

Certification of Substances Department

**Certificate of suitability**  
**No. R1-CEP 2009-356-Rev 02**

1 *Name of the substance:*  
2 **BENAZEPRIL HYDROCHLORIDE**

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**

9 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**

10 **Notice**  
11 **NOT FOR REGISTRATION PURPOSES**  
12 **For filing purposes please contact ScinoPharm Taiwan**  
13 **to obtain a complete "controlled copy" of this CEP.**  
14  
15 **ScinoPharm Taiwan- Regulatory Technical Services**  
16 **(SPT.RTS@scinopharm.com.tw)**

17 - Test for residual solvents by gas chromatography (Annex 2)  
18 Acetone not more than 1000 ppm  
19 Ethanol not more than 1000 ppm  
20 Ethyl acetate not more than 1000 ppm

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

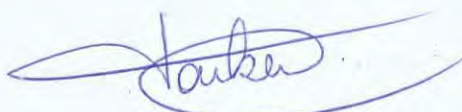
22 A risk management summary for elemental impurities has been provided. (Annex 3)

23 The re-test period of the substance is 4 years if stored in double polyethylene bags in an  
24 aluminium foil bag, placed in a polyethylene drum.

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

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

- 29 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice  
30 and in accordance with the dossier submitted.
- 31 Failure to comply with these provisions will render this certificate void.
- 32 This certificate is renewed from **4 November 2016** according to the provisions of Resolution  
33 AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent  
34 amendment, and the related guidelines.
- 35 This certificate has three annexes, the first of 1 page, the second of 5 pages, and the third of  
36 1 page.
- 37 This certificate has:  
38 lines.



On behalf of the  
Director of EDQM



Strasbourg, 16 July 2020

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

<p><b><u>Notice</u></b> <b>NOT FOR REGISTRATION PURPOSES</b> <b>For filing purposes please contact ScinoPharm Taiwan</b> <b>to obtain a complete "controlled copy" of this CEP.</b></p> <p><b>ScinoPharm Taiwan- Regulatory Technical Services</b> <b>(SPT.RTS@scinopharm.com.tw)</b></p>
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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)*: