



## CERTIFICATE OF GMP COMPLIANCE

This is to certify that the foreign manufacturer:

Name : AS "OLAINFARM"

Plant Address : RŪPNĪCU IELA 5, OLAINĒ, OLAINĒS NOVADS,  
LV-2114

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

1. Sterile
  - 1.1. Batch certification only
2. Non-sterile\*
  - 2.1. Hard capsules
  - 2.2. Tablets
  - 2.3. Other solid dosage forms

*Note: Non-sterile products are manufactured without blinding.*

*\*Quality control testing: chemical/physical, biological (testing of bacterial endotoxins), and microbiological: sterility and non-sterility*

made available in the Philippines through SUHITAS PHARMACEUTICALS, INC., with valid License to Operate No. CDRR-NCR-DI-1673, 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 **09 December 2018**. 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 02 May 2016 at Alabang, Muntinlupa City, Philippines.

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

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

CERTIFICATE NO. : CDRR-CGMP-670  
REG. STATUS : RENEWAL  
TRACK NUMBER : 20160202112148  
AMOUNT : 2020  
OR Number/ DATE : 709747 / 02 Feb 2016  
This supersedes Certificate of cGMP Compliance issued on 21 October 2015

314

