



## CERTIFICATE OF GMP COMPLIANCE

This is to certify that the foreign manufacturer:

Name : **AGIO PHARMACEUTICALS LTD.**

Plant Address : **T-81, 82, M.I.D.C., BHOSARI, PUNE 411026,  
MAHARASHTRA STATE, INDIA**

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

1. Non-sterile, Non-penicillin\*
  - 1.1. Tablets
  - 1.2. Capsules
  - 1.3. Creams
  - 1.4. Ointments
  - 1.5. Gels
  - 1.6. Balms
  - 1.7. Powders\*\*
  - 1.8. Suspensions\*\*
2. Sterile, Non-penicillin\*
  - 2.1. Small volume parenterals

\*Primary and Secondary packaging, and QC Testing: Chemical/Physical and Microbiological  
\*\*Including Veterinary medicinal product

made available in the Philippines through **AGIO PHARMACEUTICALS INC.**, with valid License to Operate No. CDRR-NCR-DI/W-332716, has complied with the requirements of **current Good Manufacturing Practice (cGMP)** after **desktop evaluation of the submitted GMP documentary evidence**, consistent with Administrative Order No. 2012-008, "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 **16 February 2025**. 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 06 December 2022 at Alabang, Muntinlupa City, Philippines.

**BY AUTHORITY OF THE DIRECTOR GENERAL**  
**Per FDA Order No. 2016-005**

**JESUSA JOYCE N. CIRUNAY, RPh**  
Director IV  
Center for Drug Regulation & Research

CERTIFICATE NO. : CDRR-CGMP-FA-22-05  
REG. STATUS : INITIAL  
TRACK NUMBER : 20220630105435  
AMOUNT : 10100  
OR Number/ DATE : 80322470815 / 03 August 2022

