衛 生 福 利 部
MINISTRY OF HEALTH AND WELFARE

CERTIFICATE OF GOOD MANUFACTURING PRACTICE

Issue Date: March 10, 2022

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 for human use that has been inspected with the following Active Pharmaceutical Ingredient(s): Anastrozole, Azacitidine, Benazepril Hydrochloride, Dantrolene Sodium, Decitabine, Desmopressin Acetate, Docetaxel, Docetaxel Trihydrate, Elagolix Sodium, Entecavir Monohydrate, Exemestane, Flumazenil, Fondaparinux Sodium, Fulvestrant, Galantamine Hydrobromide, Gemcitabine Hydrochloride, Granisetron Hydrochloride, Irinotecan Hydrochloride, Ivacaftor, Letrozole, Levonorgestrel, Lifitegrast, Ondansetron Hydrochloride, Paclitaxel, Paclitaxel 2nd, Palbociclib "SPT", Pemetrexed Disodium Hemipentahydrate, Riluzole, Tamsulosin Hydrochloride, Topiramate, Topotecan Hydrochloride, Zoledronic Acid.

From the knowledge gained during GMP inspection performed on March 19-21, 2019, April 14-16, 2020, May 10-13, 2021, and dossiers assessment concluded on May 20 and October 6 in 2021, it is considered that the manufacturer complies with the Pharmaceutical Inspection Convention/Co-operation Scheme Guide to Good Manufacturing Practice (PIC/S GMP) Part II (=GMP of WHO/ICH Q7) and Good Distribution Practice (PIC/S GDP) for medicinal products.

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)

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