

## Certification of Substances Division

NV/CB

PUBLIC DOCUMENT

*English only/Anglais seulement*

**PA/PH/CEP (11)45**

Strasbourg, July 2011

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

## MONTHLY REPORT PUBLICATION June 2011

## New applications for CEP

	Month (current)	Cumulated/year
<b>Nr of applications received</b>		
Chemical	30	196
Others (TSE, double, herbal)	1	5
Total	31	201
Nr of treated applications (chemical)	49	196
Nr of CEPs granted (all)	14	185

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)	105	552
Others (TSE, double, herbal)	4	36
Total	109	588
Nr of treated applications (chemical)	95	648
Nr of CEPs granted (all)	77	564

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

## Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
<b>Nr of answers received</b>		
Chemical	59	343
Others (TSE, double, herbal)	9	21
Total	68	364
Total treated applications (chemical)	45	389

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>1</b>	<b>10</b>
<b>Place</b>		
Asia	1	7
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## Suspended/Withdrawn CEPs: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>3</b>
<b>Nr of CEPs withdrawn by EDQM</b>	<b>0</b>	<b>9</b>
<b>Nr of CEPs withdrawn by holder</b>	<b>2</b>	<b>18</b>

## Other activities

	Month (current)	Cumulated/year
<b>Technical Advice meetings</b>	<b>2</b>	<b>9</b>

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

- Note to the attention of all holders of TSE certificates of suitability
- CEP Suspensions: Upon request from the holder, due to a temporary inability to produce the API under the approved conditions:
  - 06/06/11 : Mesalazine CEP 2005-277