Certification of Substances Division

Certificate of suitability
No. R1-CEP 2007-341-Rev 00

Name of the substance:
GRANISETRON HYDROCHLORIDE

Name of holder:
SCINOPHARM TAIWAN, LTD.
No. 1, Nan-Ke 8th Road
Taiwan-741-44 Shan-Hua, Tainan

Site(s) of production:
SEE ANNEX 1

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)

After ex… nd subsequent process… d in annex, we certify t… version of the monogr… Pharmacopoeia, current…

Any unspecified impurity detected by the test for related substances of the monograph is limited to not more than 0.10%.

In the last steps of the synthesis acetone and water are used as solvents. Their residual content is limited by the test for loss on drying described in the monograph, with a limit of not more than 0.5%.

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

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

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 **18 January 2015** 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 one annex of 1 page.

This certificate has:

lines.

On behalf of the
Director of EDQM

Strasbourg, 18 December 2014

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

hereby a

to use th 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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