

**GOVERNMENT OF HIMACHAL PRADESH**  
**Health & Family Welfare- Department, Himachal Pradesh**  
**CERTIFICATE OF PHARMACEUTICAL PRODUCTS**

No. of Certificate : HFW-H (DRUGS) 427/05/23-64  
Valid up to : 22.02.2024

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

1.0 Proprietary Name (If applicable) and Dosages form of Product : MESNA 400mg  
Sodium-2-Sulphanylethanesulphonate Injection  
100mg/ml

Active ingredient(s) and amount per unit dose:

Each ml contains:  
Sodium 2-Sulphanylethanesulphonate  
(MESNA) BP.....100mg  
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, 11/01/2023
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 certifying authority:

State Drugs Controller  
Controller-Cum-Licensing Authority  
Health and Family Welfare Department  
Sai Road, Baddi, Distt. - Solan, 173205 (H.P.) India

Name of the Authorizing person: Mr. Navneet Marwaha

Signature :

Stamp & Date :

(NAVNEET MARWAHA)  
State Drugs Controller  
Controlling cum Licensing Authority  
Baddi Distt. Solan (H. P.) - 173205  
11795-244288, sdchp@gmail.com

12.1 FEB 2023