

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

No. of Certificate : HFW-H (DRUGS) 427/05/24-374
Valid up to : 21.02.2026

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

1.0 Proprietary Name (If applicable) and Dosages form of Product : AMPHOTIN 50
Amphotericin-B for Injection USP 50mg
(Lyophilized)

Active ingredient(s) and amount per unit dose:

Each vial contains:
Amphotericin B USP.....50mg
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, 16/06/2022
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? ¹⁴ 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:

Assistant Drugs Controller
Cum-Licensing Authority
O/o State Drugs Controller
Baddi, Distt. Solan, H.P.173205,
sdc4hp@gmail.com, 01795-244288

Name of the Authorizing person: Dr. Kamlesh Naik

Signature :

(Dr. Kamlesh Naik)

Stamp & Date : Assistant Drugs Controller
Cum Licensing Authority
O/o State Drugs Controller
Baddi, Distt. Solan, H.P.173205
sdc4hp@gmail.com, 01795-244288

3 SEP 2024

THIS CERTIFICATE CONFIRMS TO THE FORMAT RECOMMENDED BY THE WORLD HEALTH ORGANIZATION
(GENERAL INSTRUCTION AND EXPLANATORY NOTES ATTACHED)