

# CERTIFICATE OF PHARMACEUTICAL PRODUCTS

No. of Certificate : HFW-H (DRUGS) 427/05/20-346      Exporting (certifying) Country : INDIA  
 Valid up to : 21.02.2024      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 ☒ 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, 26/12/2019
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 ☒ 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?<sup>14</sup> 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 ☐

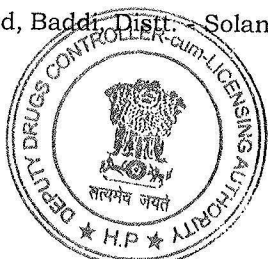
Address of the certifying authority  
 Office of the State Drugs Controller  
 Licensing Authority  
 Health & Family Welfare- Department, Himachal Pradesh

Name of the Authorizing person:

Signature :

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

Stamp & Date :



*(Dr. Manish Kapoor)*  
 22 DEC 2020  
 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

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