

Certification of Substances Department

**Certificate of suitability**  
**No. R1-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)**

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- 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.

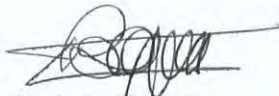
30 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice  
31 and in accordance with the dossier submitted.

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

33 This certificate is renewed from **6 July 2022** according to the provisions of Resolution AP-CSP  
34 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,  
35 and the related guidelines.

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

38 This certificate has:  
39 lines.



On behalf of the  
Director of EDQM

Strasbourg, 10 June 2022

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

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hereby :

**ScinoPharm Taiwan- Regulatory Technical Services**  
**(SPT.RTS@scinopharm.com.tw)**

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)*: