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 (PRODUCT(S)

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

Certificate No. DGDA/6-235/2019/10157 Date: 09-06-2024

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 provision of Chapter-VII, of **the Drug & Cosmetics Act, 2023 (XXIX of 2023) or any Rule made there under.**

On the basis of the inspection carried out on **02-09-2023** & **13-11-2023** we certify that the site indicated on this certificate complies with Good Manufacturing Practices recommended by world health organization (WHO) 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.**
31/1, Satrong Road, Gopalpur, Tongi I/A, Gazipur, Bangladesh.

2. Manufacturer's License No.: Biological - 315, Date of Issue: 21-10-2019
Non-Biological - 523, Date of Issue: 21-10-2019

3. Table: 01(One)

Dosage Form(s)	Category (ies)	Activity (ies)
Tablet Film-Coated Tablet, Enteric Coated Tablet, Uncoated Tablet, Chewable Tablet, Sublingual Tablet, Controlled Release /Sustained Release/Modified release/ Retard/Extended Release Tablet/Orally Dispersible Tablet	Antiulcerents, GIT Regulators, Antianginal, ACE-Inhibitor, Beta Blockers, Angiotensin Receptor Blocker, Anti-Platelet, Calcium Antagonist, Combination of Antihypertensive, Diuretics, Lipid Lowering Agent, Statin, Oral Antihistamine & Broncodilators, Hormone, Oncology (Non cytotoxic), steroid, Analgesic and Antipyretics, Antimigraine, Anti-arthrities, Macrolides antibiotics, Anti-Bacterial Combination, Antifungal, Anti-diarrhoeal, Anti-emetics, Antiviral, Anti-depressant, Oral Antidiabetics, Anti-psycotic, Neurological, Vitamins & Minerals, Anti Helminthic, Cartilage formation.	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

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Location: Moldova

Dosage Form(s)	Category (ies)	Activity (ies)
Capsule Hard Gelatin Capsule, Long Acting Capsule Controlled/ Immediate/ Time/Extend/ Delayed/ Sustained release Capsule	Antiulcerants, Vitamins and Minerals, Haematinics, Antihypertensive & Cardioprotectives, Antifungals, Antipsychotics, Hormone, Analgesic, Antidepressants, Antibiotics, Antispasmodic, Prostatic hyperplasia, Oncology (Non cytotoxic), Steroids.	Sourcing & Procurement of RM/PM Formulation design and development Dispensing of RM/PM Production: - Blending - Encapsulation Packaging Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Lot Release for Marketing - Product Quality review Documentation / Record Keeping
Soft Gelatin Capsule	Hormone	Sourcing & Procurement of RM/PM Formulation design and development Dispensing of RM/PM Production: -Gelatin cooking -Processing -Encapsulation Packaging Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Lot Release for Marketing - Product Quality review Documentation / Record Keeping

Dosage Form(s)	Category (ies)	Activity (ies)
Syrup/Solution/ Suspension/ Dry Powder for Suspension/ Emulsion	Antibiotics, Vitamins & Minerals, Antifungals, Antidiarrhoeal, Antiemetic, Laxatives, Antacid, Antispasmodics, Expectorant, Anti-asthmatics & Bronchodilators, Antihistamine, Anti Helminthic, Steroid, Hormone.	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
Injectable Solution/Suspension /Dry Powder for injection/ Lyophilized	Antibiotics, Antihypertensive, Cardioprotectives, Analgesics, Anticoagulant, Anesthetics, Antiulcer and Ulcer Healing, Steroids, Antiviral, Antiemetic, Antispasmodic, Vitamins, Hormone, Oncology (Non cytotoxic), Biosimilar [Human & Analogue Insulin, Monoclonal Antibody, Hematopoietic Agent, Colony Stimulating Factor (CSF)] Products.	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

Dosage Form(s)	Category (ies)	Activity (ies)
Prefilled Syringe/ Cartridge/pen	Biosimilar [Human & Analogue Insulin, Monoclonal Antibody, Hematopoietic Agent, Colony Stimulating Factor (CSF)] Products, Hormone, Antidiabetics, Anticoagulant.	Sourcing & Procurement of RM/PM Formulation design and development Dispensing of RM/PM Production: - Mixing in Aseptic environment - Form Fill Seal (Maintaining aseptic environment) Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Lot Release for Marketing - Product Quality review Documentation / Record Keeping
Ophthalmic Solution/ Suspension/Single Dose & Multidose in PP vial (BFS) * Ear Drop * Nasal Drop	Antibiotics, Antifungal, Antihistamine, Steroid, NSAID, Glaucoma, Vitamin, Hypertonic Solution, Lubricants, Anti cholinergic.	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

Dosage Form(s)	Category (ies)	Activity (ies)
Semi-Solid Cream/ Ointment/Gel/ Oral Paste/ External Preparation	Antibiotics, Steroid, NSAID, Antifungal, Hormone, Acne, Antiviral, Anti-Scabies, Vitamins, Mouthwash, Hand Sanitizer, Hormone.	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
Metered Dose Inhaler (MDI)/Dry Powder Inhalation (DPI) Capsule	Anti-asthmatics, Bronchodilators, Steroids, Anti-Allergic.	Sourcing & Procurement of RM/PM Formulation design and development Dispensing of RM/PM Production: - Dispensing - Mixing (Maintain Aseptic Condition) - Filling (Maintain Aseptic condition) - Gas Filling - Sealing & Leak Test Labeling & 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 ensuring the quality of the individual batches of the Pharmaceutical 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 period of 2 (Two) years from the date of issue. It becomes invalid if the activities and/or categories certified 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
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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.

06 JUN 2024