Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philipines

CERTIFICATE OF GMP COMPLIANCE

This is to certify that the foreign manufacturer:

Name : **VINH PHUC PHARMACEUTICAL JSC (VINPHACO)**
Plant Address : **MAU THONG HAMLET, KHAI QUANG WARD, VINH YEN CITY, VINH PHUC PROVINCE, VIETNAM**

engaged in the manufacture of the following pharmaceutical dosage form/s:

I. Human Medicinal Products

1. Sterile*
   - 1.1. Aseptically Prepared
     - 1.1.1. General
       - 1.1.1.1. Small Volume Parenteral
         - 1.1.1.1.1. Solution for injection (Workshop1,2,3,4)
         - 1.1.1.1.2 Lyophilized/Freeze-Dried Powder for Injection (Workshop3)
         - 1.1.1.1.3. Suspension for injection (Workshop4)
       - 1.1.1.2. Others
         - 1.1.1.2.1. Solution (Workshop4)
         - 1.1.1.2.2. Suspension (Workshop4)
     - 1.1.2. Steroid
       - 1.1.2.1. Small Volume Parenteral
         - 1.1.2.1.1. Solution for injection (Workshop1,2,3,4)
         - 1.1.2.1.2. Lyophilized/Freeze-Dried Powder for Injection (Workshop3)
       - 1.1.2.2. Others
         - 1.1.2.2.1. Solution (Workshop4)
         - 1.1.2.2.2. Suspension (Workshop4)
     - 1.1.3. Hormone
       - 1.1.3.1. Small Volume Parenteral
         - 1.1.3.1.1. Solution for Injection (Workshop2)
   - 1.2. Terminally Sterilized (Non-Parametric)
     - 1.2.1. General
       - 1.2.1.1. Small Volume Parenteral
         - 1.2.1.1.1. Solution for injection (Workshop1,2,3,4)
         - 1.2.1.1.2. Lyophilized/Freeze-Dried Powder for injection (Workshop3)
         - 1.2.1.1.3. Suspension for injection (Workshop4)
       - 1.2.1.2. Others
         - 1.2.1.2.1. Solution (Workshop4)
     - 1.2.2. Steroid
       - 1.2.2.1. Small Volume Parenteral
         - 1.2.2.1.1. Solution for injection (Workshop1,2,3,4)
         - 1.2.2.1.2. Lyophilized/Freeze-Dried Powder for injection (Workshop3)
       - 1.2.2.2. Others
         - 1.2.2.2.1. Solution (Workshop4)
2. Non-Sterile*(Workshop5)
   - 2.1. General
     - 2.2.1 Tablet-coated, plain/uncoated
     - 2.2.2. Hard capsule
     - 2.2.3. Soft capsule
     - 2.2.4. Powder
     - 2.2.5. Granules
     - 2.2.6. Solution
     - 2.2.7. Suspension
     - 2.2.8. Emulsion
     - 2.2.9. Gel
   - 2.2. Steroid
     - 2.2.1 Tablet-coated, plain/uncoated
     - 2.2.2. Solution
     - 2.2.3. Suspension

**Primary and Secondary packaging, Quality control testing: Chemical/Physical, and microbiological*

made available in the Philippines through **AMB HK ENTERPRISES INC.,** with valid License to Operate No. CDRR-NCR-DI/W-84548, has complied with the requirements of **current Good Manufacturing Practice (cGMP)** after **on-site inspection** consistent with Administrative Order No. 2012-0008, "Adoption and Implementation of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guides for the Good Manufacturing Practice (GMP) for Medicinal Products" and Administrative Order No. 2013-0022, "Guidelines for Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacturers."

This Certificate is valid until **28 March 2028**. Notwithstanding this certification, the foreign manufacturer shall be subject to inspection at any time to validate its continuous compliance with relevant FDA laws, rules, and regulations. Any violation thereof, this Office reserves the right to suspend, cancel or revoke this certificate.

Issued this 30 July 2026 at Alabang, Muntinlupa City, Philippines.

***BY THE AUTHORITY OF THE DIRECTOR GENERAL**

DR. CHARMAINE ANN M. RABAGO
Officer-in-Charge, Director IV
Center for Drug Regulation and Research

CERTIFICATE NO : **CDRR-CGMP-FA-243-02**
REG STATUS : **INITIAL**
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*Based on FDA Order No 2025-0026 and FDA Memorandum 2025-007

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