

Certificate of a Pharmaceutical Product¹

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

No. of Certificate : SDC/HR/20/22
 Exporting (certifying country) : India
 Importing (requesting country) : Mongolia

(Valid upto 30.11.2022)

Name and dosage form of product : **DACARB-200mg**
 : Dacarbazine for Injection USP 200mg (Amber Glass vial of 20ml)

1.1 Active Ingredient(s)² and amount(s) per unit dose³ : Each vial contains
 Dacarbazine USP 200mg

For complete qualitative composition including excipients : Anhydrous Citric acid USP 200mg
 Mannitol USP 80mg

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: 06.08.2019	2B 1	Applicant for certificate (name and address): N/A
2A 2	Product - license holder : M/s Getwell Pharmaceuticals (name and address) 474, Udyog Vihar, Phase V, Gurgaon, 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	2B 4	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.

Name of authorized person : N. K. Ahooja

Signature

Stamp and date

Telephone/ Fax number : 0172 - 2583557/2583189

N. K. Ahooja
 (N. K. Ahooja) 31/10/22
 State Drugs Controller-cum-Controlling &
 Licensing Authority
 Food & Drugs Administration, Haryana