

Certification of Substances Department

Certificate of suitability
No. R0-CEP 2015-278-Rev 01

1 *Name of the substance:*

2 **PACLITAXEL**

3 Produced by a semi-synthetic process, product code SPT 1308

4 *Name of holder:*

5 **SCINOPHARM TAIWAN, LTD.**

6 No. 1, Nan-Ke 8th Road

7 Taiwan-74144 Shan-Hua, Tainan

8 *Site(s) of production:*

9 **SEE ANNEX 1**

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)**

- 12 Aft
13 pro
14 cer
15 mo
16 sup
17 pro
- 18 – Test for residual solvents by ion chromatography (Annex 2)
19 Acetic acid not more than 5000 ppm
- 20 – Test for residual solvents by gas chromatography (Annex 3)
21 Acetone not more than 5000 ppm
22 *n*-Heptane not more than 5000 ppm
- 23 A risk management summary for elemental impurities has been provided. (Annex 4)
- 24 The re-test period of the substance is 5 years if stored in double polyethylene bags, placed in a
25 polyethylene drum.
- 26 The holder of the certificate has declared the absence of use of material of human or animal
27 origin in the manufacture of the substance.

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

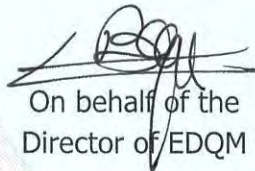
30 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice
31 and in accordance with the dossier submitted.

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

33 This certificate is granted within the framework of the procedure established by the European
34 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from
35 **6 July 2017**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and
36 Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

37 This certificate has four annexes, the first of 1 page, the second of 3 pages, the third of
38 4 pages and the fourth of 1 page.

39 This certificate has:
40 lines.


On behalf of the
Director of EDQM



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hereby authorises :.....
(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):