

Certification of Substances Department

Certificate of suitability
No. R0-CEP 2015-338-Rev 01

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**

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)**

18 Ethyl acetate not more than 5000 ppm
19 Acetone not more than 5000 ppm

20 A risk management summary for elemental impurities has been provided.

21 The substance is packed in double polyethylene bags, placed in either a polyethylene bottle or a
22 polyethylene drum.

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

25 The submitted dossier must be updated after any significant change that may alter the quality,
26 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 granted within the framework of the procedure established by the European
31 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from
32 **9 February 2017**. Moreover, it is granted according to the provisions of Directive 2001/83/EC
33 and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

34 This certificate has three annexes, the first of 1 page, the second of 3 pages and the third of
35 1 page.

36 This certificate has:
37 lines.



On behalf of the
Director of EDQM



Strasbourg, 17 March 2021

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

<p style="text-align: center;"><u>Notice</u> 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)</p>

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)*: