

Certification of Substances Department

Certificate of suitability
No. R0-CEP 2011-004-Rev 02

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

17 In the last steps of the synthesis ethanol is used as solvent. Its residual content is limited by
18 the test for loss on drying described in the monograph with a limit of not more than 0.5%.

19 – Test for residual catalysts by ICP-MS (Annex 2)
20 Palladium not more than 10 ppm
21 Nickel not more than 20 ppm

22 The re-test period of the substance is 5 years if stored in double polyethylene bags placed in a
23 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 **27 June 2013**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and
34 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, 23 February 2017

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

SCINOPHARM TAIWAN, LTD., as holder of the certificate of suitability

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(SPT.RTS@scinopharm.com.tw)

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)*:

Address: 7 Allée Kastner, CS 30026

F-67081 Strasbourg (France)

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