Date: 2023.04.22 14:19:32 EEST
Reason: MoldSign Signature
Location: Moldova

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/23/47 — Valid upto: 22.02.2026
Exporting (certifying country) : India
Importing (requesting country) : Philippines

Name and dosage form of product : ***DECIMA-50mg**
Decitabine Lyophilized Powder for Injection 50mg (Flint glass vial of 20ml)
(Lyophilized Powder for Reconstitution)

1.1 Active Ingredient(s)[2] and amount(s) per unit dose[3] : Each vial contains

Decitabine	50mg

For complete qualitative composition including excipients :

Monobasic Potassium Phosphate USP	68mg
Sodium Hydroxide USP	11.6mg

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: 17.12.2014	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 : 21 APR 2023
MANMOHAN TANEJA
State Drugs Controller-cum-Controlling & Licensing Authority
Food & Drugs Administration, Haryana

(* Product permission issued in generic name and Brand name is company trade mark in Importing Country)