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/23/65		Valid upto: 22.02.2026
Exporting (certifying country)	: India		
Importing (requesting country)	: Jamaica		
Name and dosage form of product	: Mesna Injection	400mg/4ml	(Flint glass ampoule of 5ml)
1.1 Active Ingredient(s)[2] and amount(s) per unit dose[3]	: Each ml contains Mesna BP	100 mg	
For complete qualitative composition including excipients	: Sterile Water for Injection USP/BP q.s.		
1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] (If yes, complete box 2A.If no, complete box 2B.)[6]	: Yes		
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: 19.07.2021	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] (if not or not applicable, proceed to question 4)	: Yes
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 ☒ No ☐ If no explain:	: Yes

Address of certifying authority	: State Drugs Controller (Controlling & Licensing Authority) Food & Drug Administration, Haryana SCO-94, Sector-5, Panchkula.	Name of authorized person	: Manmohan Taneja
		Signature	: 21 JUN 2023
Telephone/ Fax number	: 0172 – 2583557/2583189	Stamp and date	MANMOHAN TANEJA State Drugs Contoller-cum-Controlling & Licensing Authority Food & Drugs Administration, Haryana