Certificate of a Pharmaceutical Product[1]

(This certificate conforms to the format as recommended by the World Health Organization (general instructions and explanatory notes overleaf)

No. of Certificate : SDC/HR/23/03 Valid upto: 22.02.2026
Exporting (certifying country) : India
Importing (requesting country) : Bolivia

Name and dosage form of product : L- Asparaginase for Injection 10000 I.U. (Flint glass vial of 10ml)
(Lyophilized Powder for Reconstitution)

1.1 Active Ingredient(s)[2] and amount(s) per unit dose[3] : Each vial contains:
L- Asparaginase 10000 I.U.

For complete qualitative composition including excipients : Glycine USP q.s.

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] : Yes
(If yes, complete box 2A.If no, complete box 2B.)[6]

1.3 Is this product actually on the market in the exporting country? : Yes

2A 1	Number of Manufacturing license[7]: 225-B(H) Date of product approval: 25.08.2014	2B 1	Applicant for certificate (name and address): N/A
2A 2	Product - license holder (name and address) : M/s Getwell Pharmaceuticals 474, Udyog Vihar, Phase-V, Gurugram, Haryana - 122016, India	2B 2	Status of applicant: N/A
2A 3	Status of product license holder[8]: a ☒ b ☐ c ☐	2B 2.1	For categories b and c the name and address of the manufacturer producing the dosage form are[9]: N/A
2A 3.1	For categories b and c the name and address of the manufacturer producing the dosage form are[9]: N/A		
2A 4	Is Summary Basis of Approval appended?[10]: Yes ☐ No ☒	2B 3	Why is marketing authorization lacking? (not required ☐ not requested ☐ under consideration ☐ refused ☐): N/A
2A 5	Is the attached, officially approved product information complete and consonant with the license?[11] Yes ☐ No ☐ Not provided ☒		
2A 6	Applicant for certificate, if different from license holder[12]: N/A	2B4	Remarks[13] :

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?[14] : Yes
(if not or not applicable, proceed to question 4)

3.1 Periodicity of routine inspections (years) : Once in a year

3.2 Has the manufacturer of this type of dosage form been inspected : Yes

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15] : Yes

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product[16] : Yes
Yes ☒ No ☐ If no explain:

Address of certifying authority : State Drugs Controller
(Controlling & Licensing Authority)
Food & Drug Administration, Haryana
SCO-94,Sector-5, Panchkula.

Telephone/ Fax number : 0172 – 2583557/2583189

Name of authorized person : Manmohan Taneja

Signature

Stamp and date

22 MAR 2023
MANMOHAN TANEJA
State Drugs Contoller-cum-Controlling &
Licensing Authority
Food & Drugs Administration, Haryana