GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
OUSHAD BHABAN, MOHAKHALI
DHAKA-1212, BANGLADESH
www.dgda.gov.bd

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

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

Certificate Number: DA/6-110/06/5027 **Date:** 14 MAR 2021

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

On the basis of the inspection carried out on 27-06-2020 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1. Name & address of site : **Beacon Pharmaceuticals Limited.**
   : **Kathali, Bhaluka, Mymensingh**
   : **Bangladesh.**

2. Manufacturer's License No : **Biological License No- 258; Date of Issue: 06/07/2006**
   : **Non-Biological License No- 477; Date of Issue: 06/07/2006**

3. Table: 1

Dosage Form (s)	*Category (ies)*	*Activity (ies)*
Tablet Film Coated Tablet, Sugar Coated Tablet, Enteric Coated Tablet, Uncoated Tablet, Dispersible Tablet, Sublingual Tablet, Effervescent Tablet, Chewable Tablet, Controlled/ Sustained Release Tablet, MUPS Tablet	Antiulcerants, Analgesics & Antipyretics, Anticholinergic, Blood Anticoagulant, Antihypertensive, Antianginals, Antihistamine, Antidepressant, Vitamins & Minerals, Antispasmodics, Antibiotics (Non-β-lactum) Anticancer, Antifungal, Antiretrovirals, Antimalarial, Antivirals, Anti-inflammatory, NSAIDs, Antiemetic, Antirheumatics, Hormone, Lipid Lowering, Antiplatelete, Antianemic, Muscle Relaxants, Diuretics, Anti-infective, Antiprotozoals, Antitussive, Anticonvulsants, Anti-asthmatic, Antifibrillants, Antacid, Antiparkinsonism, Antipsychotic, Adrenergic, Antidiabetic, Antidepressant, Antimuscarinic, Musculoskeletal Agent, Antihaemorrhoidal Agent, Antihepatic Encephalopathy, Bronchodilator, Gastrointestinal Agent, Adrenergic Agent, Selective Serotonin Reuptake Inhibitor (SSRI), Vascular Protecting Agent, Hematopoietic Agent , Neuroleptic and Oral Iron Chelator.	• 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 - Batch Release

Certificate of Good Manufacturing Practices (GMP) for Pharmaceutical Product(s) *Continued to page-2*

Dosage Form (s)	*Category (ies)*	Activity (ies)
Capsule Hard Gelatin Capsule, Controlled/Sustained Release Capsule	Antiulcerants, Analgesics & Antipyretics, Antifungal, Vitamins & Minerals, Antiviral, Antiretroviral, Drug used in Anemia & other blood disorder, Antihypertensive & Cardioprotective, Antispasmodics, Anti-infective, Antiemetics, Anticonvulsants, Antiseizure, Immunosuppressant & Antirheumatic, Anticancer, Mucolytic & Expectorant, Dietary Supplement.	• Sourcing & Procurement of RM/PM • Formulation design and development • Dispensing of RM/PM • Production: - Mixing - Encapsulation • Packaging • Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Batch Release
Lyophilized Injection	NSAIDs, Anticancer, Antiulcerants, Antibiotics (Non-β-lactum), Drug used in Osteoporosis, Anticoagulant, Antiviral, Anti-infective, Antifungal, Antidote & Heavy metal Antagonist and Biological drugs.	• Sourcing & Procurement of RM/PM • Formulation design and development • Dispensing of RM/PM • Production: - Formulation & Filtration - Filling (Aseptic) - Lyophilization - Capping • Packaging • Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Batch Release
Liquid Injection	NSAIDs, Anticancer, Antiulcerants, Vitamins & Minerals, Anti-infective, Analgesic, Water for Injection, Electrolytes, Blood Volume Restorers and Caloric Agent, Antiarrhythmic, Local Anesthetics, Antispasmodic, Antiemetic, Anticoagulants, Adrenergic, Drug used in Anemia & other blood disorder, Antihemorrhagic, Drug used in Obstetrics and Biological drugs.	• Sourcing & Procurement of RM/PM • Formulation design and development • Dispensing of RM/PM • Production: - Formulation & Filtration - Filling (Aseptic) - Sealing (Ampoules), Cap Sealing (Vials) - Terminal Sterilization (where applicable) • Packaging • Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Batch Release

Dosage Form (s)	*Category (ies)*	Activity (ies)
LHGC	NSAIDs, Vitamins & Combinations, Antithyroid, Laxatives and Antispasmodic.	• Sourcing & Procurement of RM/PM • Formulation design and development • Dispensing of RM/PM • Production: - Mixing - Encapsulation - Bawdry • Packaging • Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Batch Release
Dry Powder for Suspension/ Pediatric Drops	Antibiotics (Non-β- lactum) & Chemotherapeutics and Anti-infective.	• Sourcing & Procurement of RM/PM • Formulation design and development • Dispensing of RM/PM • Production: - Mixing - Filling • Packaging • Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Batch Release
Pre-Filled Syringe	Anticoagulants, Hematopoietic, Antiviral, Drug used in Anemia, Erythropoiesis Stimulating Agent (ESAs) & other blood disorder and Biological drugs.	• Sourcing & Procurement of RM/PM • Formulation design and development • Dispensing of RM/PM • Production: - Mixing & Filtration - Filling (Aseptic) • Packaging • Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Batch Release

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Dosage Form (s)	*Category (ies)*	Activity (ies)
Intravenous Infusion	Electrolytes, Nutritional Supplement, Antibiotics (Non-β-lactum) & Chemotherapeutics, Amino Acid, Plasma Expanders, Blood Volume Restorer, Fat Emulsions, Anti-infective, Antifungal, Analgesic & Antipyretic.	• Sourcing & Procurement of RM/PM • Formulation design and development • Dispensing of RM/PM • Production: - Formulation & Filtration. - Filling (Aseptic). - Terminal Sterilization (Where applicable) • Packaging • Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Batch Release
Syrup & Oral Suspension	Anti-infective, Antitussive, Mucolytic & Expectorant, Vitamins & Minerals, Antihistamines, Antiperkinsonism, Antiinflammatory, Muscle Relaxant, Antacid, Antiulcerant.	• Sourcing & Procurement of RM/PM • Formulation design and development • Dispensing of RM/PM • Production: - Formulation & Filtration - Filling • Packaging • Quality Assurance - Manufacturing Environment Control - In-process Quality Control - Finished Product Analysis - Batch Release

The responsibly 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 practices in the manufacture and quality control (GMP) of drugs, as required under law of 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 Md Mahbubur Rahman**
Address of the certifying Authority	: Directorate General of Drug Administration. Aushad Bhaban, Mohakhali, Dhaka – 1212
Telephone	: +880-02-2222-80803
Fax No	: +880-02-9880854
E-mail	: dgda.gov@gmail.com
Web-site	: www.dgda.gov.bd

Stamp and Date:

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

Major General Md Mahbubur Rahman
Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh

14 MAR 2021