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 • Quarantine of starting and packaging materials in warehouse • Sampling and testing of starting and packaging materials • Storage of released starting and packaging materials • Dispensing of starting and packaging materials • Control of manufacturing environment • Manufacturing of Finished Products and Biotherapeutic Drug Substances • In process control of Intermediates, Bulks and Finished Products and Biotherapeutic Drug Substances

Continued to Page-2

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 • Quality Assurance of finished products and biotherapeutic drug substances • Storage of finished products • Effluent treatment and safe disposal of pharmaceutical wastes • 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

ANNEXURE - I

Annexure to the Non-Biological drug manufacturing licence No. 193 of M/S INCEPTA Pharmaceuticals Ltd., Savar, Dhaka, Bangladesh.

DAR No.	Product Name	Composition	Specification	Qty./Tablet (in mg)
116-1259-012		**Active Ingredient (s)**		
	Eltropag 25 Tablet (7, 10 , 20, 30, 50 tablets in a blister/ strip pack)	Eltrombopag Olamine	INN (eqv. to Eltrombopag 25 mg)	31.9000
		Excipients		
		Microcrystalline Cellulose (101)	BP/Ph. Eur.	98.4500
		Mannitol	USP-NF	34.0000
		Povidone (K 30)	USP-NF	3.6500
		Crospovidone (Type B)	USP-NF	20.0000
		Sodium Starch Glycolate (Type A)	BP/Ph. Eur.	10.0000
		Magnesium Stearate	BP/Ph. Eur.	2.0000
		Coating Materials		
		Opadry II Brown	In-house	6.0000
		Purified Water*	BP/Ph. Eur.	34.0000
		*Does not appear in the final product		

Inclusion Date : 27-02-2018

Valid up to : 26-02-2023

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

11 MAY 2022

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	Specification	Qty./10 ml* (in mg)
116-1329-022	**Labegest Injection** (1 vial per unit box)	**Active Ingredients**		
		Labetalol Hydrochloride (Inj. Grade)	BP/Ph. Eur.	50.0000
		Excipients:		
		Anhydrous Dextrose	USP-NF	450.0000
		Disodium Edetate	USP-NF	1.0000
		Methyl Paraben	USP-NF	8.0000
		Propyl Paraben	USP-NF	1.0000
		Citric Acid**	BP/Ph. Eur.	0.1000
		Sodium Hydroxide**	BP/Ph. Eur.	0.0500
		Water For Injections (WFI)	BP/Ph. Eur.	q.s. to 10 ml

*Fill volume is 10.5 ml.
** Quantity may vary to adjust pH.

Inclusion Date : 07-08-2019

Valid Up to : 06-08-2024

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

7 AUG 2019

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

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	Specification	Qty./Vial (in mg)
116-782-001	**Dobutin Injection** (20ml Vial in blister pack)	**Active Ingredient (s)**		
		Dobutamine Hydrochloride (Injectable Grade)	BP/Ph. Eur. (eq. to Dobutamine 250 mg)	280.2000
		Excipients		
		Sodium Metabisulfite	BP/Ph. Eur.	5.6000
		Water for Injections	BP/Ph. Eur.	q.s. to 20 ml

Inclusion Date : 06-12-2009

Valid Up to : 05-12-2024

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

02 MAR 2020

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

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./tablet (in mg)
116-898-023	**Rifamax 200 Tablet** (20, 30, 50, 100 tablets in blister/strip pack)	**Active Ingredient (s)**		
		Rifaximin	BP/Ph. Eur.	200.0000
		Excipients		
		Microcrystalline Cellulose (101)	BP/Ph. Eur.	156.0000
		Hypomellose 5 cps (Hydroxypropyl Methylcellulose 5 cps)	BP/Ph. Eur.	16.0000
		Disodium Edetate	USP-NF	2.0000
		Sodium Starch Glycolate (Type A)	BP/Ph. Eur.	20.0000
		Colloidal Silicone Dioxide (200)	USP-NF	2.0000
		Magnesium Stearate	BP/Ph. Eur.	4.0000
		Coating Materials		
		Opadry KB 310A180023 White	In-house	8.0000
		Opadry KB Red 310A150004	In-house	4.0000
		Opadry KB 310A150019	In-house	4.0000
		Purified Water*	BP/Ph. Eur.	88.0000

* Does not appear in the final product.

