

Certification of Substances Division

NV/CB

PUBLIC DOCUMENT

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PA/PH/CEP (11)16

Strasbourg, March 2011

Certification of suitability to Monographs of the European Pharmacopoeia

MONTHLY REPORT PUBLICATION February 2011

New applications for CEP

	Month (current)	Cumulated/year
Nr of applications received		
Chemical	26	63
Others (TSE, double, herbal)	1	2
Total	27	65
Nr of treated applications	9	44
Nr of CEPs granted	17	51

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)	67	178
Others (TSE, double, herbal)	8	12
Total	75	190
Nr of treated applications	101	177
Nr of CEPs granted	101	174

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

Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
Nr of answers received		
Chemical	58	113
Others (TSE, double, herbal)	1	4
Total	59	117
Total treated applications	35	90

Actual time vs. deadlines (\pm day)	+ 16
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(+) means delay

Inspections:

	Month (current)	Cumulated/year
Nr of inspections	1	5
Place		
Asia	0	4
EEA	1	1
Other places	0	0

Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
Nr of CEPs suspended	0	0
Nr of CEPs expired	0	0
Nr of CEPs withdrawn by EDQM	4	4
Nr of CEPs withdrawn by holder	6	6

Other activities

	Month (current)	Cumulated/year
Technical Advice meetings	0	3

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

- Requirements for notifications to the EDQM
- CEP Withdrawals: Due to a failure to fulfill, after a suspension, the requirements of the CEP procedure with regards to updating the application and complying with GMP:
 - 18/02/11 : Chlorpropamide CEP 2000-020
 - 18/02/11 : Tolbutamide CEP 2000-021
 - 18/02/11 : Diclofenac sodium CEP 1999-075
 - 18/02/11 : Mefenamic acid CEP 2000-043