

Certification of Substances Division

**Certificate of suitability
No. R1-CEP 2009-356-Rev 00**

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**

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11 After
12 process
13 certify
14 monog
15 edition
16 the an

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)

and subsequent
ed in annex, we
version of the
copoeia, current
below, based on

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 No elemental impurity classified in ICH Q3D is intentionally introduced in the manufacture of
23 the substance.

24 The re-test period of the substance is 3 years if stored in double polyethylene bags placed in a
25 polyethylene drum.

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

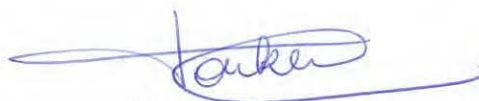
28 The submitted dossier must be updated after any significant change that may alter the quality,
29 safety or efficacy of the substance.

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)

Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu

Internet: <http://www.edqm.eu>

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



On behalf of the
Director of EDQM



Strasbourg, 18 October 2016

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

hereby

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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)*: