

Certification of Substances Division

NV/CB

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Certification of suitability to Monographs of the European Pharmacopoeia

MONTHLY REPORT PUBLICATION September 2011

New applications for CEP

	Month (current)	Cumulated/year
Nr of applications received		
Chemical	31	282
Others (TSE, double, herbal)	1	13
Total	32	295
Nr of treated applications (chemical)	23	264
Nr of CEPs granted (all)	20	254

Actual time vs. deadlines (day)	+ 13
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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)	116	847
Others (TSE, double, herbal)	6	63
Total	122	910
Nr of treated applications (chemical)	158	1004
Nr of CEPs granted (all)	136	868

Actual time vs. deadlines (day)	+ 2
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(+) means delay

Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
Nr of answers received		
Chemical	37	497
Others (TSE, double, herbal)	2	32
Total	39	529
Total treated applications (chemical)	45	568

Actual time vs. deadlines (\pm day)	+ 6
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(+) means delay

Inspections:

	Month (current)	Cumulated/year
Nr of inspections	3	15
Place		
Asia	3	12
EEA	0	1
Other places	0	2

Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
Nr of CEPs suspended	1	6
Nr of CEPs expired	0	5
Nr of CEPs withdrawn by EDQM	4	13
Nr of CEPs withdrawn by holder	3	25

Other activities

	Month (current)	Cumulated/year
Technical Advice meetings	0	11

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

- Packaging information within the certification procedure
- Clarification concerning the assessment of stability data within the Certification procedure