CERTIFICATE OF PHARMACEUTICAL PRODUCTS

No. of Certificate : HFW-H (DRUGS) 427/05/20-346
Valid up to : 21.02.2024

Exporting (certifying) Country : INDIA
Importing (requesting) Country : SRI LANKA

1.0 Proprietary Name (If applicable) and Dosages form of Product : LYOMIT 20
Mitomycin for Injection USP 20 mg (Lyophilized)

Active ingredients(s) and amount per unit dose : Each vial contains:
Mitomycin C USP.....20 mg
Excipients..... q.s.

1.1 Is this product is licensed to be placed on the market for use in exporting country?
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 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, 26/12/2019
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? [14] 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 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 :

Stamp & Date : 22 DEC 2020

(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 01795-244288

DEPUTY DRUGS CONTROLLER-cum-LICENSING AUTHORITY ★ H.P ★ सत्यमेव जयते

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

Digitally signed by Ilarion Ciobanu
Date: 2023.07.27 12:47:39 BST
Reason: MoldSign Signature
Location: Moldova