

**Certification of Substances Division**

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

1 *Name of the substance:*  
2 **GRANISETRON HYDROCHLORIDE**

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

7 *Site(s) of production:*  
8 **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)**

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process  
certify  
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and subsequent  
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version of the  
Pharmacopoeia,

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

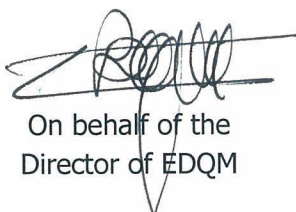
In the last steps of the synthesis acetone and water are used as solvents. Their residual content is limited by the test for loss on drying described in the monograph, with a limit of not more than 0.5%.

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.

- 27 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice  
28 and in accordance with the dossier submitted.
- 29 Failure to comply with these provisions will render this certificate void.
- 30 This certificate is renewed from **18 January 2015** according to the provisions of Resolution  
31 AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent  
32 amendment, and the related guidelines.
- 33 This certificate has one annex of 1 page.
- 34 This certificate has:
- 35 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

Marketing Authorisation(s): *(name of product(s) and marketing number(s), if known)*

following

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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)*: