衛 生 福 利 部
MINISTRY OF HEALTH AND WELFARE

CERTIFICATE OF GOOD MANUFACTURING PRACTICE

Issue Date: March 1, 2023

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: Genovior Biotech Corporation (Tainan Site)
Site address: 3F-2 / 4F-1 / 4F-2 No.5, 4F-1 No.9, Nanke 2nd Rd., Fenghua Vil., Xinshi Dist., Tainan City 744092, Taiwan (R.O.C.)
Manufacturer's license number: (AP)0458149

is the manufacturer of medicinal products for human use that has been inspected with the following pharmaceutical dosage forms:
-Sterile products: 1) Liquid dosage forms: injections (aseptic preparation-small volume liquids); 2) Solid dosage forms: freeze-dried powder/lyophilisate (aseptic preparation).

From the knowledge gained during GMP inspection performed on August 16-18, 2022 and January 3-4, 2023, it is considered that the manufacturer complies with the Pharmaceutical Inspection Convention/Co-operation Scheme Guide to Good Manufacturing Practice (PIC/S GMP) and Good Distribution Practice (PIC/S GDP) for medicinal products.

This certificate is valid until October 25, 2024.
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
Jui-Yuan Hsueh, M.D., LL.M.
Minister
Ministry of Health and Welfare
Republic of China (Taiwan)

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