

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2016-146 - Rev 00

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**

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	Methanol	not more than 1000 ppm
19	Acetone	not more than 1000 ppm
20	Dichloromethane	not more than 600 ppm
21	n-Heptane	not more than 5000 ppm
22	Ethyl acetate	not more than 1000 ppm

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

24 Acetic acid not more than 5000 ppm

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

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

27 The re-test period of the substance is 60 months if stored in double polyethylene bags with
28 desiccant bags in between, in aluminium bags with desiccant bags in between, placed in
29 polyethylene drums.

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

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

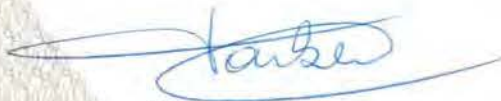
34 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice
35 and in accordance with the dossier submitted.

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

37 This certificate is renewed from **19 June 2022** according to the provisions of Resolution
38 AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent
39 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

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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):