衛 生 福 利 部
MINISTRY OF HEALTH AND WELFARE

CERTIFICATE OF GOOD MANUFACTURING PRACTICE

Issue Date: October 23, 2020

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: Shinsei Pharmaceutical Industry Co., Ltd
Site address: 313-1, Shimizutani Takatori-Cho, Takaichi-Gun, Nara, Japan
Approval number: 112-0627-1 (PMF-I0378-1)

is the manufacturer of medicinal products for human use that has been inspected with the following Pharmaceutical dosage forms:
-Non-Sterile products: 1) Suspensions (not include specifically toxic and hazardous substances); 2) Granules (not include specifically toxic and hazardous substances); 3) Primary packaging of solid dosage forms (not include specifically toxic and hazardous substances); 4) Secondary packaging.

From the knowledge gained during GMP inspection performed on June 24-28, 2019, it is considered that the manufacturer complies with the Pharmaceutical Inspection Convention/Co-operation Scheme Guide to Good Manufacturing Practice (PIC/S GMP) for medicinal products.

This certificate is valid until August 31, 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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