

# 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] 185/05/21-143 Valid Up to 05/03/2023  
Exporting (certifying) Country : India  
Importing (requesting) Country : Mexico  
1. Name and Dosage form of Product : Doxorubicin Hydrochloride For Injection USP (Lyophilized)  
1.1 Active ingredient (s)<sup>2</sup> and Each Vial Contains:-  
Amount (s) per unit dose<sup>3</sup> : Doxorubicin Hydrochloride USP 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>

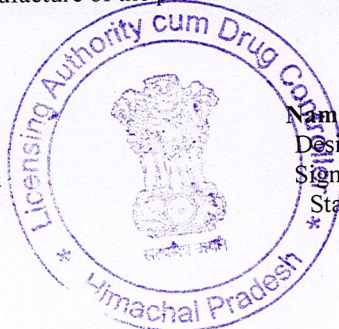
2A.  
A.1 No. of Product Licence<sup>7</sup> : MB/05/158 in form No. 28  
And date of Issue : 20.08.2020  
A.2. Product Licence holder : M/s Health Biotech Ltd.  
Vill. Sandoli, Nalagarh Road,  
Baddi, Distt. Solan [H.P.] India  
A.3. Status of the Product-license Holder<sup>8</sup> :  
a. ☒ b. c.  
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  
A.4. Is summary Basis of approval appended?<sup>10</sup> :  
YES NO ☒  
A.5. Is the attached, officially approved product information  
complete and consonant with the licence?<sup>11</sup> :  
YES NO Not Approved ☒  
A.6. Applicant for certificate if different from License holder<sup>12</sup>:  
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 Not Under  
Required Requested Consideration  
Refused  
B.4. Remark<sup>13</sup>:

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 : YES ☒ NO Not Applicable  
By the World Health Organization?<sup>15</sup>  
4. Does the information submitted by the applicant satisfy the certifying : YES ☒ NO  
Authority on all aspects of the manufacture of the product?<sup>16</sup>  
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