

**Certification of Substances Department**

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

1 *Name of the substance:*

2 **PACLITAXEL**

3 Produced by a semi-synthetic process

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**

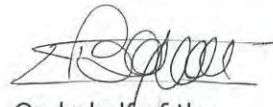
**NOT FOR REGISTRATION PURPOSES**

**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 2)
- 19 Acetone not more than 150 ppm
- 20 Hexane not more than 290 ppm
- 21 A risk management summary for elemental impurities has been provided. (Annex 3)
- 22 The re-test period of the substance is 60 months if stored in double polyethylene bags placed in  
23 a polyethylene bottle.
- 24 The holder of the certificate has declared the absence of use of material of human or animal  
25 origin in the manufacture of the substance.
- 26 The submitted dossier must be updated after any significant change that may alter the quality,  
27 safety or efficacy of the substance.
- 28 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice  
29 and in accordance with the dossier submitted.

- 30 Failure to comply with these provisions will render this certificate void.
- 31 This certificate is renewed from **1 April 2016** according to the provisions of Resolution AP-CSP  
32 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,  
33 and the related guidelines.
- 34 This certificate has three annexes, the first of 1 page, the second of 2 pages and the third of  
35 1 page.
- 36 This certificate has:  
37 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)*

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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)*: