HEALTH & FAMILY WELFARE DEPARTMENT BADDI, HIMACHAL PRADESH -173205

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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 Amount (s) per unit dose[3]	:	Paclitaxel USP	6 mg
		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]

2A.

A.1 No. of Product Licence[7] : MB/05/158 in form No. 28
And date of Issue : 02.09.2021

A2. 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[8] :
a. ☒ b. c.

A.3.1 For Categories b and c, The name and address of the Manufacturer producing the dosage form are[9]
Not Applicable

A.4. Is summary Basis of approval appended?[10] :
YES NO ☒

A.5. Is the attached, officially approved product information complete and consonant with the licence?[11] :
YES NO Not Approved ☒

A.6. Applicant for certificate if different from License holder[12]:
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 Required | Not Requested | Under Consideration | Refused

B.4. Remark[13]:

3. Does the certifying authority arrange for periodic inspection of the Manufacturing plant in which the dosage form is produced : YES ☒NO Not Applicable[14]
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] : 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

Licensing Authority cum Drug Controller * Himachal Pradesh *

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
07 OCT 2021

Digitally signed by Chiriac Ighenian
Date: 2022.12.14 20:12:01 EET
Reason: MoldSign Signature
Location: Moldova