

Certification of Substances Department

**Certificate of suitability**  
**No. R0-CEP 2018-015-Rev 00**

1 *Name of the substance:*

2 **CAPECITABINE**

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**

**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)**

Subsequent  
Annex, we  
in of the  
including  
analytical

(Annex 2)  
(Annex 3)

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

19 The substance is packed in double polyethylene bags, placed in a polyethylene drum with  
20 desiccant in between.

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

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

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

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



28 This certificate is granted within the framework of the procedure established by the European  
29 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from  
30 **22 May 2019**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and  
31 Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

32 This certificate has four annexes, the first of 1 page, the second of 3 pages, the third of 4 pages  
33 and the fourth of 1 page.

34 This certificate has:  
35 lines.



On behalf of the  
Director of EDQM



Strasbourg, 22 May 2019

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

**SCINOPHARM TAIWAN, LTD.**, as holder of the certificate of suitability

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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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F-67081 Strasbourg (France)

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