CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

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/** 046705
Exporting (Certifying) country : **INDIA**
Importing (requesting) country: **CUBA**

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 dose [3]:

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 B [6]

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 Required ☐ Not Requested ☐ Under Consideration ☐ Refused ☐
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 [13]
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	

COMMISSIONER, FOOD & DRUGS CONTROL ADMINISTRATION GANDHINAGAR GUJARAT STATE

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:

Joint Commissioner
Food & Drugs Controls Administration
Gujarat State

"SANFARM-PRIM" S.A. Nr. 1002600039012

- 3 MAY 2016

Digitally signed by Harea Ştefan
Date: 2019.03.19 09:43:56 EET
Reason: MoldSign Signature
Location: Moldova

Food & Drugs Control Administration

BLOCK NO. 8, 1St FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
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* : 91-79-232-53400

Date : **21/11/2018**

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

COMMISSIONER FOOD & DRUGS CONTROL ADMINISTRATION • GANDHINAGAR • सत्यमेव जयते GUJARAT STATE

"SAMARTH-PRIM" S.A.