edqm European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Certification of Substances Division

Certificate of suitability
No. R1-CEP 2003-268-Rev 03

Name of the substance:
OMEPRAZOLE

Name of holder:
SCINOPHARM TAIWAN, LTD.
No. 1, Nan-Ke 8th Road
Taiwan-74144 Shan-Hua, Tainan

Site(s) of production:
SCINOP
No. 1, N
Taiwan-

Notice
NOT FOR REGISTRATION PURPOSES
For filing purposes please contact ScinoPharm Taiwan to obtain a complete "controlled copy" of this CEP.

ScinoPharm Taiwan- Regulatory Technical Services
(SPT.RTS@scinopharm.com.tw)

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production mentioned above, we certify that the quality of the substance is suitably controlled by the current version of the monograph **OMEPRAZOLE** no. 942 of the European Pharmacopoeia, current edition including supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical procedure(s) given in annex.

– Test for residual solvents by gas chromatography (Annex 1)

Acetone	not more than 1000 ppm
Methylene chloride	not more than 100 ppm

In the last steps of the synthesis water is used as solvent.

The re-test period of the substance is 4 years if stored at a temperature between 2°C and 8°C in a low density polyethylene bag in an outer black low density polyethylene bag, in a HDPE bottle.

The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance.

Address: 7, allée Kastner, CS 30026
F - 67081 Strasbourg (France)
Telephone: 33 (0) 3 88 41 30 30 - Fax: 33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet : http://www.edqm.eu

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the dossier submitted.

Failure to comply with these provisions will render this certificate void.

This certificate is renewed from **9 March 2010** according to the provisions of Resolution AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has one annex of 2 pages.

This certificate has:

lines.

On behalf of the
Director of EDQM

Strasbourg, 4 April 2013

DECLAR *bility)*

hereby

(*name of the pharmaceutical company*)

to use the above-mentioned certificate of suitability in support of their application(s) for the following Marketing Authorisation(s): (*name of product(s) and marketing number(s), if known*)

The holder also certifies that no significant changes to the operations as described in the CEP dossier have been made since the granting of this version of the certificate.

Date and Signature (*of the CEP holder*):

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