European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

## Certification of Substances Division

NV/CB

PUBLIC DOCUMENT
*English only/Anglais seulement*

**PA/PH/CEP (12) 31**

Strasbourg, March 2012

# Certification of suitability to Monographs of the European Pharmacopoeia

# MONTHLY REPORT PUBLICATION
## February 2012

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## New applications for CEP

| | Month (current) | Cumulated/year |
|---|---|---|
| **Nr of applications received** | | |
| **Chemical** | **22** | **61** |
| **Others (TSE, double, herbal)** | **4** | **6** |
| **Total** | **26** | **67** |
| **Nr of treated applications (chemical)** | **26** | **43** |
| **Nr of CEPs granted (all)** | **31** | **48** |

| | |
|---|---|
| **Actual time vs. deadlines (day)** | **in time** |

(+) means delay

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

| | Month (current) | Cumulated/year |
|---|---|---|
| **Nr of applications received** | | |
| **Chemical (incl sister files)** | **89** | **192** |
| **Others (TSE, double, herbal)** | **4** | **11** |
| **Total** | **93** | **203** |
| **Nr of treated applications (chemical)** | **123** | **264** |
| **Nr of CEPs granted (all)** | **81** | **171** |

| | |
|---|---|
| **Actual time vs. deadlines (day)** | **+ 2** |

(+) means delay

## Answers to an EDQM deficiency letter

| | Month (current) | Cumulated/year |
|---|---|---|
| **Nr of answers received** | | |
| **Chemical** | **44** | **96** |
| **Others (TSE, double, herbal)** | **5** | **10** |
| **Total** | **49** | **106** |
| **Total treated applications (chemical)** | **70** | **114** |

| | |
|---|---|
| **Actual time vs. deadlines (± day)** | **+ 12** |

(+) means delay

## Inspections:

| | Month (current) | Cumulated/year |
|---|---|---|
| **Nr of inspections** | **1** | **6** |
| **Place** | | |
| **Asia** | **0** | **5** |
| **EEA** | **1** | **1** |
| **Other places** | **0** | **0** |

## Suspended/Withdrawn CEPs:

| | Month (current) | Cumulated/year |
|---|---|---|
| **Nr of CEPs suspended** | **10** | **10** |
| **Nr of CEPs expired** | **0** | **0** |
| **Nr of CEPs withdrawn by EDQM** | **2** | **3** |
| **Nr of CEPs withdrawn by holder** | **5** | **7** |

## Other activities

| | Month (current) | Cumulated/year |
|---|---|---|
| **Technical Advice meetings** | **0** | **2** |

## Information published on our Website (www.edqm.eu)

- Guideline on How to communicate with EDQM Certification Division (PA/PH/CEP (11) 70)
- Updated list of all assessors
- CEPs suspensions following the inspection of the manufacturing site(s):
  - 08/02/12 Quinine hydrochloride CEP 2005-114
  - 08/02/12 Quinine sulfate CEP 2005-117
  - 08/02/12 Digoxin CEP 2009-281
  - 08/02/12 Reserpine CEP 2010-041
  - 08/02/12 Colchicine CEP 2011-016
  - 07/02/12 Erythromycin CEP 2009-267
  - 07/02/12 Trimetazidine dihydrochloride CEP 2007-245
- CEPs suspensions due to a failure to comply with a declaration of willingness to be inspected and/or to operate according to EU GMP (e.g. refusal, of inspection, reconstruction/restoration of site(s), to achieve GMP level, and temporary closure):
  - 22/02/12 Theophylline CEP 2004-139
  - 22/02/12 Theophylline-ethylenediamine anhydrous CEP 2004-140
  - 22/02/12 Caffeine CEP 2000-366
- CEPs withdrawals as a result of an inspection of the manufacturing site(s)
  - 08/02/12 Quinine sulfate CEP 2009-387
  - 08/02/12 Quinine hydrochloride CEP 2010-069