CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

This certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes attached)

No. of certificate : **HFW-H (Drugs) 98/09 (Vol. I) / 23 - 49** **VALID UPTO: 23.12.2025**

Exporting (certifying) country : **INDIA**

Importing (requesting) country : **OTHER THAN INDIA**

1. Name and dosage form of product : **PEG L-Asparaginase Injection 3750 IU/5 ml**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] : **Each ml contains:**
PEG L-Asparaginase 750 IU
Excipients q.s

For complete qualitative composition including excipients, see attached.[4] NA

1.2 Is this product licensed to be placed on the market for use in the exporting country ?[5] Yes [×] No [ ]

1.3 Is this product actually on the market in the exporting country? Yes [×] No [ ] Unknown [ ]

If the answer to 1.2 is Yes, continue with section 2A and omit section 2B
If the answer to 1.2 is No, omit section 2A continue section 2B[6]

2A

A.1 Number of product license[7] **MB/09/749**
and date of issue : **05.03.2020**

A.2 Product license holder: **M/s Beta Drugs Ltd.,**
(Name and address) **Kharuni-Lodhimajra Road, Vill. Nandpur, Baddi, Distt. Solan (H.P.) INDIA**

A.3 Status of product license Holder[8]
a [×] b [ ] c [ ]

A3.1 For categories b and c the name and address of the manufacturer producing the dosage form are[9] : **Not Applicable**

A.4 **Is summary basis of approval appended ?[10]**
Yes [ ] No [×]

A.5 Is the attached, officially approved product information Complete and consonant with the license ?[11]
Yes [ ] No [ ] Not provided [×]

A.6 Application for certificate if different from license holder [12] : **Not Applicable**

2B

B.1 Applicant for certificate (name and address) :

B.2 Status of application :
a [ ] b [ ] c [ ] d [ ]

B.2.1 For categories b and c the name and address of the manufacturer producing the dosages form are[9]

B.3 Why is marketing authorization lacking
[ ] Not Required [ ] Not Requested [ ] under consideration [ ] refused

B.4 Remark :[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
Yes [×] No [ ] Not applicable[14] [ ]

If no or not applicable proceed to question **4**

3.1 Periodicity of routine inspections (years): **Yearly**

3.2 Has the manufacture of this type of dosage form been inspected? Yes [×] No [ ]

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation?[15]
Yes [×] No [ ] Not applicable [ ]

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]
Yes [x] No [ ] Not applicable [ ]

If no, explain:

05 JAN 2023

Address of certifying authority:
State Drugs Controller,
Controlling cum - Licensing Authority,
H.P., Baddi, Distt- Solan 173205
Ph. No.: 01795 244288
Fax. No. 01795 244288

Name of the Authorised Person: Navneet Marwaha
(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Baddi Distt.Solan (H.P.)-173205
01795-244288 sdc4hp@gmail.com
Signature:
Stamp and date: