

Certification of Substances Division

NV/CB

PUBLIC DOCUMENT

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Certification of suitability to Monographs of the European Pharmacopoeia

MONTHLY REPORT PUBLICATION May 2011

New applications for CEP

	Month (current)	Cumulated/year
Nr of applications received		
Chemical	32	166
Others (TSE, double, herbal)	2	4
Total	34	170
Nr of treated applications	38	147
Nr of CEPs granted	38	171

Actual time vs. deadlines (day)	+ 6
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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)	66	447
Others (TSE, double, herbal)	4	32
Total	70	479
Nr of treated applications	108	553
Nr of CEPs granted	85	487

Actual time vs. deadlines (day)	+ 4
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(+) means delay

Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
Nr of answers received		
Chemical	67	284
Others (TSE, double, herbal)	5	12
Total	72	296
Total treated applications	81	344

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

Inspections:

	Month (current)	Cumulated/year
Nr of inspections	2	9
Place		
Asia	0	6
EEA	0	1
Other places	2	2

Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
Nr of CEPs suspended	0	5
Nr of CEPs expired	0	2
Nr of CEPs withdrawn by EDQM	0	9
Nr of CEPs withdrawn by holder	4	16

Other activities

	Month (current)	Cumulated/year
Technical Advice meetings	0	7

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

- Note concerning CEPs for gelatin and impact of the revised EU Note for Guidance on the TSE risk
- Policy document on Suspension and Withdrawal of a CEP