

## **Certification of Substances Division**

NV/CB

PUBLIC DOCUMENT

*English only/Anglais seulement*

**PA/PH/CEP (11) 89**

Strasbourg, December 2011

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

### **MONTHLY REPORT PUBLICATION November 2011**

## New applications for CEP

	Month (current)	Cumulated/year
<b>Nr of applications received</b>		
Chemical	32	342
Others (TSE, double, herbal)	2	18
Total	34	360
<b>Nr of treated applications (chemical)</b>	<b>34</b>	<b>331</b>
<b>Nr of CEPs granted (all)</b>	<b>25</b>	<b>308</b>

<b>Actual time vs. deadlines (day)</b>	<b>in time</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)	90	1042
Others (TSE, double, herbal)	4	72
Total	94	1114
<b>Nr of treated applications (chemical)</b>	<b>99</b>	<b>1251</b>
<b>Nr of CEPs granted (all)</b>	<b>95</b>	<b>1065</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	58	610
Others (TSE, double, herbal)	9	46
Total	67	656
<b>Total treated applications (chemical)</b>	<b>70</b>	<b>696</b>

<b>Actual time vs. deadlines (<math>\pm</math> day)</b>	<b>+ 9</b>
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(+) means delay

## Inspections:

	Month (current)	Cumulated/year
<b>Nr of inspections</b>	<b>1</b>	<b>19</b>
<b>Place</b>		
Asia	1	15
EEA	0	2
Other places	0	2

## Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
<b>Nr of CEPs suspended</b>	<b>2</b>	<b>11</b>
<b>Nr of CEPs expired</b>	<b>1</b>	<b>6</b>
<b>Nr of CEPs withdrawn by EDQM</b>	<b>0</b>	<b>13</b>
<b>Nr of CEPs withdrawn by holder</b>	<b>5</b>	<b>32</b>

## Other activities

	Month (current)	Cumulated/year
<b>Technical Advice meetings</b>	<b>0</b>	<b>12</b>

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

- CEPs suspension following the inspection of the manufacturing site(s):
  - 04/11/11 Isosorbide monohydrate diluted CEP 2002-104
  - 04/11/11 Protamine sulfate CEP 2000-162