

CERTIFICATE OF A PHARMACEUTICAL PRODUCT¹

This certificate conforms to the format recommended by the **WORLD HEALTH ORGANISATION**
(General instructions and explanatory notes attached)

No. of Certificate: **MFG/COPP/FLAGSHIP BIOTECH/2016/**
Exporting (Certifying) country : **INDIA**
Importing (requesting) country: **CUBA**

046705

1. Name and dosage form of products: **NORBETOL (Labetalol Hydrochloride Injection USP 5 mg)**

1.1 Active ingredient (s)² and amount (s) per unit dose³:

Each ml contains:

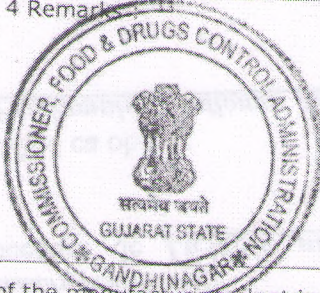
Labetalol Hydrochloride USP 5 mg

Water for Injection USP Q.S.

1.2 Is this product licensed to be placed on the market for use in the exporting country? ⁵ Yes ☒ No ☐

1.3 Is this product actually on the market in the exporting country? Yes ☒ No ☐ Unknown ☐

If the answer to 1.2 is yes, continue with section 2 A and If the answer to 1.2 is no. Continue section 2 B⁶

2A.1 Number of product license ⁷ : G/28A/5546-A In Form No. 28A And date of issue : 27/04/2015	2B. 1 Applicant for certificate (name and address)
2A.2 Product license holder : (Name and address) M/s. FLAGSHIP BIOTECH INTERNATIONAL. At: Block No.471, Dabhasa, Tal- Padra, City: Dabhasa, Dist: Vadodara-391440, Gujarat State, INDIA.	2B. 2 Status of applicant : a ☐ b ☐ c ☐ d ☐ 2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are
2A.3 Status of product - license Holder ⁸ : a ☒ b ☐ c ☐	2B.3 Why is marketing authorization lacking? Not ☐ Not ☐ Under ☐ Refused ☐ Required Requested Consideration
2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are ⁹ : N.A	2B. 4 Remarks
2A. 4 Is summary basis of Approval appended? ¹⁰ Yes ☐ No ☒	
2A.5 Is the attached officially approved product information complete and consonant with the license? ¹¹ Yes ☐ No ☐ Not Provided ☒	
2A. 6 Applicant for certificate if different from license holder ¹² : Not Applicable	

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? ¹⁴

Yes ☒ No ☐ Not applicable ☐

If no or not applicable proceed to question 4

3.1 Periodically of routine inspections (Years) : Once in a year

3.2 Has the manufacture of this type of dosage form been inspected?

Yes ☒ No ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? ¹⁶

Yes ☐ No ☐ Not applicable ☒

If no, explain:

This Certificate valid up to **2 Years from Date of Issue**

Address of certifying authority:

The Commissioner Food & Drug Control Administration

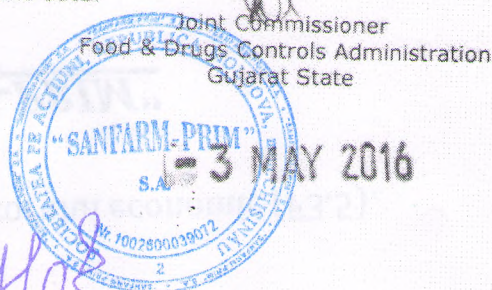
1st Floor, Block No. 8, Dr. Jivraj Mehta Bhavan,
Gandhinagar, Gujarat State, INDIA

Tel: 91-79-232 53417 Fax: 91-79-232 53400

Name of the Authorized Person: **Shri. Y.D.CHAUHAN**

Signature: 

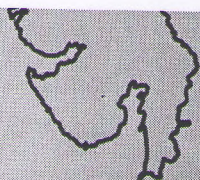
Stamp and date:





Food & Drugs Control Administration

BLOCK NO. 8, 1ST FLOOR, Dr. JIVRAJ MEHTABHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA. PIN: 382010



Certificate No. : **L/18101436**

On the basis of the inspection carried out on 26/09/2018, 27/09/2018 & 28/09/2018 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: **FLAGSHIP BIOTECH INTERNATIONAL.**

MFGD AT :- BLOCK NO. 471, DABHASA,, TAL- PADRA,

City : DABHASA, Dist : VADODARA,

GUJARAT STATE, INDIA

2 Manufacturer's Licence number : **G/25-A/4562-A G/28-A/5546-A**

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
External Preparation (Ointment / Gel / Liquid), Parenteral (SVP Ampoules & Vials)	General	Manufacturer

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until **17/03/2019** 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

Format of this certificate is as per WHO TRS No. 908 of 2003.

Address of certifying authority

Food & Drugs Control Administration,
Block No. 8, 1ST floor, Dr. Jivraj Mehta
Bhavan, Gandhinagar, Gujarat State,
India. - Pin : 382010

Email : comfdca@gujarat.gov.in

Phone : 91-79-23253417, Fax : 91-79-232-5340

Date : **21/11/2018**

Name & function of responsible Person : **(Dr. H.G. KOSHTIA)**
Commissioner

