

Certification of Substances Division

NV/CB

PUBLIC DOCUMENT

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Strasbourg, August 2011

Certification of suitability to Monographs of the European Pharmacopoeia

MONTHLY REPORT PUBLICATION July 2011

New applications for CEP

	Month (current)	Cumulated/year
Nr of applications received		
Chemical	22	218
Others (TSE, double, herbal)	5	10
Total	27	228
Nr of treated applications (chemical)	29	225
Nr of CEPs granted (all)	36	221

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)	85	637
Others (TSE, double, herbal)	9	45
Total	94	682
Nr of treated applications (chemical)	104	752
Nr of CEPs granted (all)	74	638

Actual time vs. deadlines (day)	+ 8
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(+) means delay

Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
Nr of answers received		
Chemical	47	390
Others (TSE, double, herbal)	3	24
Total	50	414
Total treated applications (chemical)	82	471

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

Inspections:

	Month (current)	Cumulated/year
Nr of inspections	0	10
Place		
Asia	0	7
EEA	0	1
Other places	0	2

Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
Nr of CEPs suspended	0	5
Nr of CEPs expired	1	4
Nr of CEPs withdrawn by EDQM	0	9
Nr of CEPs withdrawn by holder	0	18

Other activities

	Month (current)	Cumulated/year
Technical Advice meetings	2	11

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

- Updated list of assessors