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

No. of Certificate : HFW-H (DRUGS) 427/05/24-103
Valid up to : 21.02.2026

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

1.0 Proprietary Name (If applicable) and Dosages form of Product : Aprepitant Capsules USP

Active ingredient(s) and amount per unit dose:

Each Combi-pack contains:
Aprepitant Capsules USP 125 mg (1 Capsule)
Composition:
Each capsule contains:
Aprepitant USP.....125 mg
Excipients.....q.s.
Approved colours used in capsule shell.
Aprepitant Capsules USP 80 mg (2 Capsules)
Composition:
Each capsule contains:
Aprepitant USP.....80 mg
Excipients.....q.s.
Approved colours used in capsule shell.

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.
MNB/05/254, 10/03/2021
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 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 :

Stamp & Date :

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

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

04 JUL 2024