Inclusion Date : 20-02-2012

Valid Up to : 19-02-2027

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

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

13 SEP 2022

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./2ml (in mg)
116-309-022	**Veracal 2ml Injection** (1x1's, 1x2's, 1x3's, 1x4's, 1x5's, 2x5's of ampoule in Blister pack)	**Active Ingredients**		
		Verapamil Hydrochloride (Injectable grade)	BP/Ph. Eur.	5.0000
		Excipients		
		Sodium Chloride (Injectable grade)	BP/Ph. Eur.	17.0000
		Water for Injections	BP/Ph. Eur.	qs to 2 ml

Inclusion Date : 02-11-2004

Valid Up to : 01-11-2024

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
02 MAR 2020
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Govt. of the People's Republic of Bangladesh

ANNEXURE - I

Annexure to the Non-Biological drug manufacturing licence No.193 of M/S INCEPTA Pharmaceuticals Ltd., Savar, Dhaka, Bangladesh.

DAR No.	Product Name	Composition	Speci-fication	Qty./tablet (in mg)
116-598-022		**Active ingredient (s)**		
	Veracal 40 Tablet (30, 50, 100 tablets in blister/strip pack)	Verapamil Hydrochloride	BP/Ph. Eur.	40.0000
		Excipients:		
		Lactose Monohydrate (Fine)	BP/Ph. Eur.	25.0000
		Microcrystalline Cellulose (Avicel 101)	BP/Ph. Eur.	35.0000
		Maize Starch	BP/Ph. Eur.	20.0000
		Povidone (Povidone K 30)	USP-NF	2.0000
		Sodium starch Glycolate	BP/Ph. Eur.	5.0000
		Magnesium Stearate	BP/Ph. Eur.	0.5000
		Coating Materials		
		Hypromellose 15 cps (Hydroxypropyl Methylcellulose 15 cps)	BP/Ph. Eur.	1.5200
		Hypromellose 5 cps (Hydroxypropyl Methylcellulose 5 cps)	BP/Ph. Eur.	1.5200
		Macrogol 6000 (Polyethylene Glycol 6000)	BP/Ph. Eur.	0.1426
		Purified Talc/ Talc	BP/Ph. Eur.	0.1426
		Titanium Dioxide	BP/Ph. Eur.	0.2875
		Simethicone Emulsion (30%)	USP-NF	0.0250
		Purified Water*	BP/Ph. Eur.	30.0000
		*Does not appear in the final product.		

Inclusion date : 11-09-2007

Valid-Up-to : 10-09-2027

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

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

18 MAY 2023

ANNEXURE - I

Annexure to the Non-Biological drug manufacturing licence No.193 of M/S INCEPTA Pharmaceuticals Ltd., Savar, Dhaka, Bangladesh.

DAR No.	Product Name	Composition	Speci-fication	Qty./Tablet (in mg)	Overage (%)
116-185-022	**Veracal 80 Tablet** (30, 50, 100 tablets in blister/strip pack)	**Active Ingredient (s)**			
		Verapamil Hydrochloride	BP/Ph. Eur.	80.0000	
		Excipients			
		Microcrystalline Cellulose (101)	BP/Ph. Eur.	69.0874	
		Lactose Monohydrate (Fine)	BP/Ph. Eur.	50.0000	
		Maize Starch*	BP/Ph. Eur.	40.0000	10
		Povidone (K 30)	USP-NF	4.0000	
		Sodium Starch Glycolate (Type A)	BP/Ph. Eur.	10.0000	
		Magnesium Stearate	BP/Ph. Eur.	1.9126	
		Coating Materials			
		Hypromellose 15 cps (Hydroxypropyl Methylcellulose 15 cps)	BP/Ph. Eur.	3.0400	
		Hypromellose 5 cps (Hydroxypropyl Methylcellulose 5 cps)	BP/Ph. Eur.	3.0400	
		Titanium Dioxide	BP/Ph. Eur.	0.5750	
		Macrogol 6000 (Polyethylene Glycol 6000)	BP/Ph. Eur.	0.2850	
		Purified Talc/ Talc	BP/Ph. Eur.	0.2850	
		Simethicone Emulsion (30%)	USP-NF	0.0500	
		Purified Water**	BP/Ph. Eur.	60.0000	

* 10% overage given to compensate moisture loss of Maize Starch during granulation.

** Does not appear in the final product.

Inclusion Date : 19-05-2002

Valid Up to : 18-05-2027

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

Major General Mohammad Yousuf
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Govt. of the People's Republic of Bangladesh

10 JAN 2023

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	Specification	Qty./Vial** (in mg)
116- 1402-006	**Remifen Injection** (1's, 5's, 10's vial per box)	**Active Ingredient**		
		Remifentanil Hydrochloride	BP/Ph. Eur. (eqv. to Remifentanil 1mg)	1.0970
		Excipients		
		Glycine	BP/Ph. Eur.	15.0000
		Water for Injections***	BP/Ph. Eur.	qs to 1.5 ml

*Hydrochloric Acid may require to adjust pH.

**Fill volume is 1.6 ml.

***Does not appear in the final product.

Inclusion Date : 20.10.2020

Valid up to : 28.10.2025

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
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Govt. of the People's Republic of Bangladesh

29 OCT 2020