Certification of Substances Department

Certificate of suitability
No. R1-CEP 2009-209-Rev 01

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

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

Site(s) of production:
SEE ANNEX 1

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including
analytical

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

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

A risk management summary for elemental impurities has been provided. (Annex 3)

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.

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

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

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 three annexes, the first of 1 page, the second of 2 pages and the third of 1 page.

This certificate has:

lines.

On behalf of the
Director of EDQM

Strasbourg, 17 May 2019

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

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)

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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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