

Certification of Substances Department

**Certificate of suitability**  
**No. R0-CEP 2017-001-Rev 00**

1 *Name of the substance:*

2 **ENTECAVIR MONOHYDRATE**

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

18 The following elemental impurities classified in ICH Q3D are intentionally introduced in the  
19 manufacture of the substance: Copper and Lead.

20 The test for impurity F described in the monograph is not necessary since this impurity cannot  
21 be present with the route of synthesis used.

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

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

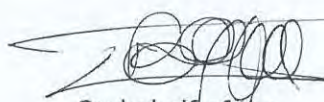
26 The submitted dossier must be updated after any significant change that may alter the quality,  
27 safety or efficacy of the substance.

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

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

31 This certificate is granted within the framework of the procedure established by the European  
32 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from  
33 **25 January 2019**. Moreover, it is granted according to the provisions of Directive 2001/83/EC  
34 and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

35 This certificate has two annexes, the first of 1 page and the second of 3 pages.  
36 This certificate has:  
37 lines.

  
On behalf of the  
Director of EDQM



Strasbourg, 25 January 2019

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

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to use the above-mentioned certificate of suitability in support of their application(s) for the following 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)*: