

ORSZÁGOS GYÓGYSZERÉSZETI INTÉZET

CERTIFICATE NUMBER: *HUN-37451-68-2007*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with :

Art. 111(5) of Directive 2001/83/EC

The competent authority of Hungary confirms the following:

The manufacturer: *ScinoPharm Taiwan Ltd.*

Site address: *No. 1., Nan-Ke 8th Road, Tainan Science-Based Industrial Park, Shan-Hua, Tainan County, Taiwan, R.O.C., 74144, Taiwan*

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on *2008-01-15*, it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC
- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC .

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted. The authenticity of this certificate may be verified with the issuing authority.

Part 2

1 Manufacturing Operations

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;

- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;

- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other potential hazardous active ingredients this should be stated under the relevant produce type and dosage form;

1.4	Other products or manufacturing activity (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), medicinal gases, herbal or homeopathic products, bulk or total manufacturing, etc).
	<i>1.4.1 Manufacture of</i> 1.4.1.4 Other: Other(en)

Manufacture of active substance. Names of substances subject to inspection:

- *GEMCITABINE HCL(en)*
- *IRINOTECAN HCL(en)*

Any restrictions or clarifying remarks related to the scope of this certificate:

MANUFACTURE OF APIs.

Hatóanyag gyártó.

2008-06-02

Name and signature of the authorised person of the
Competent Authority of Hungary



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