

Certification of Substances Department

Certificate of suitability
No. R0-CEP 2016-315-Rev 02

1 *Name of the substance:*

2 **CLADRIBINE**

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)

17 – Test for residual solvents by gas chromatography

18 Methanol

not more than 3000 ppm

(Annex 2)

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

20 A risk management summary for elemental impurities has been provided.

(Annex 3)

21 The re-test period of the substance is 36 months if stored in double polyethylene bags, placed
22 in either a polyethylene bottle or drum.

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

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

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

29 Failure to comply with these provisions will render this certificate void.
30 This certificate is granted within the framework of the procedure established by the European
31 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from
32 **26 July 2018**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and
33 Directive 2001/82/EC and any subsequent amendment, and the related guidelines.
34 This certificate has three annexes, the first of 1 page, the second of 2 pages, and the third of
35 1 page.
36 This certificate has:
37 lines.



On behalf of the
Director of EDQM



Strasbourg, 2 June 2020

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

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to
Ma

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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)*: