



CERTIFICATE OF GOOD MANUFACTURING PRACTICE

Issue Date: August 7, 2019

Issued following an inspection in accordance with Article 57 of the Pharmaceutical Affairs Law and relevant Regulations of the Republic of China (Taiwan).

The competent authority of the Republic of China confirms the following:

The manufacturer: ScinoPharm Taiwan, Ltd.

Site address: No.1, Nan-Ke 8th Road, Shan-Hua, Tainan 74144, Taiwan

Manufacturer's licence number: (C)0001019

is the manufacturer of medicinal products that has been inspected with the following Active Pharmaceutical Ingredient: Anastrozole, Azacitidine, Benazepril Hydrochloride, Dantrolene Sodium, Decitabine, Desmopressin Acetate, Docetaxel, Docetaxel Trihydrate, Entecavir Monohydrate, Exemestane, Flumazenil, Fondaparinux Sodium, Fulvestrant, Galantamine Hydrobromide, Gemcitabine Hydrochloride, Irinotecan Hydrochloride, Letrozole, Paclitaxel, Pemetrexed Disodium Hemipentahydrate, Riluzole, Tamsulosin Hydrochloride, Topiramate, Topotecan Hydrochloride, Zoledronic Acid

From the knowledge gained during inspection performed on March 19-20, 2019, it is considered that the manufacturer complies with the Pharmaceutical Inspection Convention/Co-operation Scheme Guide to Good Manufacturing Practice for medicinal products (PIC/S GMP) Part II (= GMP of WHO/ICH Q7).

This certificate is valid until April 12, 2023.

This certificate may be revoked at anytime as warranted.

Signed by

Shou-Mei Wu

Shou-Mei Wu, Ph.D.

Director-General

Food and Drug Administration

(<http://www.fda.gov.tw/TC/index.aspx>)

Under the delegated authority of

Shih-Chung Chen, D.D.S.

Minister

Ministry of Health and Welfare

Republic of China (Taiwan)

