

CERTIFICATE OF PHARMACEUTICAL PRODUCTS

No. of Certificate : HFW-H (DRUGS) 427/05/21-37

Valid up to : 22.02.2024

Exporting (certifying) Country : INDIA

Importing (requesting) Country : SYRIA

1.0 Proprietary Name (If applicable) and Dosages form of Product :

UNIBLASTIN

Vinblastin Sulphate Injection 10mg/10ml

Active ingredients(s) and amount per unit dose

: Each ml contains:

Vinblastin Sulphate USP.....1.0 mg

Sodium Chloride USP.....9.0 mg

Benzyl Alcohol USP.....0.9% v/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

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



b



c



4. Permission letter no.

Is an approved technical summary appended?

Yes



No



Not provided



5. Is the attached officially approved product Information complete and consonant with the License

Yes



No



Not provided



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 ☒ 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 the certifying authority

Office of the State Drugs Controller

Licensing Authority

Health & Family Welfare- Department, Himachal Pradesh

Sai Road, Baddi, Distt. - Solan, 173205 (H.P.) India

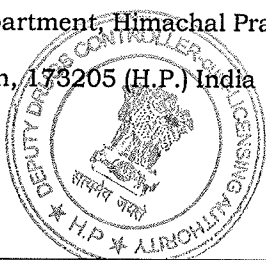
Name of the Authorizing person:

Signature :

(Dr. Manish Kapoor) 11/3/2021

DEPUTY DRUGS CONTROLLER
-cum- LICENSING AUTHORITY
O/o STATE DRUGS CONTROLLER
BADDI DISTRICT SOLAN, H.P.-173205
E mail ddc4hp@gmail.com
Phone 01795-244998

Stamp & Date :



THIS CERTIFICATE CONFIRMS TO THE FORMAT RECOMMENDED BY THE WORLD HEALTH ORGANIZATION