

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] 185/05/21-145 Valid Up to 05/03/2023
 Exporting (certifying) Country : India
 Importing (requesting) Country : Mexico
 1. Name and Dosage form of Product : Bleomycin For Injection USP (Lyophilized)
 1.1 Active ingredient (s)² and Amount (s) per unit dose³ : Each Vial Contains:-
 Bleomycin Sulfate USP
 Eq. to. Bleomycin 15 Units
 Excipients q.s.

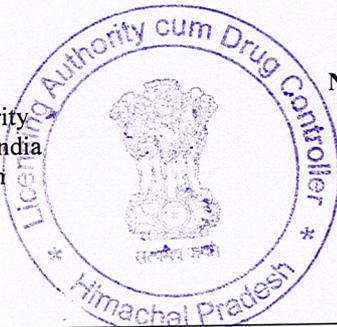
For complete qualitative composition including Excipients: NA
 1.2 Is this Product licensed to be placed on the market for use in the exporting country?⁵
 Yes No
 1.3 Is this product actually on the market in exporting country?
 YES No Unknown
 If the Answer to 1.2 is YES, continue with section 2A and omit section 2B.
 If the Answer to 1.2 is NO, omit section 2A and continue with section 2B.⁶

<p>2A. A.1 No. of Product Licence⁷ : MB/05/158 in form No. 28 And date of Issue : 18.08.2020 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. <input checked="" type="checkbox"/> 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 <input checked="" type="checkbox"/> A.5. Is the attached, officially approved product information complete and consonant with the licence?¹¹ : YES NO Not Approved <input checked="" type="checkbox"/> A.6. Applicant for certificate if different from License holder¹²: Not Applicable</p>	<p>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 Refused Consideration 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 : YES NO Not Applicable
 By the World Health Organization?¹⁵
 4. Does the information submitted by the applicant satisfy the certifying : YES NO
 Authority on all aspects of the manufacture of the product?¹⁶
 If No, explain:

Address of Certifying Authority:

State Drugs Controller
 Controlling Cum Licensing Authority
 Baddi Distt. Solan (H.P.) 173205 India
 01795 244288, sdc4hp@gmail.com



Name of the Authorized Person : Mr. Navneet Marwaha.
 Designation : State Drugs Controller
 Signature
 Stamp and Date

(NAVNEET MARWAHA)
 State Drug Controller
 Controlling cum Licensing Authority
 Baddi Distt. Solan (H.P.)-173205
 01795-244288, sdc4hp@gmail.com

30 OCT 2021