

CERTIFICATE OF PHARMACEUTICAL PRODUCTS

No. of Certificate : HFW-H (DRUGS) 427/05/18-237
Valid up to : 18.09.2019

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

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

Active Ingredient (s) and amount per unit dose: Each ml contains:
Cytarabine IP 100 mg
Water for Injections IP q.s.

1.1. Is this product is licensed to be placed on the market for use in exporting company?

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 is with Question 2A & omit question 2B & if answer is to 1.2 is no, omit the question 2A and continue with question 2B)

2A

1. Product License & date of Issue. MB/05/255 & 23/02/2016
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 <input checked="" type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/>
4. Permission letter no. Is an approved technical summary appended? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not provided <input type="checkbox"/>
5. Is the attached officially approved product Information complete and consonant with the License Yes <input type="checkbox"/> No <input type="checkbox"/> Not provided <input checked="" type="checkbox"/>
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 <input type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/>
3. Why is authorization lacking? Not Required <input type="checkbox"/> Not Required <input type="checkbox"/> Under consideration <input type="checkbox"/> Refused <input type="checkbox"/>
4. Remarks:

3. Does the certifying authority arrange for periodic inspection of manufacturing plant in which the dosage form is produced? 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

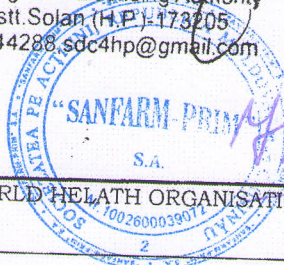
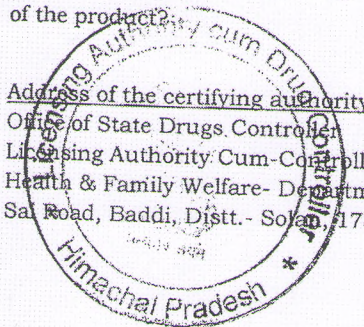
Office of State Drugs Controller
Licensing Authority: Cum-Controlling Authority
Health & Family Welfare- Department, Himachal Pradesh
Sal Road, Baddi, Distt.- Solan, 173205 (H.P) India

Name of the Authorizing person: Mr. Navneet Marwaha

Signature: (NAVNEET MARWAHA)

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

Stamp & Date:



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