



MINISTRY OF HEALTH AND WELFARE
REPUBLIC OF CHINA (TAIWAN)

Issue Date: APR 24 2018

No: 071840

GMP Certificate

Name of Manufacturer : GENERAL BIOLOGICALS CORP.

Address of Manufacturer : NO. 6, INNOVATION FIRST RD., HSINCHU
SCIENCE PARK, BAOSHAN TOWNSHIP,
TAIWAN, HSINCHU COUNTY, TAIWAN,
R.O.C.

GMP Registration Number : GMP0406

Expiry Date : March 24, 2021

Scope of Registration : As Listed in the 1-Page Attachment

The above-mentioned manufacturer has been inspected periodically by the Ministry of Health and Welfare and found to be in compliance with the medical device Good Manufacturing Practice (GMP) requirements (based on ISO 13485). This certificate is hereby issued pursuant to Paragraph 3, Article 57 of the Pharmaceutical Affairs Act.

This certificate may not be used as a product license.

Signed by

Shou-Mei Wu

Director General
Food and Drug Administration
Under the delegated authority of
Shih-Chung Chen, D.D.S., Minister
Ministry of Health and Welfare
Republic of China (Taiwan)

Attachment of GMP Certificate (GMP0406)

No. Scope of Registration

1. α -FETOASE-96(TMB)
2. CEAASE-96(TMB)
3. In-Vitro Diagnostic Kits for Hepatitis A Virus
4. In-Vitro Diagnostic Kits for Hepatitis B Virus
5. In-Vitro Diagnostic Kits for Hepatitis C Virus
6. In-Vitro Diagnostic Kits for HIV
7. Real-Time Quantitative PCR for Hepatitis B Virus
8. Real-Time Quantitative PCR for Hepatitis C Virus

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