



## CERTIFICATE OF GMP COMPLIANCE

This is to certify that the foreign manufacturer:

Name : **AGIO PHARMACEUTICALS LTD.**

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

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

1. Sterile, Non-penicillin\*
  - 1.1. Small volume parenterals
2. Non-sterile, Non-penicillin\*
  - 2.1. Tablets
  - 2.2. Capsules
  - 2.3. Creams
  - 2.4. Gels
  - 2.5. Balms
  - 2.6. Ointments
  - 2.7. Powders\*\*
  - 2.8. Suspensions\*\*

\*Primary and Secondary packaging, and Quality control testing: Chemical/Physical and Microbiological  
\*\*Including Veterinary Medicinal Products

made available in the Philippines through **HEXAGON PHARMACEUTICALS**, with valid License to Operate No. LTO-3000005226772, 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 22 August 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-22-04**  
REG. STATUS : **RENEWAL**  
TRACK NUMBER : **20211101122248**  
AMOUNT : **2020**  
OR Number/ DATE : **11022021101138900 / 02 November 2021**

This supersedes the Certificate of GMP Compliance issued on 21 September 2021



20211101122248

