衛 生 福 利 部
MINISTRY OF HEALTH AND WELFARE

CERTIFICATE OF GOOD MANUFACTURING PRACTICE

Issue Date: December 16, 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: Genovior Biotech Corporation
Site address: No.50-3/4F., No.50-5/4F., No.50-8/3F., No.50-8/4F., No.50-8/5F., No.50-9/5F., Keyan Rd., Zhunan Township, Miaoli County 35053, Hsinchu Science Park, Taiwan (R.O.C.)
Manufacturer's licence number: (AP)0455153

is the manufacturer of medicinal products for human use that has been inspected with the following pharmaceutical dosage form(s):
-Sterile products: 1) Liquid dosage forms: injections (aseptic preparation-small volume liquids); 2) Solid dosage forms: freeze-dried powder (aseptic preparation).
and following types of specifically toxic and hazardous substances: Cytotoxics:
-Sterile products: 1) Liquid dosage forms: injections (aseptic preparation-small volume liquids); 2) Solid dosage forms: freeze-dried powder (aseptic preparation).

From the knowledge gained during GMP inspection performed on August 1-3, 2022, and dossiers assessment concluded on December 13, 2022, 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 November 16, 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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