European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

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

Name of the substance:
DOCETAXEL

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

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE

...bsequent ...nnex, we ...n of the ... including ...analytical

... (Annex 2)

Methanol	not more than 1000 ppm
Acetone	not more than 1000 ppm
Dichloromethane	not more than 600 ppm
n-Heptane	not more than 5000 ppm

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

Acetic acid	not more than 5000 ppm

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

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

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

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

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 granted within the framework of the procedure established by the European Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from **19 June 2017**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has four annexes, the first of 1 page, the second of 3 pages, the third of 2 pages and the fourth of 1 page.
This certificate has:
lines.

On behalf of the
Director of EDQM

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*):

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