

## **Certification of Substances Division**

NV/CB

PUBLIC DOCUMENT

*English only/Anglais seulement*

**PA/PH/CEP (11) 62**

Strasbourg, September 2011

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

## **MONTHLY REPORT PUBLICATION August 2011**

## New applications for CEP

	Month (current)	Cumulated/year
<b>Nr of applications received</b>		
Chemical	33	251
Others (TSE, double, herbal)	2	12
Total	35	263
Nr of treated applications (chemical)	16	241
Nr of CEPs granted (all)	13	234

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
<b>Nr of applications received</b>		
Chemical (incl sister files)	94	731
Others (TSE, double, herbal)	12	57
Total	106	788
Nr of treated applications (chemical)	94	846
Nr of CEPs granted (all)	83	721

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

## Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
<b>Nr of answers received</b>		
Chemical	70	460
Others (TSE, double, herbal)	6	30
Total	76	489
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
<b>Nr of inspections</b>	<b>2</b>	<b>12</b>
<b>Place</b>		
Asia	2	9
EEA	0	1
Other places	0	2

## Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
<b>Nr of CEPs suspended</b>	<b>0</b>	<b>5</b>
<b>Nr of CEPs expired</b>	<b>1</b>	<b>5</b>
<b>Nr of CEPs withdrawn by EDQM</b>	<b>0</b>	<b>9</b>
<b>Nr of CEPs withdrawn by holder</b>	<b>4</b>	<b>22</b>

## Other activities

	Month (current)	Cumulated/year
<b>Technical Advice meetings</b>	<b>0</b>	<b>11</b>

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

- Report on the international API inspection pilot programme
- Revised application forms for new application as well as for revision and renewal