FDA-2016DATC7NXJ2TFH4LZFEPOC

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

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 forms:

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. Suspension**
2. Sterile, Non-penicillin*
   - 2.1. Small volume parenterals

**Primary and Secondary packaging: Quality control testing: Chemical/Physical and Microbiological*
***Also Veterinary medicinal products*

made available in the Philippines through **AMBICA INTERNATIONAL CORPORATION,** with valid License to Operate No. CDRR-NCR-DI/W-1562, has complied with the requirements of **current Good Manufacturing Practice (cGMP)** after **on-site inspection** 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 2019**. Notwithstanding this certification, the foreign manufacturer shall be subject to inspection at anytime 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 19 August 2016 at Alabang, Muntinlupa City, Philippines.

BY AUTHORITY OF THE DIRECTOR GENERAL
Per FDA Order No. 2015-002

MELODY M. ZAMUDIO, RPh, MGM-ESP
OIC, Center for Drug Regulation & Research

CERTIFICATE NO. : CDRR-CGMP-FA-22-01
REG. STATUS : INITIAL
TRACK NUMBER : 20160629105202
AMOUNT : 3030
OR Number/ DATE : 677226 / 14 Oct 2015

312 20160629105202

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph