Health & Family Welfare Department **Himachal Pradesh** Baddi, Distt. Solan

Certificate of Good Manufacturing Practices

This one page certificate conforms to the format recommended by the World Health Organization [General Instructions and Explanatory Notes attached].

Certificate No. HFW-H [Drugs] 427/05

On the basis of the inspection carried out on 9th February 2021 and 10th February 2021, we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table I:

1. Names and Address of Site:

M/s United Biotech (P) Ltd., Bagbania, Baddi-Nalagarh, Road, Distt. Solan [H.P.]-174101.

2. Manufacturer's License No:

Valid upto 21.02.2026 MNB/05/254 & MB/05/255

3. Table-I:

Dosage Form[s]	Category[ies]	Activity[ies]
Tablets	General, Betalactam & Oncology	Production, Packing & Quality Control
Capsules (Hard & Soft Gelatin)	General, Betalactam & Oncology	Production, Packing & Quality Control
Oral Sachet (Powder & Granules)	General	Production, Packing & Quality Control
Injectables (Liquid, dry & Lyophilized)	General & Oncology	Production, Packing & Quality Control
Dry Syrups	Betalactam	Production, Packing & Quality Control
Liquid Orals	General	Production, Packing & Quality Control
Ointments	General	Production, Packing & Quality Control
Eye/Ear/Nasal Preparations	General	Production, Packing & Quality Control
Dry Powder Injections	Betalactam	Production, Packing & Quality Control
Dry Powder Injections with Diluents	Cephalosporin	Production, Packing & Quality Control
Soft Gelatin Capsules	General	Production, Packing & Quality Control

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 22.02.2024. It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Name & Function of Responsible person:

Address of Certifying Authority:

Date:-



Deputy Drugs Controller -cum- Licensing Authority O/o State Drugs controller, Baddi, Distt. Solan, H.P.173205 01795-244288,ddc4hp@gmail.com

(Manish Kapoor) Deputy Drugs Controller -cum- Licensing Authority O/o State Durgs Controller, H.P 01795-244288, ddc4hp@gmail.com

Signature: Stamp:

(Dr. Manish Kapoor) 23/2/21 EPUTY DRUGO -cum-LICENSING AUTHORITY O/0 STATE DRUGS CONTROLLER BADDI DISTRICT SOLAN, H.P-173205 E mail ddc4hp@gmail.com 01795-244288 Phone

Health & Family Welfare- I	Department	t, Himachal Pradesh
l up to : 22.02.2024		Exporting (certifying) Country: INDIA Importing (requesting) Country: MEXICO DACMED 200 Dacarbazine for Injection USP 200mg (Lyophilized)
Active ingredient(s) and amount per unit dose:		Each vial contains: Dacarbazine USP200 mg Citric Acid Monohydrate BP200 mg Mannitol BP75 mg Water for Injection BPq.s.
Yes No Not applicable		exporting country?
	2A & omit Qu	
produced? ¹⁴ Yes <u>No</u> No Periodicity of routine inspection: Once in a year. Has the manufacturer of this type of dosage forms b	(Name 2. Statu categ 3. Why i Not I Not I Unde Refu 4. Rema spection of ma t applicable	arks: anufacturing plant in which the dosage form is d? : Yes No
		No Not applicable
manufacturer of the product? Yes	tisfy the certif	fying Authority on all aspects of the if no explain
Address of certifying authority: State Drug Controller-Cum-Licensing Authority O/o State Drug Controller Health and Family Welfare Department Baddi, Distt Solan, 173205 (H.P.) India	<u>Name of</u> Signatur Stamp &	
	Health & Family Weifare-1 CERTIFICATE OF PHA f Certificate HFW-H (DRUGS) 427/05/ up to 22.02.2024 Proprietary Name (If applicable) and Dosages form Active ingredient(s) and amount per unit dose: Is this product is licensed to be placed on the mark Yes No Not applicable Is this product naturally on the market in the export (If the answer to 1.2 is yes, continue with Question Question 2A and continue with Question 2B) 1. Product License & date of Issue. MB/05/255, 26/02/2021 2. Product License & date of Issue. MB/05/255, 26/02/2021 3. Product License holder (Name and add.) United Biotech (P) Limited Bagbania, Baddi-Nalagarh Road District-Solan (HP) 174101 India 3. Status of applicant a/b/c (key in appropriate Category as define in note) a b c c a b b c c 4. Permission letter no. Is an approved technical summary appended? Yes No Mot provided Motor 5. Is the attached officially approved product Information complete and consonant with the License Yes No Mot provided Yes Obes the certifying authority arrange for periodic improduced? ¹⁴ Yes No No Does the certifying authority arrange for periodic improduced? ¹⁴ Yes No No Does the facility and operation conform to GMP as r Yes / No / Not applicable Yes Obes the information submitted by the applicant sati manufacturer of the p	up to 22.02.2024 Proprietary Name (If applicable) and Dosages form of Product : Active ingredient(s) and amount per unit dose: Active ingredient(s) and amount per unit dose: Is this product is licensed to be placed on the market for use in of Yes Yes No No Not applicable Is this product naturally on the market in the exporting country? (If the answer to 1.2 is yes, continue with Question 2A & omit Q Question 2A and continue with Question 2B 1. Product License & date of Issue. MB/05/255, 26/02/2021 2. Product License holder (Name and add.) United Biotech (P) Limited Bagbania, Baddi-Nalagarh Road District-Solan (HP) 174101 India 3. Status of applicant a/b/c (key in appropriate Category as define in note) a

