

Certification of Substances Department

Certificate of suitability
No. R0-CEP 2015-278-Rev 00

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)

18 – Test for residual solvents by gas chromatography

(Annex 3)

19 Acetone

not more than 5000 ppm

20 *n*-Heptane

not more than 5000 ppm

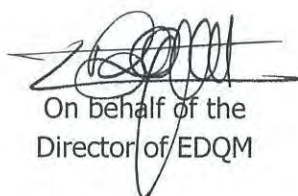
21 No elemental impurity classified in ICH Q3D is intentionally introduced in the manufacture of
22 the substance.

23 The re-test period of the substance is 2 years if stored in double polyethylene bags placed in a
24 polyethylene drum.

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

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

- 29 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice
30 and in accordance with the dossier submitted.
- 31 Failure to comply with these provisions will render this certificate void.
- 32 This certificate is granted within the framework of the procedure established by the European
33 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from
34 **6 July 2017**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and
35 Directive 2001/82/EC and any subsequent amendment, and the related guidelines.
- 36 This certificate has three annexes, the first of 1 page, the second of 3 pages and the third of
37 4 pages.
- 38 This certificate has:
39 lines.


On behalf of the
Director of EDQM



Strasbourg, 6 July 2017

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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*):