by EDQM	0	13
Nr of CEPs withdrawn by holder	2	27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