^	GOVERNMENT OF	HIMACHAI	L PRADESH	
Health & Family Welfare- Department, Himachal Pradesh				
	CERTIFICATE OF PH	IARMACEU?	TICAL PRODU	
	of Certificate : HFW-H (DRUGS) 427/05/	21-324	Exporting (certifying) Country: INDIA	
	l up to : 22.02.2024		Importing (requesting) Country: MEXICO	
1.0	Proprietary Name (If applicable) and Dosages form	of Product :	LYOBLE 15	
-			Bleomycin for Injection USP 15 Units (Lyophilized)	
	Active ingredient(s) and amount per unit dose:		Each vial contains:	
	3 · · · · · · · · · · · · · · · · · · ·		Bleomycin Sulfate USP	
			eq. to Bleomycin15 Units	
1 1			Water for Injection USPq.s.	
1.1	Is this product is licensed to be placed on the marked Yes No Not applicable	et for use in e	exporting country?	
			Beneficianse and Language and Langua	
1.2	Is this product naturally on the market in the expor	ting country?	Yes No Unknown	
	(If the answer to 1.2 is yes, continue with Question	2A & omit O	uestion 2B & if answer to 1.2 is No omit the	
	Question 2A and continue with Question 2B)			
2A		יייא 2B		
	1. Product License & date of Issue.		icant for certificate	
	MB/05/255, 26/02/2021		e & Address)	
	2. Product License holder (Name and add.)			
	United Biotech (P) Limited	2. Statı	us of applicant a/b/c (key in appropriate	
	Bagbania, Baddi-Nalagarh Road	categ	gory as define in note)	
	District-Solan (HP) 174101 India			
	3. Status of applicant a/b/c (key in appropriate			
	Category as define in note)			
	a b c c			
	Is an approved technical summary appended?	2 Why	is authorization lacking?	
	Yes No Not provided		Required	
	5. Is the attached officially approved product	F F	Required Required	
	Information complete and consonant with the		er consideration	
	License	Refu		
	Yes No Not provided			
	6. Applicant for certificate, if different from	4. Rema	arks:	
	license holder (name & add.) : SAME			
3.	Does the certifying authority arrange for periodic in	anastion of m	onufocturing alogt in which the decays from it	
0.		t applicable	anulacturing plant in which the dosage form is	
3. 1	Periodicity of routine inspection: Once in a year.	t applicable	L	
• •				
3.2	Has the manufacturer of this type of dosage forms b	een inspected	d?: Yes No	
3.3	Does the facility and operation conform to GMP as r	ecommended	by the World Health Organization?	
	Yes / No / Not applicable Yes	\sim	No Not applicable	
4.	Does the information submitted by the applicant sat			
	manufacturer of the product? Yes	< No 🗌	if no explain	
	Address of certifying authority:	Name of t	he Authorizing person: Mr. Navneet Marwaha	
	State Drug Controller	<u></u>	in inavitor marwalla	
	Controller-Cum-Licensing Authority	Signature	; :	
	Health and Family Welfare Department	Ū.		
	Baddi, Distt Solan, 173205 (H.P.) India	Stamp & I	Date :	
	A Carlo and A C			
			1/ 1069	
			(NAVNEET M/RWAMA)	
			State Drugs Controlle	
			Controlling cum Licensing Authority	
	the second secon		BeddiDisit.Solan (H. P.)>173205 01795-244288,sdc4hp@gmail.com	
			ATTAC SULVAVAAA UMANAAA	
,	THIS CERTIFICATE CONFIRMS TO THE FORMAT RECOMMENDED BY THE WORLD HEALTH ORGANIZATION			

(GENERAL INSTRUCTION AND EXPLANATORY NOTES ATTACHED)

No. of	Certificate: HFW-H (DRUGS) 427/05/21-182	Exporting (certifying) Country : INDIA
Valid u	up to : 22/02/2024	importing (requesting) Country : PERU
Ac	oprietary Name (If applicable) and Dosages form of Product: etive Ingredient (s) and amount per unit dose : this product is licensed to be placed on the market for use in e	Pegasparagase Injection 750 IU/5ml Each ml contains: Pegasparagase (Pegylated L-Asparaginase) 750 IU
Yes	No	Not applicable
(if the a continu	this product naturally on the market in the exporting country? answer to 1.2 is Yes, continue is with Question 2A & omit que te with question 2B)	estion 2B & if answer is to 1.2 is no, omit the question 2A ar
2A	 Product License & date of Issue. MB/05/255, 23/02/21 Product License holder (name and add.) United Biotech Pvt. Limited Bagbania, Baddi-Nalagarh Rd., Disst – Solan. –HP Status of applicant a/b/c (key in appropriate category as define in note) a b c Permission letter no. Is an approved technical summary appended? Yes No Not provided Is the attached officially approved product Information complete and consonant with the License Yes No Not provided Applicant for certificate, if different from License holder (name & add.) : SAME 	2B 1. Applicant for certificate (Name & Address) 2. Status of applicant a/b/c (key in appropriate category as define in note) a b c a b c 3. Why is authorization lacking? Not Required Not Required Under consideration Refused 4. Remarks: 4. Remarks:
3.	Does the certifying authority arrange for periodic inspectio Yes NO	n of manufacturing plant in which the dosage form is produc Not Applicable
3.1	Periodicity of routine inspection: Twice in	a year.
3.2	Has the manufacturer of this type of dosage forms been ins	pected? Yes No
3.3	Does the facility and operation confirm to GMP as recomm Yes/No/Not applicable Yes	
4.	Does the information submitted by the applicant satisfy the	e certifying Authority on all aspects of the manufacturer of the
Offi Lice Hea	dress of the certifying authority ice of the State Drugs Controller ensing Authority Cum Controlling Authority alth & Family Welfare- Department, Himachal Pradesh Road, Baddi, Distr. Solan, 173205 (H.P.) India	Name of the Authorizing person: Signature : 23.02.20 Stamp & Dat DEPUTY DRUGS CONTROLLER -cum-LICENSING AUTHORITY O/o STATE DRUGS CONTROLLER BADDI, DISTRICT SOLAN, H.P17320 E mail ddc4hp@gmail.com

<u>GENERAL INSRUCTION</u>: Please refer to the guidelines for full instructions how to complete with form an information on the implementation of the scheme. The forms are suitable for generation by computers. They should always be submitted as hard copy with responses printed in type rather hand written additional sheets should be appended, as necessary, to accommodate remarks and explanations.

EXPLANATORY NOTES

- 1. This certificate which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country, it is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
- 2. Use, where possible, international Nonproprietary Name (INNs) or national nonproprietary names.
- 3. The formula (Complete composition) of the dosage from should be given on the certificate or be appended.
- 4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product –licence holder.
- 5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
- 6. Sections 2A and 2B are mutually exclusive.
- 7. Indicate, when applicable, if the licence is provisional or the product has not yet been approved.
- 8. Specify whether the person responsible for placing the product on the market ;
 - (a) Manufactures the dosage form;
 - (b) Packages and / or label a dosage form manufactured by an independent company ; or
 - (c) Is involved in none of the above.
- 9. This information can be provided only with the consent of the product –licence holder or , in the case of non –registered products , the applicant . Non –completion of this section indicates that the party concerned has not agreed to inclusion of this information.

It should be noted that information concerning the site of production is part of the product licnece. If the production site is changed, the licence must be updated or it will cease to be valid.

- 10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
- 11. This refers to product information approved by the competent national regulatory authority, such as a summary of Product Characteristics (SPC).
- 12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission must be provided to the authority by the applicant.
- 13. Please indicate the reason that the applicant has provided for not requesting registration:
 - (a) The product has been developed exclusively for the treatment of conditions-particularly tropical diseases not endemic in the country of export;
 - (b) The product has been reformulated with a view to improving its stability under tropical conditions.
 - (c) The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import:
 - (d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient;
 - (e) Any other reason, please specify.
- 14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
- 15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the expert committee on specifications for pharmaceutical preparations (WHO technical report series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO expert committee on biological standardization (WHO technical report series, No. 822, 1992, Annex 1).
- 16. This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

No. of	Certificate: HFW-H (DRUGS) 427/05/21-315	Exporting (certifying) Country : INDIA
Valid u	up to : 22/02/2024	importing (requesting) Country : PERU
Ac	oprietary Name (If applicable) and Dosages form of Product: etive Ingredient (s) and amount per unit dose : this product is licensed to be placed on the market for use in o	Calcium Folinate Injection BP 30mg/3ml Each ml contains: Calcium Folinate BP eq. to Folinic acid 10mg Water for Injections BP q.s.
Yes	No No	Not applicable
101		
	this product naturally on the market in the exporting country?	
	answer to 1.2 is Yes, continue is with Question 2A & omit que the with question 2B)	estion 2B & if answer is to 1.2 is no, omit the question 2A ar
2A		2B
	1. Product License & date of Issue. MB/05/255, 23/02/21	1 Applicant for cortificate
	2. Product License holder (name and add.)	1. Applicant for certificate (Name & Address)
	United Biotech Pvt. Limited	2. Status of applicant a/b/c (key in appropriate
	Bagbania, Baddi-Nalagarh Rd., Disst – Solan. –HP	category as define in note)
	3. Status of applicant a/b/c (key in appropriate category as define in note)	
		3. Why is authorization lacking?
	4. Permission letter no.	Not Required
	Is an approved technical summary appended?	Not Required
	Yes No Not provided	Under consideration
	5. Is the attached officially approved product Information complete and consonant with the License Yes No Not provided	Refused
	6. Applicant for certificate, if different from License holder (name & add.) : SAME	4. Remarks:
3.	Does the certifying authority arrange for periodic inspection Yes NO	on of manufacturing plant in which the dosage form is produced in the second seco
3.1	Periodicity of routine inspection: Twice in	a year.
3.2	Has the manufacturer of this type of dosage forms been ins	spected? Yes No
3.3	Does the facility and operation confirm to GMP as recomm Yes/No/Not applicable Yes	
4.	Does the information submitted by the applicant satisfy the	e certifying Authority on all aspects of the manufacturer of th
Offi	dress of the cemilving authority ice of the State Drugs Controller ensing Authority Cum Controlling Authority	Name of the Authorizing person:
Hea	alth & Family Welfare- Department, Himachal Pradesh	(MANISH KAPOOR) 23.02.20
581	Road, Baddi, Distr. Solan, 173205 (H.P.) India	Stamp & Date EPUTY DRUGS CONTROLLER -cum-LICENSING AUTHORITY O/o STATE DRUGS CONTROLLER BADDI, DISTRICT SOLAN, H.P1732
		E mail ddc4hp@gmail.com

<u>GENERAL INSRUCTION</u>: Please refer to the guidelines for full instructions how to complete with form an information on the implementation of the scheme. The forms are suitable for generation by computers. They should always be submitted as hard copy with responses printed in type rather hand written additional sheets should be appended, as necessary, to accommodate remarks and explanations.

EXPLANATORY NOTES

- 1. This certificate which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country, it is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
- 2. Use, where possible, international Nonproprietary Name (INNs) or national nonproprietary names.
- 3. The formula (Complete composition) of the dosage from should be given on the certificate or be appended.
- 4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product –licence holder.
- 5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
- 6. Sections 2A and 2B are mutually exclusive.
- 7. Indicate, when applicable, if the licence is provisional or the product has not yet been approved.
- 8. Specify whether the person responsible for placing the product on the market ;
 - (a) Manufactures the dosage form;
 - (b) Packages and / or label a dosage form manufactured by an independent company ; or
 - (c) Is involved in none of the above.
- 9. This information can be provided only with the consent of the product –licence holder or , in the case of non –registered products , the applicant . Non –completion of this section indicates that the party concerned has not agreed to inclusion of this information.

It should be noted that information concerning the site of production is part of the product licnece. If the production site is changed, the licence must be updated or it will cease to be valid.

- 10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
- 11. This refers to product information approved by the competent national regulatory authority, such as a summary of Product Characteristics (SPC).
- 12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission must be provided to the authority by the applicant.
- 13. Please indicate the reason that the applicant has provided for not requesting registration:
 - (a) The product has been developed exclusively for the treatment of conditions-particularly tropical diseases not endemic in the country of export;
 - (b) The product has been reformulated with a view to improving its stability under tropical conditions.
 - (c) The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import:
 - (d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient;
 - (e) Any other reason, please specify.
- 14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
- 15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the expert committee on specifications for pharmaceutical preparations (WHO technical report series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO expert committee on biological standardization (WHO technical report series, No. 822, 1992, Annex 1).
- 16. This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

CERTIFICATE OF PHARMACEUTICAL PRODUCTS			
No. of Certificate : HFW-H (DRUGS) 427/05/21-3 Valid up to : 22.02.2024 1.0 Proprietary Name (If applicable) and Dosages form of P Active ingredients(s) and amount per unit dose	Importing (requesting) Country : SRI LANKA		
 1.1 Is this product is licensed to be placed on the market for Yes No Not applicable 1.2 Is this product naturally on the market in the exporting (If the answer to 1.2 is yes, continue with Question 2A 2A and continue with Question 2B) 			
 2A 1. Product License & date of Issue. MNB/05/254 & MB/05/255, 02/03/2021 2. Product License holder (Name and add.) United Biotech (P) Limited Bagbania, Baddi-Nalagarh Road District-Solan (HP) 174101 India 3. Status of applicant a/b/c (key in appropriate Category as define in note) a b c 4. Permission letter no. Is an approved technical summary appended? Yes No Not provided 5. Is the attached officially approved product Information complete and consonant with the License Yes No Not provided 6. Applicant for certificate, if different from license holder (name & add.) : SAME 	1. Applicant for certificate (Name & Address) 2. Status of applicant a/b/c (key in appropriate category as define in note) a b a b c 3. Why is authorization lacking? Not Required Not Required Quider consideration Refused 4. Remarks:		
	ction of manufacturing plant in which the dosage form is oplicable		
3.2 Has the manufacturer of this type of dosage forms been	n inspected? : Yes No		
3.3 Does the facility and operation conform to GMP as reco	mmended by the World Health Organization?		
Yes / No / Not applicable Yes	Not applicable		
4. Does the information submitted by the applicant satisfy the product? Yes	y the certifying Authority on all aspects of the manufacturer of No if no explain		
<u>Address of the certifying authority</u> Office of the State Drugs Controller Licensing Authority Health & Family Welfare- Department, Himachal Prade	Name of the Authorizing person: Signature :		
Sai Road, Baddi, Distt Solan, 173205 (H.P.) India	Stamp & Date : (Dr. Manish Kapoor) DEPUTY DRUGS CONTROLLER -cum-LICENSING AUTHORITY O/o STATE DRUGS CONTROLLER BADDI DISTRICT SOLAN, H.P-173205 E mail ddc4hp@gmail.com Phone 01795-244288		
THIS CERTIFICATE CONFIRMS TO THE FORMAT RECO	OMMENDED BY THE WORLD HEALTH ORGANIZATION		