

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

No. of Certificate : HFW-H (DRUGS) 427/05/23-139 Exporting (certifying) Country: INDIA  
 Valid up to : 22.02.2024 Importing (requesting) Country: GUATEMALA

1.0 Proprietary Name (If applicable) and Dosages form of Product : UNICRISTIN  
 Vincristine Sulfate Injection USP 1.0mg/1.0ml

Active ingredients(s) and amount per unit dose

Each ml contains:  
 Vincristine Sulfate USP.....1.0mg  
 Methylparaben USP .....0.13%w/v  
 Propylparaben USP.....0.02% w/v  
 Water for Injection USP.....q.s.

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

1.2 Is this product naturally on the market in the exporting country? Yes  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

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

2B

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

3. Does the certifying authority arrange for periodic inspection of manufacturing plant in which the dosage form is produced?<sup>14</sup> Yes  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  No

3.3 Does the facility and operation conform to GMP as recommended by the World Health Organization?  
 Yes / No / Not applicable Yes  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  No  if no explain

Address of certifying authority:  
 State Drugs Controller  
 Controller-Cum-Licensing Authority  
 Health and Family Welfare Department  
 Sai Road, Baddi, Distt. - Solan, 173205 (H.P.) India

Name of the Authorizing person: Mr. Navneet Marwaha

Signature :

Stamp & Date :



(NAVNEET MARWAHA)  
 State Drugs Controller  
 Controlling cum Licensing Authority  
 Baddi Distt. Solan (H. P.)-173205  
 91795-244288, sdc4hp@gmail.com

26 APR 2023