

**HEALTH & FAMILY WELFARE DEPARTMENT BADDI, HIMACHAL PRADESH -173205**  
**CERTIFICATE OF A PHARMACEUTICAL PRODUCT<sup>1</sup>**

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

No. of Certificate : HFW-H [Drugs] 185/05/21-141 Valid Up to 05/03/2023  
 Exporting (certifying) Country : India  
 Importing (requesting) Country : Mexico  
 1. Name and Dosage form of Product : Epirubicin Hydrochloride For Injection (Lyophilized)  
 1.1 Active ingredient (s)<sup>2</sup> and Amount (s) per unit dose<sup>3</sup> : Epirubicin Hydrochloride BP 10 mg  
 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?<sup>5</sup>  
 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.<sup>6</sup>

<p>2A.</p> <p>A.1 No. of Product Licence<sup>7</sup> : MB/05/158 in form No. 28                  And date of Issue : 20.08.2020</p> <p>A.2. 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-license Holder<sup>8</sup> :                  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 are<sup>9</sup>                  Not Applicable</p> <p>A.4. Is summary Basis of approval appended?<sup>10</sup> :                  YES NO <input checked="" type="checkbox"/></p> <p>A.5. Is the attached, officially approved product information complete and consonant with the licence?<sup>11</sup> :                  YES NO Not Approved <input checked="" type="checkbox"/></p> <p>A.6. Applicant for certificate if different from License holder<sup>12</sup>:                  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.                  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 Required Under                  Required Requested Consideration                  Refused</p> <p>B.4. Remark<sup>13</sup>:</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 Applicable<sup>14</sup>  
 If No or Not Applicable, proceed to Question 4

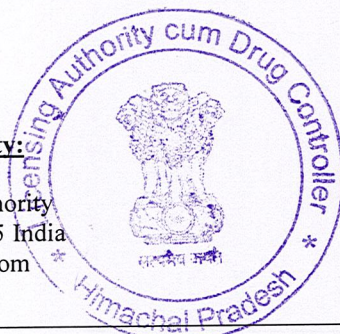
3.1 Periodicity of routine inspection (Years) : Once in a Year

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?<sup>15</sup> : 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?<sup>16</sup> : YES ☒ NO  
 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 Drugs Controller  
 Controlling cum Licensing Authority  
 Baddi Distt. Solan (H.P.)-173205  
 01795-244288, sdc4hp@gmail.com

**30 OCT 2021**