

HEALTH & FAMILY WELFARE DEPARTMENT BADDI, HIMACHAL PRADESH -173205
CERTIFICATE OF A PHARMACEUTICAL PRODUCT¹

This certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes attached)

No. of Certificate : HFW-H [Drugs] 185/05/20-160 Valid Up to 05/03/2023
Exporting (certifying) Country : India
Importing (requesting) Country : Mozambique
1. Name and Dosage form of Product : Phenytoin Injection BP (2 ml, 5 ml)
1.1 Active ingredient (s)² and Amount (s) per unit dose³ : Each ml Contains:-
Phenytoin Sodium BP 50 mg
Water For Injections BP q.s.

For complete qualitative composition including Excipients: NA

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 exporting country?
YES ☒ No Unknown

If the Answer to 1.2 is YES, continue with section 2A and omit section 2B.

If the Answer to 1.2 is NO, omit section 2A and continue with section 2B.⁶

2A.

- A.1 No. of Product Licence⁷ : MB/05/158 in form No. 28
And date of Issue : 14.08.2020
A.2. Product Licence holder : M/s Health Biotech Ltd.
Vill. Sandoli, Nalagarh Road,
Baddi, Distt. Solan [H.P.] India
A.3. Status of the Product-license Holder⁸ :
a. ☒ b. c.
A.3.1 For Categories b and c, The name and address of the
Manufacturer producing the dosage form are⁹
Not Applicable
A.4. Is summary Basis of approval appended?¹⁰ :
YES NO ☒
A.5. Is the attached, officially approved product information
complete and consonant with the licence?¹¹ :
YES NO Not Approved ☒
A.6. Applicant for certificate if different from License holder¹²:
Not Applicable

2. B.

- B. 1. Applicant for Certificate
(name and address)
B.2. Status of the Applicant:
a. b. c.
B.2.1. For categories b and c the name and
address of the manufacture producing
the dosage form are
B.3. Why is marketing authorization
lacking?
Not Required Under
Required Requested Consideration
Refused
B.4. Remark¹³:

3. Does the certifying authority arrange for periodic inspection of the
Manufacturing plant in which the dosage form is produced
If No or Not Applicable, proceed to Question 4

: YES ☒ NO Not Applicable¹⁴

3.1 Periodicity of routine inspection (Years)

: Once in a Year

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

: YES ☒ NO

3.3 Do the facilities and operations conform to GMP as recommended
By the World Health Organization?¹⁵

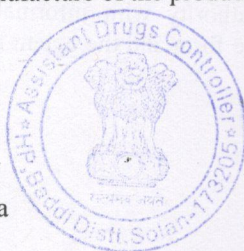
: YES ☒ NO Not Applicable

4. Does the information submitted by the applicant satisfy the certifying
Authority on all aspects of the manufacture of the product?¹⁶
If No, explain:

: YES ☒ NO

Address of Certifying Authority:

Deputy Drugs Controller-cum
-Licensing Authority
O/o State Drugs Controller
Baddi Distt. Solan (H.P.) 173205 India
01795 244288, sdc4hp@gmail.com



Name of the Authorized Person: (Dr. Kamlesh Naik)

Designation

: Assistant Drugs Controller

Signature

Stamp and Date

(Dr. KAMLESH NAIK)
ASSISTANT DRUGS CONTROLLER
-cum-LICENSING AUTHORITY
O/o STATE DRUGS CONTROLLER
BADDI, DISTRICT SOLAN, H.P.-173205
Email ddc4hp@gmail.com
Phone: 01795-244288

29 SEP 2020