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:

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

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.

Address of Certifying Authority:

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

Name & Function of Responsible person:

(Manish Kapoor)

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

Telephone/Fax No:

Date:-

Signature: Stamp:

(Dr. Marish Kapoor)
DEPUTY DRUGS CONTROLLER
-cum-LICENSING AUTHORITY
O/o STATE DRUGS CONTROLLER
BADDI DISTRICT SOLAN, H.P-173405
E mail ddc4hp@gmail.com

E mail ddc4hp@gmail con Phone 01795-244968

CERTIFICATE OF PHARMACEUTICAL PRODUCTS No. of Certificate: HFW-H (DRUGS) 427/05/21-167 Exporting (certifying) Country: INDIA Valid up to : 22/02/2024 importing (requesting) Country: MACAU 1. Proprietary Name (If applicable) and Dosages form of Product: AMPHOTIN Amphotericin B Injection USP Active Ingredient (s) and amount per unit dose Each vial contains: Amphotericin B USP 50 mg **Excipients** q.s. 1.1. Is this product is licensed to be placed on the market for use in exporting company? Yes Not applicable 1.2 Is this product naturally on the market in the exporting country? Yes Unknown (if the answer to 1.2 is Yes, continue is with Question 2A & omit question 2B & if answer is to 1.2 is no, omit the question 2A and continue with question 2B) 2A 2B 1. Product License & date of Issue. MB/05/255, 23/02/21 1. Applicant for certificate (Name & Address) 2. Product License holder (name and add.) 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) b 3. Why is authorization lacking? Not Required 4. Permission letter no. Is an approved technical summary appended? Not Required No t provided Under consideration 5. Is the attached officially approved product Information complete and consonant with the License Refused ٦ ^{No} Not provided 6. Applicant for certificate, if different from Remarks: License holder (name & add.): SAME luced?

3.	Does the certifying authority arrange for period Yes	lic inspection of ma	nufacturing plant in Not Applicable	which the dosage	form is produce
3.1	Periodicity of routine inspection:	Twice in a year.		-	
3.2	Has the manufacturer of this type of dosage for	ms been inspected?	Yes	No No	
3.3	Does the facility and operation confirm to GMI Yes/No/Not applicable	P as recommended by Yes	by the World Health	Organization? Not applicable	
1 .	Does the information submitted by the applican	nt satisfy the certifyi	ing Authority on all	aspects of the man	ufacturer of the
		\geq			

Address of the corniving authority Office of the State Drugs Controller Licensing Authority Cum controlling Authority Health & F Department, Himachal Pradesh Sai Road o) n, 173205 (H.P.) India

Name of the Authorizing person:

Signature

23.02.2021 (MANISH KAPOOR)

Stamp & DatePUTY DRUGS CONTROLLER -cum-LICENSING AUTHORITY O/o STATE DRUGS CONTROLLER BADDI, DISTRICT SOLAN, H.P.-173205

E mail ddc4hp@gmail.com

THIS CERTIFICATE CONFIRMS TO THE FORMAT RECOMMENDED BY THE WORLD HEALTH 1286 ANIZATION

GENERAL INSRUCTION: 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.

- 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) 427/05/21-210	Exporting (certifying) Country: INDIA			
Valid up to : 22/02/2024	importing (requesting) Country : NIGERIA			
Proprietary Name (If applicable) and Dosages form of Product: Active Ingredient (s) and amount per unit dose :	CLUTA-B 50 Bicalutamide Tablets USP 50mg Each film coated tablet contains: Bicalutamide USP 50mg Colour: Titanium Dioxide BP.			
1.1. Is this product is licensed to be placed on the market for use in e				
Yes No	Not applicable			
1.2 Is this product naturally on the market in the exporting country?	Yes Unknown Unknown			
(if the answer to 1.2 is Yes, continue is with Question 2A & omit que continue with question 2B) $^{\circ}$	estion 2B & if answer is to 1.2 is no, omit the question 2A and			
2A	2B			
Product License & date of Issue. MB/05/255, 23/02/21 Product License holder (name and add.) United Biotech Pvt. Limited	Applicant for certificate (Name & Address)			
Bagbania, Baddi-Nalagarh Rd., Disst – Solan. –HP	2. Status of applicant a/b/c (key in appropriate category as define in note)			
3. 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?			
4. Permission letter no.	Not Required			
Is an approved technical summary appended? Yes No Not provided	Not Required			
5. Is the attached officially approved product Information complete and consonant with the License Yes No Not provided	Under consideration 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	n of manufacturing plant in which the dosage form is produced? 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	pccted? Yes No			
3.3 Does the facility and operation confirm to GMP as recomm Yes/No/Not applicable Yes	nended by the World Health Organization? No Not applicable			
4. Does the information submitted by the applicant satisfy the	certifying Authority on all aspects of the manufacturer of the			
Address of the certifying authority Office of the State Drops Controller Licensing Authority Cum Controlling Authority Health & Family Wedare-Department, Himachal Pradesh Sai Road, Bandi, Djatt. Solan, 173205 (H.P.) India	Name of the Authorizing person: Signature: (MANISH KAPOOR) Stamp & Dalberty Drugs Controller -cum-LICENSING AUTHORITY O/o STATE Drugs Controller BADDI, DISTRICT SOLAN, H.P173205 E mail ddc4hp@gmail.com			
THIS CERTIFICATE CONFIRMS TO THE FORMAT RECOMM	IENDED BY THE WORLD IT BALTH 42 BOANIZATION			

<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.

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 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.
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- 11. This refers to product information approved by the competent national regulatory authority, such as a summary of Product Characteristics (SPC).
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- 13. Please indicate the reason that the applicant has provided for not requesting registration:
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 - (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).
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CERTIFICATE OF PHARMACEUTICAL PRODUCTS No. of Certificate: HFW-H (DRUGS) 427/05/21-315 Exporting (certifying) Country: INDIA Valid up to : 22/02/2024 importing (requesting) Country: CHILE 1. Proprietary Name (If applicable) and Dosages form of Product: UNIFOLIN 30 Leucovorin Calcium Injection USP 30mg/3ml Active Ingredient (s) and amount per unit dose Each ml contains: Leucovorin Calcium USP Eq. to Leucovorin 10mg Water for Injection USP q.s. 1.1. Is this product is licensed to be placed on the market for use in exporting company? Yes Not applicable 1.2 Is this product naturally on the market in the exporting country? Yes Unknown (if the answer to 1.2 is Yes, continue is with Question 2A & omit question 2B & if answer is to 1.2 is no, omit the question 2A and continue with question 2B) 2A 2B1. Product License & date of Issue. MB/05/255, 23/02/21 1. Applicant for certificate (Name & Address) 2. Product License holder (name and add.) 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) Why is authorization lacking Not Required 4. Permission letter no. Is an approved technical summary appended? Not Required No Not provided Under consideration 5. Is the attached officially approved product Information complete and consonant with the License Refused Not provided 6. Applicant for certificate, if different from Remarks: License holder (name & add.): SAME 3. Does the certifying authority arrange for periodic inspection of manufacturing plant in which the dosage form is produced? NO Not Applicable 3.1 Periodicity of routine inspection: Twice in a year. 3.2 Has the manufacturer of this type of dosage forms been inspected? Yes No Does the facility and operation confirm to GMP as recommended by the World Health Organization? 3.3 Yes/No/Not applicable Yes _ No L Not applicable 4. Does the information submitted by the applicant satisfy the certifying Authority on all aspects of the manufacturer of the Address of the corniving authority Name of the Authorizing person: Office of the State Drugs Controller Licensing Authority Cum Controlling Authority Signature Health & Family Water- Department, Himachal Pradesh (MANIŠH KAPOOR) 38)4n, 173205 (H.P.) India Stamp & Date DEPUTY DRUGS CONTROLLER (J. 430 *

THIS CERTIFICATE CONFIRMS TO THE FORMAT RECOMMENDED BY THE MORLO 19 DALTH 12 RG ANIZATION

-cum-LICENSING AUTHORITY O/o STATE DRUGS CONTROLLER BADDI, DISTRICT SOLAN, H.P.-173205

E mail ddc4hp@gmail.com

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- 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.
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 - (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.
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Proprietary Name (If applicable) and Dosages form of Product: IFOMID 50	for Injection USP 500rng
Ifosfamide Active ingredients(s) and amount per unit dose Ifosfamide Is this product is licensed to be placed on the market for use in exporting covered to be placed on the market for use in exporting country? Yes Status of applicant for cere (Name & Addres 2. Status of applicant a placed 3. Why is authorize and add.) 1. Product License & date of Issue. 1. Applicant for cere (Name & Addres 2. Status of applicant applicant a placed 2. Status of applicant app	for Injection USP 500mg
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1.2 Is this product naturally on the market in the exporting country? Yes	
(If the answer to 1.2 is yes, continue with Question 2A & omit Question 2B & Question 2A and continue with Question 2B) 2A 1. Product License & date of Issue. MB/05/255, 08/03/2021 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	antry?
Question 2A and continue with Question 2B) 2A 1. Product License & date of Issue. MB/05/255, 08/03/2021 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	No Unknown
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MB/05/255, 08/03/2021 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 Does the certifying authority arrange for periodic inspection of manufacturin produced? Yes No Not applicable Periodicity of routine inspection: Once in a year. Has the manufacturer of this type of dosage forms been inspected?: Yes Does the facility and operation conform to GMP as recommended by the Wor Yes / No / Not applicable Does the information submitted by the applicant satisfy the certifying Author.	
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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 Does the certifying authority arrange for periodic inspection of manufacturing produced? 14 Yes No Not applicable Periodicity of routine inspection: Once in a year. Has the manufacturer of this type of dosage forms been inspected?: Yes Does the facility and operation conform to GMP as recommended by the Work Yes / No / Not applicable Yes No Does the information submitted by the applicant satisfy the certifying Authority arrange for periodic inspection of manufacturing produced? 14 Yes No Does the facility and operation conform to GMP as recommended by the Work Yes / No / Not applicable Yes No Does the information submitted by the applicant satisfy the certifying Authority arrange for periodic inspection of manufacturing produced? 14 Yes No Does the information submitted by the applicant satisfy the certifying Authority arrange for periodic inspection of manufacturing produced? 14 Yes No Does the information submitted by the applicant satisfy the certifying Authority arrange for periodic inspection of manufacturing produced? 14 Yes No Does the information submitted by the applicant satisfy the certifying Authority arrange for periodic inspection of manufacturing produced? 14 Yes No Does the information submitted by the applicant satisfy the certifying Authority arrange for periodic inspection of manufacturing produced? 14 Yes No Does the information submitted by the applicant satisfy the certifying Authority arrange for periodic inspection of manufacturing produced? 15 Yes No Does the facility and operation conformation submitted by the applicant satisfy the certifying Authority arrange for periodic inspection of manufacturing produced? 15 Yes No Does the facility arrange for periodic inspection of manufacturing produced? 15 Yes No Does the facility arrange for periodic inspection of manufacturing produced?	tion lacking?
6. Applicant for certificate, if different from license holder (name & add.): SAME 3. Does the certifying authority arrange for periodic inspection of manufacturing produced? 14 Yes No Not applicable Periodicity of routine inspection: Once in a year. 3.1 Periodicity of routine inspection: Once in a year. 3.2 Has the manufacturer of this type of dosage forms been inspected?: Yes 3.3 Does the facility and operation conform to GMP as recommended by the Work Yes / No / Not applicable Yes No Does the information submitted by the applicant satisfy the certifying Author	ation [
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Does the facility and operation conform to GMP as recommended by the Wor Yes / No / Not applicable Yes No Does the information submitted by the applicant satisfy the certifying Autho	
Yes / No / Not applicable Yes No No Does the information submitted by the applicant satisfy the certifying Author	No No
Does the information submitted by the applicant satisfy the certifying Autho	ld Health Organization?
Does the information submitted by the applicant satisfy the certifying Authomanufacturer of the product? Yes No	Not applicable
	rity on all aspects of the if no explain
Address of the certifying authority Name of the Author Office of the State Drugs Controller	izing person:
Licensing Authority Signature : Health & Family Welfare- Department, Himachal Pradesh	boundar
Sai Road, Baddi, Distt. Solan 173205 (H.P.) India Stamp & Date:	e Tanakapeor) 16 MAR 202

THIS CERTIFICATE CONFIRMS TO THE FORMAT RECOMMENDED BY THE WORLD HEALTH ORGANIZATION

CERTIFICATE OF PHARM	ACEUTICAL PRODUCTS
No. of Certificate: HFW-H (DRUGS) 427/05/21-197	Exporting (certifying) Country : INDIA
Valid up to : 22/02/2024	importing (requesting) Country: PERU
 Proprietary Name (If applicable) and Dosages form of Product: Active Ingredient (s) and amount per unit dose : 1.1. Is this product is licensed to be placed on the market for use in expression. 	Fluorouracil Injection USP 250mg Each ml contains: Fluorouracil USP 50mg Water for Injection USP q.s.
Yes No	Not applicable
1.2 Is this product naturally on the market in the exporting country?	
(if the answer to 1.2 is Yes, continue is with Question 2A & omit queentinue with question 2B) $^{\circ}$	estion 2B & if answer is to 1.2 is no. omit the question 2A and
2A	2B
1. Product License & date of Issue. MB/05/255, 23/02/21 2. Product License holder (name and add.) United Biotech Pvt. Limited Bagbania, Baddi-Nalagarh Rd., Disst – Solan. –HP 3. Status of applicant a/b/c (key in appropriate category as define in note) a	1. Applicant for certificate (Name & Address) 2. Status of applicant a/b/c (key in appropriate category as define in note) a
Yes NO [on of manufacturing plant in which the dosage form is produced? 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	spected? Yes No
Does the facility and operation confirm to GMP as recomm Yes/No/Not applicable Yes	nended by the World Health Organization? No Not applicable
4. Does the information submitted by the applicant satisfy the	e certifying Authority on all aspects of the manufacturer of the
Address of the certifying authority Office of the State Drugs Controller Licensing Authority Cum Controlling Authority Health Camilly Water-Department, Himachal Pradesh Sai Road, Bandi, Diet. Solan, 173205 (H.P.) India	Name of the Authorizing person: Signature (MANISH KAPOOR) Stamp & Da BEPUTY DRUGS CONTROLLER -cum-LICENSING AUTHORITY O/o STATE DRUGS CONTROLLER BADDI, DISTRICT SOLAN, H.P173205 E mail ddc4hp@gmail.com

GENERAL INSRUCTION: 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.

- 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) 427/05/21-93 Exporting (certifying) Country : INDIA Importing (requesting) Country: SYRIA
	Proprietary Name (If applicable) and Dosages form of Product : IFOMID 1.0 Ifosfamide for Injection USP 1.0g
	Active ingredients(s) and amount per unit dose : Each vial containing: Ifosfamide USP
	Is this product is licensed to be placed on the market for use in exporting country? Yes No Not applicable
	1.2 Is this product naturally on the market in the exporting country? Yes No Unknown
	(If the answer to 1.2 is yes, continue with Question 2A & omit Question 2B & if answer to 1.2 is No, omit the Question 2A and continue with Question 2B)
3.	1. Product License & date of Issue. MB/05/255, 08/03/2021 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 ab b c ab b c ab b c ab b c at 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 4. Remarks: Does the certifying authority arrange for periodic inspection of manufacturing plant in which the dosage form is produced? Yes No Not applicable
3,	and the map could be a year.
3.	No No
3.	and operation comorni to GMP as recommended by the World Health Organization?
4.	Yes / No / Not applicable Yes No Not applicable Does the information submitted by the applicant satisfy the certifying Authority on all aspects of the manufacturer of the product? Yes No if no explain
	Address of the certifying authority Office of the State Drugs Controller Licensing Authority Signature: Health & Family Welfare- Department, Himachal Pradesh
	Sai Road, Baddi, Distt. 80 AR 2005 (H.P.) India Stamp & Date:

THIS CERTIFICATE CONFIRMS TO THE FORMAT RECOMMENDED BY THE WORLD HEALTH ORGANIZATION

GOVERNMENT OF HIMACHAL PRADESH Health & Family Welfare- Department, Himachal Pradesh CERTIFICATE OF PHARMACEUTICAL PRODUCTS

No. of Certificate Valid up to	: HFW-H (DRUGS) 427/05 : 22.02.2024	5/21-361	Exporting (certifying) Country : INDIA Importing (requesting) Country : PANAMA
	ry Name (If applicable) and Dosages forr	m of Product :	UNIBLASTIN Vinblastine Sulfate Injection 10mg/10ml
Active in	gredients(s) and amount per unit dose	;	Each ml contains: Vinblastine Sulfate USP
1.1 Is this pr	oduct is licensed to be placed on the ma	rket for use in	
Yes	No Not applicable		
1.2 Is this pr	oduct naturally on the market in the exp	porting country	? Yes NoUnknown
Question	swer to 1.2 is yes, continue with Questic 2A and continue with Question 2B)		uestion 2B & if answer to 1.2 is No, omit the
1. Produce MB/05 2. Produce United Bagba Districe 3. Status Catego a 4. Permis Is an a Yes [5. Is the a Inform License Yes [6. Applica	at License & date of Issue. 2/255, 26/02/2021 t License holder (Name and add.) Biotech (P) Limited ata, Baddi-Nalagarh Road t-Solan (HP) 174101 India of applicant a/b/c (key in appropriate ry as define in note) b	(Nan 2. State cates 3. Why Not	<u> </u>
3. Does the produced and periodicity and a perio	certifying authority arrange for periodic is 14 Yes No	Not applicable s been inspected s recommended fes satisfy the certi No [No Not applicable fying Authority on all aspects of the if no explain function for the Authorizing person: Navneet Marwha re:

THIS CERTIFICATE CONFIRMS TO THE FORMAT RECOMMENDED BY THE WORLD HEALTH ORGANIZATION (GENERAL INSTRUCTION AND EXPLANATORY NOTES ATTACHED)