

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] 185/05/21-96 Valid Upto 05/03/2023
Exporting (certifying) Country : India
Importing (requesting) Country : LAOS
1. Name and Dosage form of Product : (PACLISON) Paclitaxel Injection USP
(5.0 mL, 16.7 mL, 43.4 mL, and 50.0 mL)
1. Name and Dosage form of Product : Each mL Contains:-
1.1 Active ingredient (s)² and : Paclitaxel USP 6 mg
Amount (s) per unit dose³ : Polyoxyl 35 Castor Oil USP-NF 527 mg
Dehydrated Alcohol USP 49.7 % v/v

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.</p> <p>A.1 No. of Product Licence⁷ : MB/05/158 in form No. 28 And date of Issue : 02.09.2021</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 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 License 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 : YES ☒ NO Not Applicable¹⁴

Manufacturing plant in which the dosage form is produced

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 Applicable¹⁵
By the World Health Organization?

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:

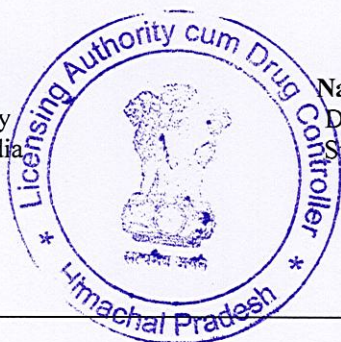
Address of Certifying Authority:

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 Drugs Controller

Controlling cum Licensing Authority

Baddi Distt. Solan (H.P.)-173205

01795-244288, sdc4hp@gmail.com

107 OCT 2021