# ANNEXURE - II

## Annexure to the Biological Drug Manufacturing Licence No. 108 of M/S INCEPTA Pharmaceuticals Ltd., Savar, Dhaka, Bangladesh.

| DAR No. | Product Name | Composition | Speci-fication | Qty./10ml** (in mg) |
|---|---|---|---|---|
| 116-851-026 | **Integril 2 IV Injection** (10 ml Vial per pack) | **Active Ingredient (s)** | | |
| | | Eptifibatide (As Eptifibatide Acetate) | INN/In-house | 20.0000 |
| | | **Excipients** | | |
| | | Citric Acid Monohydreate* | BP/Ph. Eur. | 52.5000 |
| | | Sodium Hydroxide* | BP/Ph. Eur. | 11.0000 |
| | | Water for Injections | BP/Ph. Eur. | q.s. to 10ml |

* Quantity may vary to adjust the pH.

** Fill volume is 10.10ml.

Inclusion Date : 09-01-2011

Valid Up to : 08-01-2026

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 22 FEB 2021
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Govt. of the People's Republic of Bangladesh

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 (PRODUCTS)

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

**Certificate Number: DA/6-91/04/** 14599 **Date:** 30-08-2022

It is hereby certified that M/s. **Incepta Pharmaceuticals 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.**

On the basis of inspection carried out on 07-04-2021 & 28-07-2021 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: **Incepta Pharmaceuticals Ltd**
   Dewan Idris Road, Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-1341, Bangladesh
2. Manufacturer's License No.: Non-Biological-193 Date of Issue: 27-06-1967
   Biological-108 Date of Issue: 27-06-1989
3. Table: 1

| Dosage Form(s) | Category(ies) | Activity(ies) |
|---|---|---|
| Tablet (Uncoated, Coated, Delayed-Release, Extended-Release, Controlled Release, Modified Release, Sublingual, Buccal, Cheweble, Effervescent, Orodispersible, MUPS, Vaginal Tablets), Hard Capsule (Powder Filled, Pellet Filled, Liquid Filled), Powders, Coated Granules, Oral Drops, Powder for Oral Drops, Nasal drops, Eye Drops (Solution, Suspension, Emulsion), Nasal Sprays (Solution, Suspension), Syrup, Injectables (Injections – Intravenous, Intramuscular, Subcuteneous, Intra-Articular, Lyophilized Injections, Powder for Injections, Intravenous Infusions), | Antibiotics (Cephalosporins; beta-lactam (except Cephalosporins); Non beta-lactam), Antihypertensive and Cardioprotectives, Analgesics and Antipyretics, Steroids, Antidiarrhoeal, Antacids and Antiulcerants, Hematinics, Vitamins and Minerals, Antifungals, Antidiabetics, Anthelmintics, Antiamebics, Antiemetics, Laxatives, Antispasmodics, Antihistamines and Antiallergics, Expectorants, Antiasthmatics and Bronchodilators, Anxiolytics, Antidepressants, Antimigraine, Nutrient supplements, Gynaecological drugs, Antipsychotic, Anti-inflamatory, Opthalmics, Antiepileptics, Anticonvulsants, Anticoagulants, Antiplatelets, Diuretics, Insulins, Lipid lowering agents, Medication for Hepatitis B and C, Antivirals, | • Procurement of starting and packaging materials from approved sources<br>• Quarantine of starting and packaging materials in warehouse<br>• Sampling and testing of starting and packaging materials<br>• Storage of released starting and packaging materials<br>• Dispensing of starting and packaging materials<br>• Control of manufacturing environment<br>• Manufacturing of Finished Products and Biotherapeutic Drug Substances<br>• In process control of Intermediates, Bulks and Finished Products and Biotherapeutic Drug Substances |

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| Dosage Form(s) | Category(ies) | Activity(ies) |
|---|---|---|
| Oral solution, Powder for Oral solution, Nebulized Solution, Nebulizer Suspension, Oral suspension, Oral Emulsion, Powder for Oral Suspension, Elixir, Respiratory Solution, Dry Powder for Inhalation, Biotherapeutic Drug Product, Biotherapeutic Drug Substance | Immunosuppressants, Anesthetics, Antifibrinolytics, Antimalarial, Tinibs, Monoclonal Antibody (mAbs), Cytokines, Hematopoietic Agents, Antigout, Urologicals, Tyrosine Kinase Inhibitors, CDK 4/6 Inhibitor, Antirheumatic. | • Control of packaging and labeling<br>• Quality Assurance of finished products and biotherapeutic drug substances<br>• Storage of finished products<br>• Effluent treatment and safe disposal of pharmaceutical wastes<br>• Stability studies |

The responsibility for 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 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 the Certifying Authority : **Directorate General of Drug Administration**
Mohakhali, Dhaka-1212
Telephone : 02-2222-80803
Fax No : 02-2222-80854
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 Mohammad Yousuf**
Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Govt. of the People's Republic of Bangladesh

29 AUG 2022