Certification of Substances Department

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

Name of the substance:
DOCETAXEL
Code SPT1298

Name of holder:
SCINOPHARM TAIWAN, LTD.
No. 1, Nan-Ke 8th Road
Taiwan-74144 Shan-Hua, Tainan

Site(s) of production:
SEE ANNEX 1

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– Test for residual solvents by gas chromatography (Annex 2)

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

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

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

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

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

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

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

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

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

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*):