European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Division

Certificate of suitability
No. R1-CEP 2009-209-Rev 00

Name of the substance:
PACLITAXEL
Produced by a semi-synthetic process

Name of holder:
SCINOPHARM TAIWAN, LTD.
No. 1, Nan-Ke 8th Road
Taiwan-741-44 Shan-Hua, Tainan

Site(s) of production:
SEE ANNEX 1

After [illegible] and subsequent process[illegible] in annex, we certify [illegible]ersion of the monog[illegible]tion including supple[illegible] the analytical procedure(s) given in annex.

– Test for residual solvents by gas chromatography (Annex 2)

Acetone	not more than 150 ppm
Hexane	not more than 290 ppm

The re-test period of the substance is 60 months if stored in double polyethylene bags placed in a polyethylene 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.

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.

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +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

This certificate is renewed from **1 April 2016** 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 two annexes, the first of 1 page and the second of 2 pages.

This certificate has:

lines.

On behalf of the
Director of EDQM

Strasbourg, 26 February 2016

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

ScinoPharm Taiwan, Ltd., as holder of the certificate of suitability

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)

hereby

to use

llowing

Market

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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F-67081 Strasbourg (France)
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