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. R1-CEP 2017-163 - Rev 00

Name of the substance:
IRINOTECAN HYDROCHLORIDE TRIHYDRATE

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

Site(s) of production:
SEE ANNEX 1

quent
x, we
f the
pean
est(s)

ex 2)

Ethanol	not more than 4000 ppm	
Ethyl acetate	not more than 1000 ppm	
Dichloromethane	not more than 300 ppm	

A risk management summary for elemental impurities has been provided. (Annex 3)

– Test for elemental impurities by ICP-MS (Annex 4)

Palladium	not more than 1 ppm
Platinum	not more than 1 ppm

The substance is packed in double polyethylene bags, placed in a polyethylene drum.

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.

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – e-mail: cep@edqm.eu
Internet: https://www.edqm.eu

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 **7 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 four annexes, the first of 1 page, the second of 4 pages, the third of 1 page and the fourth of 2 pages.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 20 July 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*):