Certification of Substances Department

Certificate of suitability
No. R1-CEP 2011-011-Rev 00

Name of the substance:
GALANTAMINE HYDROBROMIDE
Produced by a synthetic process

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

Site(s) of production:
SEE ANNEX 1

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– Test for residual solvents by gas chromatography (Annex 2)

Ethanol	not more than 5000 ppm
Isopropanol	not more than 500 ppm

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

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

The test for palladium described in the monograph is not necessary since this compound is not used in the synthesis.

The re-test period of the substance is 60 months if stored in double polyethylene bags placed in a polyethylene drum.

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

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

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

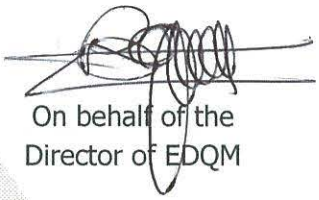
Failure to comply with these provisions will render this certificate void.

This certificate is renewed from **16 July 2017** according to the provisions of Resolution AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

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

This certificate has:

lines.



On behalf of the
Director of EDQM

Strasbourg, 16 June 2017

[illegible] hereby authorises .....

(*name of the pharmaceutical company*)

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*):

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