

Certification of Substances Department

**Certificate of suitability**  
**No. R1-CEP 2017-163 - Rev 00**

1 *Name of the substance:*  
2 **IRINOTECAN HYDROCHLORIDE TRIHYDRATE**

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**

9  
10 **Notice**  
11 **NOT FOR REGISTRATION PURPOSES**  
12 **For filing purposes please contact ScinoPharm Taiwan**  
13 **to obtain a complete "controlled copy" of this CEP.**  
14  
15 **ScinoPharm Taiwan- Regulatory Technical Services**  
16 **(SPT.RTS@scinopharm.com.tw)**

17  
18 Ethanol not more than 4000 ppm  
19 Ethyl acetate not more than 1000 ppm  
20 Dichloromethane not more than 300 ppm  
21 A risk management summary for elemental impurities has been provided. (Annex 3)  
22 – Test for elemental impurities by ICP-MS (Annex 4)  
23 Palladium not more than 1 ppm  
24 Platinum not more than 1 ppm  
25 The substance is packed in double polyethylene bags, placed in a polyethylene drum.  
26 The holder of the certificate has declared the absence of use of material of human or animal  
27 origin in the manufacture of the substance.  
28 The submitted dossier must be updated after any significant change that may alter the quality,  
29 safety or efficacy of the substance.

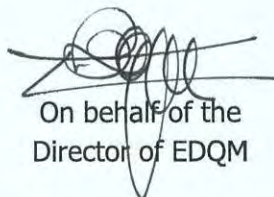
30 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice  
31 and in accordance with the dossier submitted.

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

33 This certificate is renewed from **7 August 2023** according to the provisions of Resolution AP-CSP  
34 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,  
35 and the related guidelines.

36 This certificate has four annexes, the first of 1 page, the second of 4 pages, the third of 1 page  
37 and the fourth of 2 pages.

38 This certificate has:  
39 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)*

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**(SPT.RTS@scinopharm.com.tw)**

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)*: