

Certification of Substances Department

**Certificate of suitability**  
**No. R0-CEP 2016-146-Rev 01**

1 *Name of the substance:*

2 **DOCETAXEL**

3 *Name of holder:*

4 **SCINOPHARM TAIWAN, LTD.**

5 No. 1, Nan-Ke 8th Road

6 Taiwan-74144 Shan-Hua, Tainan

7 *Site(s) of production:*

8 **SEE ANNEX 1**

9 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**

10 **Notice**

11 **NOT FOR REGISTRATION PURPOSES**  
12 **For filing purposes please contact ScinoPharm Taiwan**  
13 **to obtain a complete "controlled copy" of this CEP.**

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

16

18 Methanol	not more than 1000 ppm
19 Acetone	not more than 1000 ppm
20 Dichloromethane	not more than 600 ppm
21 <i>n</i> -Heptane	not more than 5000 ppm

22 – Test for residual solvents by ion chromatography (Annex 3)

23 Acetic acid not more than 5000 ppm

24 In the last steps of the synthesis water is used as solvent.

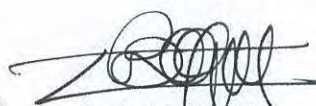
25 A risk management summary for elemental impurities has been provided. (Annex 4)

26 The re-test period of the substance is 48 months if stored in double polyethylene bags with  
27 desiccant bags in between, in aluminium bags with desiccant bags in between, placed in  
28 polyethylene drums.

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



- 31 The submitted dossier must be updated after any significant change that may alter the quality,  
 32 safety or efficacy of the substance.
- 33 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice  
 34 and in accordance with the dossier submitted.
- 35 Failure to comply with these provisions will render this certificate void.
- 36 This certificate is granted within the framework of the procedure established by the European  
 37 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from  
 38 **19 June 2017**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and  
 39 Directive 2001/82/EC and any subsequent amendment, and the related guidelines.
- 40 This certificate has four annexes, the first of 1 page, the second of 3 pages, the third of 2 pages  
 41 and the fourth of 1 page.
- 42 This certificate has:  
 43 lines.

  
 On behalf of the  
 Director of EDQM



**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)**

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):