

Certification of Substances Department

## Certificate of suitability No. CEP 2017-001 - Rev 01

1 *Name of the substance:*

2 **ENTECAVIR MONOHYDRATE**

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

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**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)

The re-test period of the substance is 5 years if stored under nitrogen in double polyethylene bags, placed in either a polyethylene bottle or a polyethylene drum.

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

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

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

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

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

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

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

36 This certificate is valid from 30 January 2024.

On behalf of the  
Director of EDQM



Helene BRUGUERA

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