Certification of Substances Department

ATTESTATION OF INSPECTION

Inspected site	SCINOPHARM TAIWAN, LTD. No. 1, Nan-Ke 8th Road Taiwan-74144 Shan-Hua, Tainan
Holder of the Certificate of Suitability	SCINOPHARM TAIWAN, LTD. No. 1, Nan-Ke 8th Road Taiwan-74144 Shan-Hua, Tainan
References of CEP dossier	CEP 2006-272 / Gemcitabine hydrochloride
Inspection dates	10/10/2016 to 12/10/2016
Inspector / Name of organisation	Mr EISELT Miklavz Tadej, AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES OF THE REPUBLIC OF SLOVENIA Dr HECKER Thomas, EDQM, COUNCIL OF EUROPE
Scope of the inspection	The inspection focused on the compliance with the information provided in the above-mentioned application for a certificate of suitability, as well as the implementation of a suitable Quality Management System based on the Good Manufacturing Practice as laid down in the EU Rules governing Medicinal Products in the European Union, Volume 4.
Conclusion	The company operates in accordance with the application submitted and the requirements of the Resolution AP-CSP (07) 1. This attestation is valid only in conjunction with a valid version of a CEP for the dossier mentioned above.

EDQM Inspection Reference number: INSP 2013-029 P02

Strasbourg, 25 April 2017

On behalf of the
Director of EDQM

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