

Certification of Substances Department

**Certificate of suitability**  
**No. R0-CEP 2015-338-Rev 00**

1 *Name of the substance:*

2 **FULVESTRANT**

3 *Name of holder:*

4 **SCINOPHARM TAIWAN, LTD.**

5 No. 1, Nan-Ke 8th Road

6 Taiwan-74144 Shan-Hua, Tainan

7 *Site(s) of production:*

8 **SEE ANNEX 1**

9 After e

10 proces

11 certify

12 monog

13 suppl

14 proced

15 – Test

16 Ethy

**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)**

and subsequent  
ed in annex, we  
version of the  
dition including  
n the analytical

(Annex 2)

17 The following elemental impurities classified in ICH Q3D are intentionally introduced in the  
18 manufacture of the substance: Copper and Lithium.

19 The substance is packed in double polyethylene bags placed in either a polyethylene bottle or a  
20 polyethylene drum.

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.

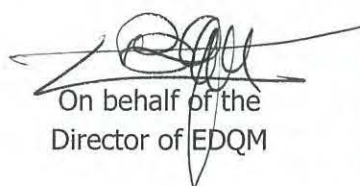
27 Failure to comply with these provisions will render this certificate void.

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 **9 February 2017**. Moreover, it is granted according to the provisions of Directive 2001/83/EC  
31 and 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, 9 February 2017

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

**SCINOPHARM TAIWAN, LTD.**, as holder of the certificate of suitability

**R0-CEP 2015-338-Rev 00 for Fulvestrant**

hereby

to use t  
Marketi

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)*: