

## Certification of Substances Division

NV/CB

PUBLIC DOCUMENT

*English only/Anglais seulement*

**PA/PH/CEP (11)12**

Strasbourg, February 2011

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

## **MONTHLY REPORT PUBLICATION January 2011**

## New applications for CEP

	Month (current)	Cumulated/year
<b>Nr of applications received</b>		
Chemical	37	37
Others (TSE, double, herbal)	1	1
Total	38	38
Nr of treated applications	35	35
Nr of CEPs granted	34	34
Actual time vs. deadlines (day)	+ 15	+ 15

(+) means delay

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

	Month (current)	Cumulated/year
<b>Nr of applications received</b>		
Chemical (incl sister files)	111	111
Others (TSE, double, herbal)	4	4
Total	115	115
Nr of treated applications	76	76
Nr of CEPs granted	73	73
Actual time vs. deadlines (day)	+ 5	+ 5

(+) means delay

## Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
<b>Nr of answers received</b>		
Chemical	55	55
Others (TSE, double, herbal)	3	3
Total	58	58
Total treated applications	55	55
Actual time vs. deadlines ( $\pm$ day)	+ 13	+ 13

(+) means delay

## Inspections:

	Month (current)	Cumulated/year
<b>Nr of inspections</b>	<b>4</b>	<b>4</b>
<b>Place</b>		
<b>Asia</b>	<b>4</b>	<b>4</b>
<b>EEA</b>	<b>0</b>	<b>0</b>
<b>Other places</b>	<b>0</b>	<b>0</b>

## Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
<b>Nr of CEPs suspended</b>	<b>0</b>	<b>0</b>
<b>Nr of CEPs expired</b>	<b>0</b>	<b>0</b>
<b>Nr of CEPs withdrawn by EDQM</b>	<b>0</b>	<b>0</b>
<b>Nr of CEPs withdrawn by holder</b>	<b>0</b>	<b>0</b>

## Other activities

	Month (current)	Cumulated/year
<b>Technical Advice meetings</b>	<b>3</b>	<b>3</b>

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

- Updated list of assessors