

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] 185/05/20-70 Valid Up to 05/03/2023
 Exporting (certifying) Country : INDIA
 Importing (requesting) Country : Syria
 1. Name and Dosage form of Product : Amphotericin B for Injection USP (Lyophilized)
 Each Vial Contains:-
 1.1 Active ingredient (s)² and : Amphotericin B USP 50 mg
 Amount (s) per unit dose³ : Excipients q.s.

1.2 For complete qualitative composition including Excipients:-NA
 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

<p>2A.</p> <p>A.1 No. of Product Licence⁷ : MB/05/158 in form No. 28 And date of Issue : 06.06.2018</p> <p>A2. Product Licence holder : M/s Health Biotech Ltd. Vill. Sandoli, Nalagarh Road, Baddi, Distt. Solan [H.P.] India</p> <p>A.3. Status of the Product-licence Holder⁸ : a. <input checked="" type="checkbox"/> b. c.</p> <p>A.3.1 For Categories b and c, The name and address of the Manufacturer producing the dosage form are⁹ Not Applicable</p> <p>A.4. Is summary Basis of approval appended?¹⁰ : YES NO <input checked="" type="checkbox"/></p> <p>A.5. Is the attached, officially approved product information complete and consonant with the licence?¹¹ : YES NO Not Approved <input checked="" type="checkbox"/></p> <p>A.6. Applicant for certificate if different from Licence holder¹²: Not Applicable</p>	<p>2. B.</p> <p>B. 1. Applicant for Certificate (name and address)</p> <p>B.2. Status of the Applicant: a. b. c.</p> <p>B.2.1. For categories b and c the name and address of the manufacture producing the dosage form are</p> <p>B.3. Why is marketing authorization Lacking? Not Not Under Required Requested Consideration Refused</p> <p>B.4. Remark¹³:</p>
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3. Does the certifying authority arrange for periodic inspection of the
 Manufacturing plant in which the dosage form is produced

: YES ☒ NO Not Applicable¹⁴

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

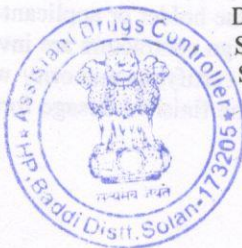
: YES ☒ NO Not Applicable

4. Does the information submitted by the applicant satisfy the certifying
 Authority on all aspects of the manufacture of the product?¹⁶ 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 (Dr. KAMLESH NAIK)
 Stamp and Date

ASSISTANT DRUGS CONTROLLER
 -cum-LICENSING AUTHORITY
 O/o STATE DRUGS CONTROLLER
 BADDI, DISTRICT SOLAN, H.P.-173205
 E mail ddc4hp@gmail.com
 Phone : 01795-244288

10/3/2020