European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2016-320 - Rev 00

Name of the substance:
CELECOXIB

Name of holder:
SCINOPHARM TAIWAN, LTD.
No. 1, Nan-Ke 8th Road
Taiwan-74144 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)

quent
ex, we
of the
luding
lytical

lex 2)

4-(2-(1-(*p*-Tolyl)ethylidene)hydrazinyl)-benzenesulfonamide (CEL-E) — not more than 3.75 ppm

– Test for the following impurity by liquid chromatography (Annex 3)
4-Sulfonamidophenylhydrazine hydrochloride (4-SAPH) — not more than 3.75 ppm

– Test for residual solvents by gas chromatography (Annex 4)
Isopropanol — not more than 5000 ppm

– Test for residual solvents by liquid chromatography (Annex 5)
Trifluoroacetic acid — not more than 3000 ppm

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

A risk management summary for elemental impurities has been provided. (Annex 6)

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – e-mail: cep@edqm.eu
Internet: https://www.edqm.eu

The re-test period of the substance is 60 months if stored in a double polyethylene bag, in an aluminium foil bag placed in a polyethylene drum.

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 December 2022** 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 six annexes, the first of 1 page, the second, the third and the fourth of 3 pages each, the fifth of 2 pages and the sixth of 1 page.

This certificate has:

lines

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

R1-CEP 2016-320 - Rev 00 for Celecoxib

hereby authorises .....
(*name of the pharmaceutical company*)

to use the above-mentioned certificate of suitability in support of their application(s) for the 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*):