HEALTH & FAMILY WELFARE DEPARTMENT BADDI, HIMACHAL PRADESH -173205

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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 dose[3] : 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.

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Date: 2023.01.04 10:10:56 EET
Reason: MoldSign Signature
Location: Moldova

2A.

A.1 No. of Product Licence[7] : MB/05/158 in form No. 28
And date of Issue : 14.08.2020

A2. 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 Holder[8] :
a. ☒ b. c.

A.3.1 For Categories b and c, The name and address of the Manufacturer producing the dosage form are[9]
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 holder[12]:
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 | Not Requested | Under Consideration | Refused

B.4. Remark[13]:

3. Does the certifying authority arrange for periodic inspection of the Manufacturing plant in which the dosage form is produced : YES ☒NO Not Applicable[14]
If No or Not Applicable, proceed to Question 4

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] : YES ☒ NO
If No, explain:

29 SEP 202

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

Assistant Drugs Controller HP Baddi Distt. Solan-173205

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