

## **Certification of Substances Division**

NV/CB

PUBLIC DOCUMENT

*English only/Anglais seulement*

**PA/PH/CEP (11)26**

Strasbourg, April 2011

## **Certification of suitability to Monographs of the European Pharmacopoeia**

### **MONTHLY REPORT PUBLICATION March 2011**

## New applications for CEP

	Month (current)	Cumulated/year
<b>Nr of applications received</b>		
Chemical	42	105
Others (TSE, double, herbal)	0	2
Total	42	107
<b>Nr of treated applications</b>	<b>33</b>	<b>77</b>
<b>Nr of CEPs granted</b>	<b>34</b>	<b>85</b>

<b>Actual time vs. deadlines (day)</b>	<b>+ 10</b>
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(+) means delay

## Revisions (including notifications and renewals) of CEP applications

	Month (current)	Cumulated/year
<b>Nr of applications received</b>		
Chemical (incl sister files)	109	287
Others (TSE, double, herbal)	10	22
Total	119	309
<b>Nr of treated applications</b>	<b>150</b>	<b>327</b>
<b>Nr of CEPs granted</b>	<b>120</b>	<b>294</b>

<b>Actual time vs. deadlines (day)</b>	<b>in time</b>
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(+) means delay

## Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
<b>Nr of answers received</b>		
Chemical	40	153
Others (TSE, double, herbal)	1	5
Total	41	158
<b>Total treated applications</b>	<b>83</b>	<b>173</b>

<b>Actual time vs. deadlines (day)</b>	<b>+ 17</b>
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(+) means delay

## Inspections:

	Month (current)	Cumulated/year
<b>Nr of inspections</b>	<b>2</b>	<b>7</b>
<b>Place</b>		
Asia	2	6
EEA	0	0
Other places	0	1

## Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
<b>Nr of CEPs suspended</b>	<b>1</b>	<b>1</b>
<b>Nr of CEPs expired</b>	<b>2</b>	<b>2</b>
<b>Nr of CEPs withdrawn by EDQM</b>	<b>5</b>	<b>9</b>
<b>Nr of CEPs withdrawn by holder</b>	<b>1</b>	<b>7</b>

## Other activities

	Month (current)	Cumulated/year
<b>Technical Advice meetings</b>	<b>1</b>	<b>4</b>

## Information published on our Website ([www.edqm.eu](http://www.edqm.eu))

- CEP Suspensions: Due to a temporary inability to produce API(s) under the approved conditions:
  - 09/03/11: Metronidazole CEP 1997-083
- 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:
  - 14/03/11: Cloxacillin sodium CEP 1997-131
  - 11/03/11 : Amoxicillin trihydrate CEP 1997-129
  - 07/03/11 : Ephedrine hydrochloride CEP 2004-152
  - 07/03/11 : Pseudoephedrine hydrochloride CEP 2004-153