

Certification of Substances Department

Certificate of suitability
No. R0-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)**

18 Dichloromethane

not more than 600 ppm

19 *n*-Heptane

not more than 5000 ppm

20 – Test for residual solvents by ion chromatography

(Annex 3)

21 Acetic acid

not more than 5000 ppm

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

23 The following elemental impurity classified in ICH Q3D is intentionally introduced in the
24 manufacture of the substance: Lithium.

25 The re-test period of the substance is 36 months if stored in double polyethylene bags with
26 desiccant bags in between, in aluminium bags with desiccant bags in between, placed in
27 polyethylene drums.

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

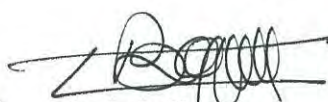
Address: 7 Allée Kastner, CS 30026

F-67081 Strasbourg (France)

Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 – e-mail: cep@edqm.eu

Internet: <http://www.edqm.eu>

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


On behalf of the
Director of EDQM



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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):