

CERTIFICATE OF PHARMACEUTICAL PRODUCTS

No. of Certificate : HFW-H (DRUGS) 427/05/21-129
 Valid up to : 22.02.2024

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

1. Proprietary Name (If applicable) and Dosages form of Product : ONCOTAR 1000
 Cytarabine Injection BP 1000 mg/10 ml

Active ingredient(s) and amount per unit dose: Each ml contains:
 Cytarabine BP.....100 mg
 Sterile Water for Injections BP.....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

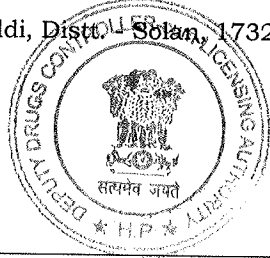
3. Why is authorization lacking?
 Not Required
 Not Required
 Under consideration
 Refused

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 : *Manish Kapoor* 6 MAR 2021



Stamp & Date
 (Dr. Manish Kapoor)
 DEPUTY DRUGS CONTROLLER
 -cum- LICENSING AUTHORITY
 O/o STATE DRUGS CONTROLLER
 BADDI DISTRICT SOLAN, H.P.-173205
 E mail ddc4hp@gmail.com
 Phone 01795-241218