

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2011-011-Rev 01

1 *Name of the substance:*
2 **GALANTAMINE HYDROBROMIDE**
3 Produced by a synthetic process

4 *Name of holder:*
5 **SCINOPHARM TAIWAN, LTD.**
6 No. 1, Nan-Ke 8th Road
7 Taiwan-74144 Shan-Hua, Tainan

8 *Site(s) of production:*
9 **SEE ANNEX 1**

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

- 18 – Test for residual solvents by gas chromatography (Annex 2)
19 Ethanol not more than 5000 ppm
20 Isopropanol not more than 500 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 60 months if stored in double polyethylene bags, placed
24 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 **16 July 2017** according to the provisions of Resolution AP-CSP
33 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,
34 and the related guidelines.

35 This certificate has three annexes, the first of 1 page, the second of 3 pages and the third of
36 1 page.

37 This certificate has:
38 lines.


On behalf of the
Director of EDQM



Strasbourg, 13 January 2020

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

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ScinoPharm Taiwan- Regulatory Technical Services
(SPT.RTS@scinopharm.com.tw)

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)*: