GOVERNMENT OF HIMACHAL PRADESH
Health & Family Welfare- Department, Himachal Pradesh
CERTIFICATE OF PHARMACEUTICAL PRODUCTS

No. of Certificate : HFW-H (DRUGS) 427/05/21-325
Valid up to : 22.02.2024

Exporting (certifying) Country: INDIA
Importing (requesting) Country: MEXICO

1.0 Proprietary Name (If applicable) and Dosages form of Product : DACMED 200
Dacarbazine for Injection USP 200mg (Lyophilized)

Active ingredient(s) and amount per unit dose:

Each vial contains:
Dacarbazine USP.....200 mg
Citric Acid Monohydrate BP.....200 mg
Mannitol BP.....75 mg
Water for Injection BP.....q.s.

1.1 Is this product is licensed to be placed on the market for use in exporting country?
Yes [X] No [ ] Not applicable [ ]

1.2 Is this product naturally on the market in the exporting country? Yes [X] No [ ] Unknown [ ]

(If the answer to 1.2 is yes, continue with Question 2A & omit Question 2B & if answer to 1.2 is No, omit the Question 2A and continue with Question 2B)

2A

1. Product License & date of Issue.
   MB/05/255, 26/02/2021
2. Product License holder (Name and add.)
   United Biotech (P) Limited
   Bagbania, Baddi-Nalagarh Road
   District-Solan (HP) 174101 India
3. Status of applicant a/b/c (key in appropriate Category as define in note)
   a [X] b [ ] c [ ]
4. Permission letter no.
   Is an approved technical summary appended?
   Yes [ ] No [X] Not provided [ ]
5. Is the attached officially approved product Information complete and consonant with the License
   Yes [ ] No [ ] Not provided [X]
6. Applicant for certificate, if different from license holder (name & add.) : SAME

2B

1. Applicant for certificate (Name & Address)
2. Status of applicant a/b/c (key in appropriate category as define in note)
   a [ ] b [ ] c [ ]
3. Why is authorization lacking?
   Not Required [ ]
   Not Required [ ]
   Under consideration [ ]
   Refused [ ]
4. Remarks:

3. Does the certifying authority arrange for periodic inspection of manufacturing plant in which the dosage form is produced? [14] Yes [X] No [ ] Not applicable [ ]

3.1 Periodicity of routine inspection: Once in a year.

3.2 Has the manufacturer of this type of dosage forms been inspected? : Yes [X] No [ ]

3.3 Does the facility and operation conform to GMP as recommended by the World Health Organization?

Yes / No / Not applicable Yes [X] No [ ] Not applicable [ ]

4. Does the information submitted by the applicant satisfy the certifying Authority on all aspects of the manufacturer of the product? Yes [X] No [ ] if no explain [ ]

Address of certifying authority:
State Drug Controller-Cum-Licensing Authority
O/o State Drug Controller
Health and Family Welfare Department
Baddi, Distt. - Solan, 173205 (H.P.) India

Name of the Authorizing person: Navneet Marwha

Signature :
Stamp & Date :

29 JUN 2021
(NAVNEET MARWHA)
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt.Solan (H.P.) 173205
01795-244288,sdc4hp@gmail.com

Digitally signed by Harea Stefan
Date: 2023.07.27 12:47:50 BST
Reason: MoldSign Signature
Location: Moldova

THIS CERTIFICATE CONFIRMS TO THE FORMAT RECOMMENDED BY THE WORLD HEALTH ORGANIZATION
(GENERAL INSTRUCTION AND EXPLANATORY NOTES ATTACHED)