

## Certification of Substances Division

NV/CB

PUBLIC DOCUMENT

*English only/Anglais seulement*

**PA/PH/CEP (12)13**

Strasbourg, February 2012

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

## **MONTHLY REPORT PUBLICATION January 2012**

## New applications for CEP

	Month (current)	Cumulated/year
<b>Nr of applications received</b>		
<b>Chemical</b>	<b>39</b>	<b>39</b>
<b>Others (TSE, double, herbal)</b>	<b>2</b>	<b>2</b>
<b>Total</b>	<b>41</b>	<b>41</b>
<b>Nr of treated applications</b>	<b>17</b>	<b>17</b>
<b>Nr of CEPs granted</b>	<b>17</b>	<b>17</b>

<b>Actual time vs. deadlines (day)</b>	<b>- 6</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>		
<b>Chemical (incl sister files)</b>	<b>103</b>	<b>103</b>
<b>Others (TSE, double, herbal)</b>	<b>7</b>	<b>7</b>
<b>Total</b>	<b>110</b>	<b>110</b>
<b>Nr of treated applications</b>	<b>141</b>	<b>141</b>
<b>Nr of CEPs granted</b>	<b>90</b>	<b>90</b>

<b>Actual time vs. deadlines (day)</b>	<b>- 1</b>
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(+) means delay

## Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
<b>Nr of answers received</b>		
<b>Chemical</b>	<b>52</b>	<b>52</b>
<b>Others (TSE, double, herbal)</b>	<b>5</b>	<b>5</b>
<b>Total</b>	<b>57</b>	<b>57</b>
<b>Total treated applications</b>	<b>44</b>	<b>44</b>

<b>Actual time vs. deadlines (± day)</b>	<b>+ 14</b>
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(+) means delay

### Inspections:

	Month (current)	Cumulated/year
<b>Nr of inspections</b>	<b>5</b>	<b>5</b>
<b>Place</b>		
<b>Asia</b>	<b>5</b>	<b>5</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### Suspended/Withdrawn CEPs: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Nr of CEPs withdrawn by EDQM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>1</b>	<b>1</b>
<b>Nr of CEPs withdrawn by holder</b>	<b>2</b>	<b>2</b>

### Other activities

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