



Certification of Substances Division

Certificate of suitability No. R1-CEP 2006-114-Rev 00

1	Name	of	the	sub	star	ce:

- 2 FLUMAZENIL
- 3 Name of holder:
- 4 SCINOPHARM TAIWAN, LTD.
- 5 No.1, Nan-Ke 8th Road
- 6 Taiwan-74144 Shan-Hua, Tainan

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Notice

NOT FOR REGISTRATION PURPOSES

For filing purposes please contact ScinoPharm Taiwan to obtain a complete "controlled copy" of this CEP.

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ScinoPharm Taiwan- Regulatory Technical Services (SPT.RTS@scinopharm.com.tw)

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processes (including purification) for this substance on the site(s) of production mentioned above, we certify that the quality of the substance is suitably controlled by the current version of the monograph **FLUMAZENIL** no. 1326 of the European Pharmacopoeia, current edition including supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical procedure(s) given in annex.

19 - Tests for residual solvents by gas chromatography

20	Ethanol	not more than 1000 ppm	(Annex 1)
21	<i>t</i> -Butanol	not more than 1000 ppm	(Annex 2)
		500	

Tetrahydrofuran not more than 500 ppm
23 Ethyl acetate not more than 1000 ppm
24 Dimethylformamide not more than 500 ppm
25 Total solvents not more than 3000 ppm

- In the last steps of the synthesis water is used as solvent.
- The re-test period of the substance is 60 months if stored in an amber glass bottle sealed with polytetrafluoroethylene liner placed in a polyethylene bottle.

polytetrafluoroethylene liner placed in a polyethylene bottle.

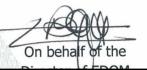
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Telephone: 33 (0) 3 88 41 30 30 - Fax: 33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu

Internet: http://www.edqm.eu

- 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,
- 32 safety or efficacy of the substance.
- 33 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice
- and in accordance with the dossier submitted.
- 35 Failure to comply with these provisions will render this certificate void.
- This certificate is renewed from 17 April 2013 according to the provisions of Resolution AP-CSP
- 37 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,
- 38 and the related guidelines.
- 39 This certificate has two annexes of 2 pages each.
- 40 This certificate has:
- 41 lines.





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hereby authorises			
, and the same of	(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):