GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION

CERTIFICATE OF GOOD MANUFACTURING PRACTICE (GMP) FOR PHARMACEUTICAL (PRODUCTS(S)

This certificate conforms to the format recommended by the World Health Organization (WHO)

Certificate No. DA /6-194 /2015 / 22740 — Date: 22 DEC 2022

It is hereby certified that **M/S. Drug International Ltd.**, a drug (Pharmaceutical Products) manufacturing and marketing organization, has been given license to manufacture and sell its products freely in the People's Republic of Bangladesh as lawfully required and granted in pursuance of **The Drugs Act, 1940 (XXIII of 1940) and The Drugs (Control) Ordinance, 1982** & it's amendment.

On the basis of the inspection carried out on 28-09-2021 & 03-11-2021 we certify that the site indicated on this certificate complies with Good Manufacturing Practices and regulatory norms for the dosage forms, categories & activities listed in Table 1.

The License information are as below:

1. Name & address of site : **M/S. Drug International Ltd.**
13A & 14A, Tongi Industrial Area, Squibb Road, Tongi, Gazipur, Bangladesh.

2. Manufacturer's License No. : Biological-220, Date of Issue: 17-12-1997
Non-Biological- 511, Date of Issue: 18-12-2016

3. Table: 01(One)

Dosage Form(s)	Category (ies)	Activity (ies)
Tablet Film-Coated Tablet, Uncoated Tablet,	Penicillin, Cephalosporin antibiotics, Steroid, Oncology.	Sourcing & Procurement of RM/PM Formulation design and development Dispensing of RM/PM Production: - Granulation - Compression - Coating (if applicable) Packaging Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Lot Release for marketing - Product Quality Review Documentation / Record Keeping

Digitally signed by Chitic Vlad
Date: 2023.09.27 22:04:15 EEST
Reason: MoldSign Signature
Location: Moldova

Certificate of Good Manufacturing Practices (GMP) for Pharmaceutical Product(s)

DIRECTORATE GENERAL OF DRUG ADMINISTRATION DHAKA GOVT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

Dosage Form(s)	Category (ies)	Activity (ies)
Capsule Hard Gelatin Capsule	Penicillin, Cephalosporin antibiotics, Oncology.	Sourcing & Procurement of RM/PM Formulation design and development Dispensing of RM/PM Production: - Blending -Filling Packaging Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Lot Release for Marketing - Product Quality review Documentation / Record Keeping
Syrup/Suspension/ Dry Powder for Suspension/ Paediatric drops	Penicillin, Cephalosporin antibiotics.	Sourcing & Procurement of RM/PM Formulation design and development Dispensing of RM/PM Production: - Mixing - Filling & Sealing Labeling & Packaging Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Lot Release for Marketing - Product Quality review Documentation / Record Keeping
Injection/ Dry Powder for Injection/ Lyophilized Injection/ Injectable Suspension & Solution/ Vial/ Ampoule/Prefilled Syringe/Cartridge	Cephalosporin antibiotics, Steroid, Oncology, Antidiabetic (Insulin), Biological/Biosimilar Products, Monoclonal Antibody (Mab).	Sourcing & Procurement of RM/PM Formulation design and development Dispensing of RM/PM Production: - Mixing in Aseptic environment - Form Fill Seal (Maintaining aseptic environment) Labeling & Packaging Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Lot Release for Marketing - Product Quality review Documentation / Record Keeping

DIRECTORATE GENERAL OF DRUG ADMINISTRATION DHAKA GOVT. OF THE PEOPLE'S REPUBLIC OF BANGLADESH

Dosage Form(s)	Category (ies)	Activity (ies)
Ophthalmic Solution /Suspension	Steroid	Sourcing & Procurement of RM/PM Formulation design and development Dispensing of RM/PM Production: - Mixing in Aseptic environment - Aseptic Filtration - Form Fill Seal (Maintaining aseptic environment) Labeling & Packaging Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Lot Release for Marketing - Product Quality review Documentation / Record Keeping
Semi-Solid Cream/Ointment/Gel	Steroid	Sourcing & Procurement of RM/PM Formulation design and development Dispensing of RM/PM Production: - Dispensing - Mixing in two or more phases - Filling & tube Crimping Packaging Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Lot Release for Marketing - Product Quality review Documentation / Record Keeping

The responsibility for the quality of the individual batches of the Pharmaceuticals Products Manufactured through this process lies with the manufacturer.

The manufacturing plant in which the pharmaceutical products are produced is subject to inspection at suitable intervals.

The manufacturer conforms to the requirements for good manufacturing practices **(GMP)** in the manufacture and quality control of drugs, as required under law in this country, as well as recommended by the **World Health Organization (WHO)** in respect of pharmaceutical products to be manufactured, sold or distributed within the country of origin or to be exported.

This certificate remains valid for a peiod of 2 (Two) years from the date of issue. It becomes invalid if the activities &/or categories certificate herewith are changed or if the site is no longer considered to be in compliance with **GMP**.

Name of authorized person	**: Major General Mohammad Yousuf**
Address of certifying authority	: Directorate General of Drug Administration Aushad Bhaban, Mohakhali, Dhaka-1212
Telephone	: 022222-80803
Fax No	: +880-(O) 2-980854
E-Mail	: dgda.gov@gmail.com
Web site	: www.dgda.gov.bd

Stamp and Date:

Major General Mohammad Yousuf
Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh.

22 DEC 2022

MINISTRY OF HEALTH & FAMILY WELFARE ★ DIRECTORATE GENERAL OF DRUG ADMINISTRATION ★ GOVT. OF THE PEOPLE'S REPUBLIC OF BANGLADESH
DHAKA

Certificate of Good Manufacturing Practices (GMP) for Pharmaceutical Product(s)