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 [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 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 [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? 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 the certifying authority
Office of State Drugs Controller
Licensing Authority Cum-Controlling Authority
Health & Family Welfare- Department, Himachal Pradesh
Sai Road, Baddi, Distt.- Solan, 173205 (H.P) India

Licensing Authority cum Drugs Controller Himachal Pradesh

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:

"SANFARM-PRIM" S.A.

THIS CERTIFICATE CONFIMS TO THE FORMAT RECOMMENDED BY THE WORLD HELATH ORGANISATION

Digitally signed by Harea Ştefan
Date: 2019.03.05 12:29:25 EET
Reason: MoldSign Signature
Location: Moldova