CERTIFICATE OF PHARMACEUTICAL PRODUCTS

No. of Certificate: HFW-H (DRUGS) 4427/052/9-105
Valid up to : 22.02.2024

Exporting (certifying) Country : INDIA
Importing (requesting) country : PERU

1. Proprietary Name (If applicable) and Dosages form of Product: **ONCONASE PEG**
(Pegaspargase Injection 3750 IU/5ml)

Active Ingredient (s) and amount per unit dose :
Each 5 ml vial contains:
Pegaspargase
(Pegylated L-Asparaginase) 3750 IU

1.1. Is this product is licensed to be placed on the market for use in exporting company?

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 is with Question 2A & omit question 2B & if answer is to 1.2 is no, omit the question 2A and continue with question 2B)

2A

1. Product License & date of Issue.
MB/05/255, 04/05/2016

2. Product License holder (name and add.)
United Biotech (P) Limited
Bagbania, Baddi-Nalagarh Rd.,
Disst – 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?
Yes [X] NO [ ] Not Applicable [ ]

3.1 Periodicity of routine inspection: Twice 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 confirm 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 State Drugs Controller
Licensing Authority Cum-Controlling Authority
Health and Family Welfare Department, Himachal Pradesh
Sai Road, Baddi, District – Solan, 174101 (H.P.) India

Name of the Authorizing person
Signature:

Stamp & Date: 08.11.19

(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Baddi,Distt.Solan (H.P.)-173205
01795-244288,sdc4hp@gmail.com

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

Digitally signed by Harea Ştefan
Date: 2023.07.27 12:48:52 BST
Reason: MoldSign Signature