

Certification of Substances Department

Certificate of suitability No. CEP 2018-015 - Rev 01

1 *Name of the substance:*

2 **CAPECITABINE**

3 *Details of holder:*

4 **SCINOPHARM TAIWAN, LTD.**

5 No. 1, Nan-Ke 8th Road

6 Taiwan-741014 Shan-Hua, Tainan

7 SPOR ORG ID: 100012108

8 SPOR LOC ID: 100019515

9 After examination of the information provided on the production method and control strategy for the

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

42

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)

18 No material of human or animal origin is used in the production of the substance.

19 The holder of the certificate should fulfil the following conditions in order to maintain the validity of
20 this certificate.

21 The dossier submitted must be updated in accordance with EDQM guidance on the requirements
22 for revision of certificates of suitability.

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

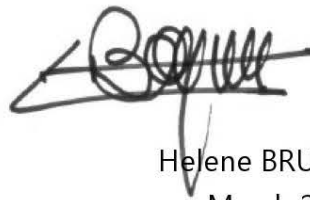
25 Necessary information from the submitted dossier shall be shared with authorised users in order
26 to enable them to evaluate the suitability of this substance for its intended use. This includes
27 informing them of any relevant change in the associated dossier.

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

29 This certificate is granted within the framework of Resolution AP-CSP (07) 1 adopted by the Council
30 of Europe Public Health Committee (Partial Agreement) (CD-P-SP) in February 2007. With regard
31 to its use in the member states of the European Union/European Economic Area, it is granted in
32 accordance with the provisions of Directive 2001/83/EC and Regulation (EU) 2019/6 as amended,
33 and the related guidelines.

34 This certificate is valid from 20 March 2024.

On behalf of the
Director of EDQM



Helene BRUGUERA
March 20, 2024

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)