

Certification of Substances Division

**Certificate of suitability
No. R0-CEP 2014-128-Rev 00**

1 *Name of the substance:*

2 **ANASTROZOLE**

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)

sequent
annex, we
of the
including
analytical
annex 2)

16 7-Heptane not more than 5000 ppm
17 Ethyl acetate not more than 5000 ppm

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

19 The re-test period of the substance is 60 months if stored in double polyethylene bags placed in
20 polyethylene drums.

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

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

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

- 27 Failure to comply with these provisions will render this certificate void.
- 28 This certificate is granted within the framework of the procedure established by the European
29 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from
30 **30 July 2015**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and
31 Directive 2001/82/EC and any subsequent amendment, and the related guidelines.
- 32 This certificate has two annexes, the first of 1 page and the second of 3 pages.
- 33 This certificate has:
- 34 lines.



On behalf of the
Director of EDQM



Strasbourg, 30 July 2015

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

he
to
Ma

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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)*: