

Certification of Substances Department

**Certificate of suitability
No. R1-CEP 2016-339 - Rev 00**

1 *Name of the substance:*

2 **DOCETAXEL**
3 Code SPT1298

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 Dichloromethane not more than 600 ppm
20 *n*-Heptane not more than 5000 ppm

21 No elemental impurity classified in ICH Q3D is intentionally introduced in the manufacture of
22 the substance.

23 The substance is packed in double polyethylene bags or polyethylene tubings wrapped with
24 aluminium foil bag with desiccant in between, placed in either polyethylene bottles or drums.

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

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

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

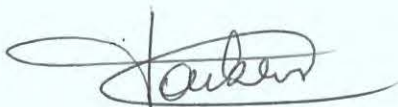
31 Failure to comply with these provisions will render this certificate void.

32 This certificate is renewed from **29 August 2023** according to the provisions of Resolution
33 AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent
34 amendment, and the related guidelines.

35 This certificate has two annexes, the first of 1 page and the second of 3 pages.

36 This certificate has:

37 lines.



On behalf of the
Director of EDQM

Strasbourg, 17 August 2023

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)*: