UT ADMINISTRATION OF DNH, DAMAN & DIU DRUGS LICENSING AUTHORITY DRUGS CONTROL DEPARTMENT PRIMARY HEALTH CENTER DAMAN - 396 220

DATED: 04/07/2022.

WHO-GMP CERTIFICATE

THIS IS TO CERTIFY THAT M/S. BRUCK PHARMA PRIVATE LIMITED, PLOT NO. 188/1 TO 6, 189/1, 190/2 TO 4, ATIYAWAD, DABHEL, DAMAN- 396210, INDIA IS HOLDING VALID DRUG MANUFACTURING LICENCES IN FORM NO. 25 & FORM NO. 28 BEARING LICENCE NO. DD/793 & DD/794, DATED 28/04/2017 RESPECTIVELY, ISSUED BY THIS ADMINISTRATION UNDER THE PROVISIONS OF DRUGS & COSMETICS ACT, 1940 AND RULES THEREUNDER. UNDER THE SAID LICENCES THE FIRM IS PERMITTED TO MANUFACTURE AND SELL THEIR PRODUCTS COVERED UNDER THE CATEGORIES OF ANTICANCER - LIQUID INJECTIONS, LYOPHILIZED INJECTIONS AND ORAL SOLID DOSAGE.

THE FIRM HAS EMPLOYED COMPETENT PERSONS IN MANUFACTURING AND QUALITY CONTROL DEPARTMENTS. THE FIRM IS FOLLOWING GOOD MANUFACTURING PRACTICES AS PER WORLD HEALTH ORGANIZATION RECOMMENDATIONS IN THE MANUFACTURING AND TESTING OF THE SAID CATEGORIES OF ANTICANCER - LIQUID INJECTIONS, LYOPHILIZED INJECTIONS AND ORAL SOLID DOSAGE.

THE MANUFACTURING PLANT IS SUBJECT TO REGULAR INSPECTION BY THE COMPETENT AUTHORITY UNDER THE ACT.

THIS CERTIFICATE IS VALIDUP TO 04/03/2025.

(DR. V. K. DAS) DIRECTOR,

MEDICAL & HEALTH SERVICES
DRUGS LICENSING AUTHORITY,
UT OF DNH, DAMAN & DIU,
DAMAN.

Administration of Daman & Diu, Drugs Licensing Authority, **Drugs Control Department,** Primary Health Centre, Daman - 396220.

Certificate of a Pharmaceutical Product¹

This certificate conforms to the format recommended by the World Health Organization

(General instructions and explanatory notes attached)

No. of Certificate

: DD/794/34C/2022-1-211-2

Valid up to: 04/03/2025

Exporting (Certifying) Country

: INDIA

Importing (Requesting) Country

: As per Annexure-II

Name and dosage form of product

: Epirubicin Hydrochloride for Injection 10mg/vial

1.1 Active ingredient (s)² and amount (s) per unit dose³: Composition:

Each Lyophilized Vial Contains:

Epirubicin hydrochloride USP......10mg Lactose monohydrate NF.....50mg

For complete qualitative composition including Excipients, see attached $^{f 4}$: Annexure - I

- Is this product licensed to be placed on the market for use in the exporting country?⁵ Yes
- Is this product actually on the market in the exporting country? Yes

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue section 2B 6.

A.1 Number of product license 7: DD/794 And date of issue : 11/12/2019

- A.2 Product license holder Bruck Pharma Pvt. Ltd. Survey No. 188/1 to 6, 189/1, 190/2 to 4, Atiyawad, Dabhel, Daman - 396210
- A.3 Status of product license holder 8: a

Manufacturing of Dosage forms

- A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are 9 : Not applicable
- A.4 Is summary basis of Approval appended? 10

A.5 Is the attached, officially approved product information complete and consonant with the license?¹¹

Not provided

A.6 Applicant for certificate if different from license holder: 12 : Not applicable.

2 B Not applicable.

B.1 Application for certificate: (Not applicable.)

(Name and address)

B.2 Status of applicant (Not applicable.)

- B.2.1 For categories b and c the name and address of the Manufacturer producing the dosage form are 9 : Not applicable
- B. 3 Why is marketing authorization lacking? : Not applicable

Required Requested Consideration

B.4 Remark: 13 -(Not applicable

Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the desage form is

If no or not applicable proceed to question 4.

- 3.1 Periodicity of routine inspections (years): Yearly
- 3.2 Has the manufacture of this type of dosage form been inspected?
- 3.3 Do the facilities and operations conform to GMP as recommended by Yes the World Health Organization ?15
- Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? 16 Yes If no, explain

Address of certifying authority:

Drugs Licensing Authority, Administration of Daman & Diu, **Drugs Control Department,** Primary Health Centre, Daman - 396220. Telephone Number: (0260) 2230470 Fax Number: (0260) 2230570

Name of authorized person: Dr. V.K. DAS

Signature:

औरपी लाईहेंस प्राधिकारी DRUGS CONTROL DEPARTMENT

औषधी निवंत्रण विभाग

UT OF DAMAN & DIU, DAMAN

Stamp and date: सध प्रदेश दमण एव दीव, दमण

1 2 APR 2022

ANNEXURE - 1

CERTIFICATE NO. DD/794/34C/2022-1-211-2

VALID UPTO 04/03/2025

ACTIVE AND INACTIVE COMPOSITION – QUALITATIVE AND QUANTITATIVE

Name of Product

Epirubicin Hydrochloride for Injection 10mg/vial

Composition

Each Lyophilized Vial Contains:

Epirubicin hydrochloride USP......10mg Lactose monohydrate NF......50mg

Ingredients	Specifications	Quantity Input (mg / ml)
Epirubicin Hydrochloride	USP	8.334
Lactose Monohydrate	SINU	AUT 47:666
Methyl Paraben	disp.	9/7
Water for injection	100 Pa.	9.5
	Epirubicin Hydrochloride Lactose Monohydrate Methyl Paraben	Epirubicin Hydrochloride Lactose Monohydrate Methyl Paraben

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.: 0091-0260-2230470 Fax No.: 0091-0260-2230570

Name of Authorized Person: Dr. V.K. DAS

Signature Stamp & Date DRUGS LICENSING AUTHORITY जीवनी लाईमेंस प्रतिकारी DRUGS CONTROL DEPARTMENT जीवनी विजेजन विभाग UT OF DAMAN & DIU, DAMAN सभ प्रदेश दमण एव दीव, दमन

1 2 APR 2022

ANNEXURE-II

No. of Certificate

: DD/794/34C/2022-1-211-2

Valid up to: 04/03/2025

Name of the Product : Epirubicin Hydrochloride for Injection 10mg/vial

List of countries / Institution to which the above product will be Exported / Locally supplied.

Afabaniatan	44, Cuba	85. Iran	128. Morocco	171. South Korea
. Afghanistan	45. Cyprus	86. Iraq	129. Mozambique	172. Spain
. Albania	46. Czech Republic	87, Ireland	130. Myanmar	173. Sri Lanka
. Algeria	47. Czechoslovakia¹	88. Israel	131. Namibia	174. Sudan
. Angola		89. Italy	132. Nepal	175. Suriname
. Argentina	48. Democratic		133. Netherlands	176. Swaziland
i. Armenia	Republic of Congo	90. Ivory Coast	Antilles	
		91. Jamaica	134. Netherlands	177. Sweden
'. Aruba	49. Denmark	92. Japan	135. New Zealand	178. Switzerland
. Australia	50. Djibouti	93. Jordan	136. Nicaragua	179. Syria
). Austria	51. Dominica	94. Kazakhstan	137. Niger	180. Tadzhikistan
0. Azerbaijan	52. Dominican Republic	95. Kenya	138. Nigeria	181. Taiwan
1. Bahamas	53. Ecuador	96. Kingdom of Tonga	139. North Korea	182. Tajikistan
2. Bahrain	54. Egypt		140. Norway	183. Tanzania
3. Baltic	55. El Salvador	97. Kiribati	141. Oman	184. Thailand
4. Bangladesh	56. Equatorial Guinea	98. Korea	142. Pakistan	185. Tobago
5. Barbados	57. Eritrea	99. Korea Republic of	143. Palau	186. Togo
16. Belarus	58. Estonia	100. Kosova	144. Panama	187. Tonga
17. Belgium	59. Ethiopia	101. Kuwait		
18. Belize	60. European Community	102. Kyrgyzstan	145. Papua New Guinea	188. Trinidad
	61. Fiji	103. Laos	146. Paraguay	189. Tunisia
19. Benin	62. Finland	104. Latvia	147. Peru	190. Turkey
20. Bhutan		105. Lebanon	148. Puerto Rico	191. Turkmenistan
21. Bolivia	63. France	106. Lesotho	149. Philippines	192. UAE
22. Bosnia	64. Gabon	107. Liberia	150. Poland	193. Uganda
23. Botswana	65. Gambia	108. Libya	151. Portugal	194. Ukraine
24. Brazil	66. Guatemala	109. Libyan Arab	152. Qatar	195. Union of Soviet
25. Brunei	67. Georgia	Jamahiriya		Socialist
26. Bulgaria		Jamannya	153. Republic of Benin	Republics ¹
26. Bulgaria	68. German Democratic		154. Republic de	196.United Arab
27. Burkina Faso	Republic ²	110. Liechtenstein	Guinee	Emirates
ZI. DUIKINA FASO			155. Republic of	197. United Kingdom
on Burundi	69. Germany Federal	111. Liochtonstoin	Maldives	
28. Burundi	Republic of ²	112. Lithuania	456 Demonia	C 198 United States
29. Byelorussia		112. Littuania	156. Romania	199. Uruguay
30. Cambodia	70. Germany	113. Luxembourg	158. Rwanda	200. USA
31. Cameroon	71. Ghana	114. Macau	159. Saudi Arabia	2 201 Uzbekistan
32. Canada	72. Greece	115. Madagascar	160. Senegal	202 Vanuatu
33.Central African	73. Grenada	116. Malawi	160. Serbia and ∰	203. Venezuela
Republic	74. Guinea	117. Malaysia	Montenegro	204: Vietnam
34. Chad	75. Guinea Equatorial	118. Maldives	162. Seychelles	205: West Indies
35. Chile	76. Guyana	119. Mali	163. Sierra Leone	206/ Worldn
36. China	77. Haiti	120. Malta		207 Yemen
37. Cook Islands	78. Holland	121. Marshall Islands	164. Singapore	208 Yugoslavia
38. Colombia	79. Honduras	122. Mauritania	165. Slovakia	209. Zaire
	80. Hong Kong	123. Mauritius	166. Slovenia	200 Hambia
39. Columbia	81. Hungary	124. Mexico	167. Solomon Islands	211. Zimbabwe
40. Congo	82. Iceland	125. Moldova	168. Somalia	Z11. Zimbabwe
41. Costa Rica	83. India	126. Monaco	169. Somaliland	
42. Council of Europe	84. Indonesia	127. Mongolia	170. South Africa	

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No. : 0091-0260-2230470 Fax No. : 0091-0260-2230570



Name of Authorized Person: Dr. V.K. DAS

और भी साधित प्राधिकारी DRUGS CONTROL DEPARTMENT

Signature Stamp & Date

ओवधो निवंत्रण विभाग UT OF DAMAN & DIU, DAMAN सम्म प्रदेश दमण एव दीब, दमण

Administration of Daman & Diu, Drugs Licensing Authority, Drugs Control Department, Primary Health Centre, Daman – 396220.

Certificate of a Pharmaceutical Product¹

This certificate conforms to the format recommended by the World Health Organization (General instructions and explanatory notes attached)

No. of Certificate

: DD/794/51C/2022-1-211-2

Valid up to: 04/03/2025

Exporting (Certifying) Country

: INDIA

Importing (Requesting) Country

: As per Annexure-II

1. Name and dosage form of product

: IFOSFAMIDE FOR INJECTION USP 1 GM / VIAL

1.1 Active ingredient (s) 2 and amount (s) per unit dose 3 : Composition:

Each Lyophilized Vial Contains:

Ifosfamide USP (Sterile)1 gm Excipientsq.s.

For complete qualitative composition including Excipients, see attached 4: Annexure - I

- 1.2 Is this product licensed to be placed on the market for use in the exporting country?⁵ Yes
- 1.3 Is this product actually on the market in the exporting country? Yes

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue section 2B 6

2 4

A.1 Number of product license⁷: DD/794 And date of issue: 18/09/2019

A.2 Product license holder:
Bruck Pharma Pvt. Ltd.
Survey No. 188/1 to 6, 189/1, 190/2 to 4,
Atiyawad, Dabhel, Daman - 396210

A.3 Status of product license holder 8: a

Manufacturing of Dosage forms

 A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are⁹
 : Not applicable

A.4 Is summary basis of Approval appended? 10

No

A.5 Is the attached, officially approved product information complete and consonant with the license?¹¹

Not provided

A.6 Applicant for certificate if different from license holder: ¹²: Not applicable.

2 B Not applicable.

B.1 Application for certificate: (Not applicable.)

(Name and address)

- B.2 Status of applicant (Not applicable.)
- B.2.1 For categories b and c the name and address of the Manufacturer producing the dosage form are 9: Not applicable

B. 3 Why is marketing authorization last : Not applicable

Required Requested Consideration

B.4 Remark: 13 -(Not applicable.)

age form is produced?

Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
 Yes If no or not applicable proceed to question 4

- 3.1 Periodicity of routine inspections (years): Yearly
- 3.2 Has the manufacture of this type of dosage form been inspected? Yes
- 3.3 Do the facilities and operations conform to GMP as recommended by $\mbox{ Yes }$ the World Health Organization $?^{15}$
- 4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? 16

Yes If no, explain

Address of certifying authority:

Drugs Licensing Authority, Administration of Daman & Diu, Drugs Control Department, Primary Health Centre, Daman – 396220. Telephone Number: (0260) 2230470 Fax Number: (0260) 2230570 Name of authorized person: Dr. V.K. DAS

DRUGS LICENSING AUTHORITY

Signature: अीवधी लाईसेंस प्राधिकारी

DRUGS CONTROL DEPARTMENT

औषधी नियंत्रण विभाग

Stamp and date: UT OF DAMAN & DIU, DAMAN মহ মুট্টা ব্যক্ত ব্যক্ত

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the scheme. The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheet 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, whenever possible, international Nonproprietary Names (INNs) or National Nonproprietary names.
- 3. The formula (Complete composition) of the dosage form 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-license 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 license.
- 6. Sections 2A and 2B are mutually exclusive.
- 7. Indicate, when applicable, if the license 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 labels 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-license 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 license. If the production site is changed, the license has to be updated or it is no longer valid.
- 10. This refers to the document, prepared by some national regulatory authori-ties that summarizes the technical basis on which the product has been licensed.
- 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-license 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 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.
- The requirements for good practice 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).
- This section is to completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 8 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.

The layout for Model Certificate is available on diskette in World Perfect from the Division of Drug Management and policies, World Health Organization, 1211 Geneva 27, Switzerland.

ANNEXURE - I

CERTIFICATE NO. DD/794/51C/2022-1-211-2

VALID UPTO- 04/03/2025

ACTIVE AND INACTIVE COMPOSITION – QUALITATIVE AND QUANTITATIVE

Name of Product :

IFOSFAMIDE FOR INJECTION USP 1GM / VIAL

Composition

Each Lyophilized Vial Contains:

Ifosfamide USP (Sterile).....1 gm Excipientsq.s.

Sr. No.	Ingredients	Specifications	Quantity Input (mg / vial)
1,	Ifosfamide*	USP	1005
2.	Mannitol	USP	502.5
3.	Sodium Hydroxide	USP	q.s.

*Actual quantity of active material will vary depending on Assay and

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.: 0091-0260-2230470 Fax No.

: 0091-0260-2230570

Name of Authorized Person: Dr. V.K. DAS

DRUGS LICENSING AUTHORITY

औवधी लाईसेंस प्राधिकारी

DRUGS CONTROL DEPARTMENT औषधी नियंत्रण विभाग Signature

L'T OF DAMAN & DIU, DAMAN

संघ प्रदेश दमण एव दीव, दमण

Stamp & Date

ANNEXURE-II

No. of Certificate

: DD/794/51C/2022-1-211-2

Valid up to: 04/03/2025

Name of the Product : IFOSFAMIDE FOR INJECTION USP 1GM / VIAL

List of countries / Institution to which the above product will be Exported / Locally supplied.

1. Afghanistan	44. Cuba	85. Iran	128. Morocco	171. South Korea
2. Albania	45. Cyprus	86. Iraq	129. Mozambique	172. Spain
3. Algeria	46. Czech Republic	87. Ireland	130. Myanmar	173. Sri Lanka
4. Angola	47. Czechoslovakia1	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic	89. Italy	132. Nepal	175. Suriname
6. Armenia	Republic of Congo	90. Ivory Coast	133. Netherlands Antilles	176. Swaziland
7. Aruba	49. Denmark	91. Jamaica	134. Netherlands	177, Sweden
8. Australia	50. Djibouti	92. Japan	135. New Zealand	178. Switzerland
9. Austria	51. Dominica	93. Jordan	136. Nicaragua	179. Syria
10. Azerbaijan	52. Dominican Republic	94. Kazakhstan	137. Niger	180. Tadzhikistan
11. Bahamas	53. Ecuador	95. Kenya	138. Nigeria	181. Taiwan
12. Bahrain	54. Egypt	96. Kingdom of Tonga	139. North Korea	182. Tajikistan
13. Baltic	55. El Salvador	97. Kiribati	140. Norway	183. Tanzania
14. Bangladesh	56. Equatorial Guinea	98. Korea	141. Oman	184. Thailand
15. Barbados	57. Eritrea	99. Korea Republic of	142. Pakistan	185. Tobago
16. Belarus	58. Estonia	100. Kosova	143. Palau	186. Togo
17. Belgium	59. Ethiopia	101. Kuwait	144. Panama	187. Tonga
18. Belize	60. European Community	102. Kyrgyzstan	145. Papua New Guinea	188. Trinidad
19. Benin	61. Fiji	103. Laos	146. Paraguay	189. Tunisia
20. Bhutan	62. Finland	104. Latvia		1190. Turkey
21. Bolivia	63. France	105. Lebanon	148. Puerto Rico .	1912 Turkmenistan
22. Bosnia	64. Gabon	106. Lesotho	149. Philippines \\1	192 VAE
23. Botswana	65. Gambia	107. Liberia	150 Polend	193. Uganda
24. Brazil	66. Guatemala	108. Libya	15 Portugal	194/Ukraine
25. Brunei	67. Georgia	109. Libyan Arab	152. Qatarc	195. Union of Soviet
26. Bulgaria	68. German Democratic	Jamahiriya	153. Republic of Benin	Socialist -Republics1
27. Burkina Faso	Republic ²	110. Liechtenstein	154 Republic de Hull Dan	196 United Frab
28. Burundi	69. Germany Federal Republic of ²	111. Liochtonstoin	155. Republic of ਸ਼ਸ਼ਹ	197. United Kingdom
29. Byelorussia		112. Lithuania	156. Romania / ///////	1798 United States
30. Cambodia	70. Germany	113. Luxembourg	157. Russia	199. Uruguay
31. Cameroon	71. Ghana	114. Macau	158. Rwanda	200. USA
32. Canada	72. Greece	115. Madagascar	159. Saudi Arabia	201. Uzbekistan
33.Central African	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
Republic	74. Guinea	117. Malaysia	161. Serbia and	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives	Montenegro	204. Vietnam
35. Chile	76. Guyana	119. Mali	162. Seychelles	205. West Indies
36. China	77. Haiti	120. Malta	163. Sierra Leone	206. World
37. Cook Islands	78. Holland	121. Marshall Islands	164. Singapore	207. Yemen
38. Colombia	79. Honduras	122. Mauritania	165. Slovakia	208. Yugoslavia ¹
39. Columbia	80. Hong Kong	123. Mauritius	166. Slovenia	209. Zaire
10. Congo	81. Hungary	124. Mexico	167. Solomon Islands	210. Zambia
11. Costa Rica	82. Iceland	125. Moldova	168. Somalia	211. Zimbabwe
12. Council of Europe	83. India	126. Monaco	169. Somaliland	

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.:

0091-0260-2230470

Fax No.

0091-0260-2230570

Name of Authorized Person: Dr. V.K. DAS

DRUGS LICENSING AUTHORITY

औषधी लाईसेंस प्राधिकारी

DRUGS CONTROL DEPARTMENT

औषधी नियंत्रण विभाग UT OF DAMAN & DIU, DAMAN

Stamp & Date

Signature

सध प्रदेश दमण एव दीव, दमण

Administration of Daman & Diu. Drugs Licensing Authority, **Drugs Control Department,** Primary Health Centre, Daman - 396220.

Certificate of a Pharmaceutical Product¹

This certificate conforms to the format recommended by the World Health Organization (General instructions and explanatory notes attached)

No. of Certificate

: DD/794/75C/2022-1-211-2

: INDIA

Valid up to: 04/03/2025

Exporting (Certifying) Country Importing (Requesting) Country

: As per Annexure-II

Name and dosage form of product

: MESNA INJECTION 400 MG/4ML

1.1 Active ingredient (s)² and amount (s) per unit dose³: Composition:

Each ml contains:

Mesna USP.....100 mg

Water for Injections USP...... q.s.

For complete qualitative composition including Excipients, see attached 4: Annexure - I

- Is this product licensed to be placed on the market for use in the exporting country?⁵ Yes
- Is this product actually on the market in the exporting country? Yes

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue section 2B 6.

- A.1 Number of product license⁷: DD/794 And date of issue : 09/10/2019
- A.2 Product license holder: Bruck Pharma Pvt. Ltd. Survey No. 188/1 to 6, 189/1, 190/2 to 4, Atiyawad, Dabhel, Daman - 396210
- A.3 Status of product license holder 8: a

Manufacturing of Dosage forms

- A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are 9 : Not applicable
- A.4 Is summary basis of Approval appended? 10

No

- A.5 Is the attached, officially approved product information complete and consonant with the license?¹¹
 - Not provided
- A.6 Applicant for certificate if different from license holder: 12 : Not applicable.

- 2 B Not applicable.
- B.1 Application for certificate: (Not applicable.)

(Name and address)

- B.2 Status of applicant (Not applicable.)
- B.2.1 For categories b and c the name and address of the Manufacturer producing

: Not applicable

B. 3 Why is marketing : Not applicab

Required Request

B.4 Remark: 13 -(No

- Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes If no or not applicable proceed to question 4.
- 3.1 Periodicity of routine inspections (years): Yearly
- 3.2 Has the manufacture of this type of dosage form been inspected?
- $3.3\,$ Do the facilities and operations conform to GMP as recommended by $\,$ Yes the World Health Organization ? 15
- Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? 16

Yes If no, explain

Address of certifying authority:

Drugs Licensing Authority, Administration of Daman & Diu, Drugs Control Department, Primary Health Centre, Daman - 396220. Telephone Number: (0260) 2230470 Fax Number: (0260) 2230570

Name of authorized person: Dr. V.K. DAS UTHORITY

Signature:

DRUGS CONTROL DEPARTMENT

Stamp and date:

UT OF DAMAN & DIU, DAMAN

2 0 JUN 2022

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the scheme. The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheet 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, whenever possible, international Nonproprietary Names (INNs) or National Nonproprietary names.
- 3. The formula (Complete composition) of the dosage form 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-license 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 license.
- 6. Sections 2A and 2B are mutually exclusive.
- 7. Indicate, when applicable, if the license 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 labels a dosage form manufactured by an independent company; or
 - (c) is involved in none of the above.
- This information can be provided only with the consent of the product-license 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 license. If the production site is changed, the license has to be updated or it is no longer valid.
- This refers to the document, prepared by some national regulatory authori-ties 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-license 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.

WAS AND DESIGNATION OF REAL PROPERTY.

- 14. Not applicable means that 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.
- The requirements for good practice 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).
- This section is to completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 8 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.

The layout for Model Certificate is available on diskette in World Perfect from the Division of Drug Management and policies, World Health Organization, 1211 Geneva 27, Switzerland.

ANNEXURE - I

CERTIFICATE NO.: DD/794/75C/2022-1-211-2

VALID UPTO 04/03/2025

ACTIVE AND INACTIVE COMPOSITION – QUALITATIVE AND QUANTITATIVE

Name of Product

MESNA INJECTION 400MG/4ML

Composition

: Each ml contains:

Mesna USP......100 mg Water for Injection USP......q.s.

Sr. No.	Ingredients	Specifications	Quantity Input (mg/ml)
1.	Mesna	USP	100
2.	Disodium EDTA	USP	q.s
3.	Benzyl Alcohol	USP	q.s
4.	Sodium Hydroxide	USPAG AL	q.s.

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.: 0091-0260-2230470 Fax No.: 0091-0260-2230570

Name of Authorized Person

Person: Dr. V.K. DAS DRUGS LICENSING AUTHORIT

ओवची लाहिन प्राचिकारी DRUGS CONTROL DEPARTMENT ओवची निवंत्रण विजल

Signature sheet flair fl

तम प्रदेश दसन एव बीच, उपन

Stamp & Date

2 0 JUN 2022

ANNEXURE-II

No. of Certificate

: DD/794/75C/2022-1-211-2

Valid up to: 04/03/2025

Name of the Product : MESNA INJECTION 400MG/4ML

List of countries / Institution to which the above product will be Exported / Locally supplied.

1. Afghanistan	44. Cuba	85. Iran	128. Morocco	171. South Korea
2. Albania	45. Cyprus	86. Iraq	129. Mozambique	172. Spain
3. Algeria	46. Czech Republic	87. Ireland	130. Myanmar	173. Sri Lanka
4. Angola	47. Czechoslovakia1	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic	89. Italy	132. Nepal	175. Suriname
6. Armenia	Republic of Congo	90. Ivory Coast	133. Netherlands Antilles	176. Swaziland
7. Aruba	49. Denmark	91. Jamaica	134. Netherlands	177. Sweden
8. Australia	50. Diibouti	92. Japan	135. New Zealand	178. Switzerland
9. Austria	51. Dominica	93. Jordan	136. Nicaragua	179. Syria
10. Azerbaijan	52. Dominican Republic	94. Kazakhstan	137. Niger	180. Tadzhikistan
11. Bahamas	53. Ecuador	95. Kenya	138. Nigeria	181. Taiwan
12. Bahrain	54. Egypt	96. Kingdom of Tonga	139. North Korea	182. Tajikistan
13. Baltic	55. El Salvador	97. Kiribati	140. Norway	183. Tanzania
14. Bangladesh	56. Equatorial Guinea	98. Korea	141. Oman	184. Thailand
15. Barbados	57. Eritrea	99. Korea Republic of	142. Pakistan	185. Tobago
16. Belarus	58. Estonia	100. Kosova	143. Palau	186. Togo
17. Belgium	59. Ethiopia	101. Kuwait	144. Panama	187. Tonga
18. Belize	60. European Community	102. Kyrgyzstan	145. Papua New Guinea	188. Trinidad
19. Benin	61. Fiji	103. Laos	146. Paraguay	189. Tunisia
20. Bhutan	62. Finland	104. Latvia	147. Peru	190. Turkey
21. Bolivia	63. France	105. Lebanon	148. Puerto Rico	401 Turkmenistan
22. Bosnia	64. Gabon	106. Lesotho	149. Philippines	192 UNE
23. Botswana	65. Gambia	107. Liberia	150. Poland	193/ Mganda
24. Brazil	66. Guatemala	108. Libya	149. Philippines 150. Poland 151. Porty gal	194: Uktarne
25. Brunei	67. Georgia	109. Libyan Arab	152. Qater 5	195 Union of Soviet
26. Bulgaria	68. German Democratic	Jamahiriya	150. Poland 151. Portugal 152. Qatir 153. Republic of Benin	Socialist Republice
27. Burkina Faso	Republic ²	110. Liechtenstein	Guines	Emirates
28. Burundi	69. Germany Federal Republic of ²	111. Liochtonstoin		197 United Kingdom
29. Byelorussia	Republic of	112. Lithuania	156. Romania 157. Russia 158. Rwanda 159. Saudi Arabi	198. United States
30. Cambodia	70. Germany	113. Luxembourg	157. Russia 🥠 📆 🤿	199. Urugua
31. Cameroon	71. Ghana	114. Macau	158. Rwanda * Or p	200 USA
32. Canada	72. Greece	115. Madagascar	159. Saudi Arabia	201. U bekistan
33.Central African	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
Republic	74. Guinea	117. Malaysia	161. Serbia and	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives	Montenegro	204. Vietnam
35. Chile	76. Guyana	119. Mali	162. Seychelles	205. West Indies
36. China	77. Haiti	120. Malta	163. Sierra Leone	206. World
37. Cook Islands	78. Holland	121. Marshall Islands	164. Singapore	207. Yemen
38. Colombia	79. Honduras	122. Mauritania	165. Slovakia	208. Yugoslavia ¹
39. Columbia	80. Hong Kong	123. Mauritius	166. Slovenia	209. Zaire
40. Congo	81. Hungary	124. Mexico	167. Solomon Islands	210. Zambia
41. Costa Rica	82. Iceland	125. Moldova	168. Somalia	211. Zimbabwe
42. Council of Europe	83. India	126. Monaco	169. Somaliland	
43. Croatia	84. Indonesia	127. Mongolia	170. South Africa	1

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.:

0091-0260-2230470

Fax No.

0091-0260-2230570

Name of Authorized Person: DELY KINDASTHORITY Signature

औषवी लाईसँस प्राधिकारी DRUGS CONTROL DEPARTMENT औषधी निवंत्रम विमान

Stamp & Date

UT OF DAMAN & DIU, DAMAN तथ प्रवेश वयण एव दीव, दमन

2 0 JUN 2022

Administration of Daman & Diu, Drugs Licensing Authority, **Drugs Control Department,** Primary Health Centre, Daman - 396220.

Certificate of a Pharmaceutical Product¹

This certificate conforms to the format recommended by the World Health Organization (General instructions and explanatory notes attached)

No. of Certificate

: DD/793/21A/2022-1-211-2

Valid up to: 04/03/2025

Exporting (Certifying) Country

: INDIA

Importing (Requesting) Country

: As per Annexure-II :Sorafenib Tablets BP 200mg

1. Name and dosage form of product

1.1 Active ingredient (s)² and amount (s) per unit dose³: Composition:

Each film coated tablet contains:

Sorafenib Tosilate BP

Equivalent to Sorafenib 200 mg Excipients Color: Titanium Dioxide & Ferric Oxide Red.

For complete qualitative composition including Excipients, see attached 4: Annexure - I

- Is this product licensed to be placed on the market for use in the exporting country?⁵ Yes
- Is this product actually on the market in the exporting country? Yes

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue section 2B 6.

A.1 Number of product license⁷: DD/793 And date of issue : 21/03/2020

A.2 Product license holder: Bruck Pharma Pvt. Ltd. Survey No. 188/1 to 6, 189/1, 190/2 to 4, Atiyawad, Dabhel, Daman - 396210

A.3 Status of product license holder 8: a

Manufacturing of Dosage forms

A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are 9 : Not applicable

A.4 Is summary basis of Approval appended?¹⁰

A.5 Is the attached, officially approved product information complete and consonant with the license?¹¹

Not provided

A.6 Applicant for certificate if different from license holder: 12 : Not applicable.

Not applicable.

B.1 Application for certificate: (Not applicable.)

(Name and address)

- B.2 Status of applicant (Not applicable.)
- B.2.1 For categories b and c the name and address of the Manufacturer producing the dosage form are 9. Not applicable

B. 3 Why is marketing author : Not applicable

Required

B.4 Remark: 13 -(N applicable.)

Requeste

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the Yes If no or not applicable proceed to question 4

- 3.1 Periodicity of routine inspections (years): Yearly
- 3.2 Has the manufacture of this type of dosage form been inspected?
- 3.3 Do the facilities and operations conform to GMP as recommended by Yes the World Health Organization ?¹⁵
- 4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? 16

Yes If no, explain

Address of certifying authority:

Drugs Licensing Authority, Administration of Daman & Diu, **Drugs Control Department,** Primary Health Centre, Daman - 396220. Telephone Number: (0260) 2230470 Fax Number: (0260) 2230570

Name of authorized person: Dr. V.K. DAS

DRUGS LICENSING AUTHORITY

Signature:

Stamp and date:

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the scheme. The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten

Additional sheet 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.
- Use, whenever possible, international Nonproprietary Names (INNs) or National Nonproprietary names.
- 3. The formula (Complete composition) of the dosage form should be given on the certificate or be appended.
- Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license 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 license.
- Sections 2A and 2B are mutually exclusive.
- Indicate, when applicable, if the license is provisional, or the product has not yet been approved.
- Specify whether the person responsible for placing the product on the market.
 - (a) manufactures the dosage form:
 - (b) Packages and/or labels a dosage form manufactured by an independent company; or
 - (c) is involved in none of the above.
- This information can be provided only with the consent of the product-license 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 license. If the production site is changed, the license has to be updated or it is no longer 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-license holder. This permission must be provided to the authority by the applicant.
- 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.

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- 14. Not applicable means that 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.
- The requirements for good practice 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).

 This section is to completed when the product-license holder or applicant conforms to status (b) or (c) as
- This section is to completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 8 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.

The layout for Model Certificate is available on diskette in World Perfect from the Division of Drug Management and policies, World Health Organization, 1211 Geneva 27, Switzerland.

ANNEXURE - I

CERTIFICATE NO. DD/793/21A/2022-1-211-2

VALID UPTO 04/03/2025

ACTIVE AND INACTIVE COMPOSITION - QUALITATIVE AND QUANTITATIVE

Name of Product :

Sorafenib Tablets BP 200mg

Composition

Each film coated tablet contains:

Sorafenib Tosilate BP

Equivalent to Sorafenib 200mg Excipientsq.s. Color: Titanium Dioxide & Ferric Oxide Red.

Sr. No.	. Ingredients		Specifications	Quantity Input Mg/Tablet	
1.	Sorafenib Tosilate		BP	274.00	
2.	Microcrystalline cellulose		BP	110.00	
3.	Croscarmellose sodium		BP	15.00	
4,	Sodium Lauryl Sulfate		BP	14.00	
5.	Hypromellose	- Au-	BP	13.72	
6.	Croscarmellose sodium	SIND AUTH	BP	17.28	
7.	Microcrystalline cellulose	क्षाम प्राहित	BP	35.00	
8.	Magnesium stearate	13 % THE	BP	11.00	
9.	Opadry Brown	INE CONTRACTOR	• IH	14.70	
10.	Isopropyl alcohol	म्बराकः । जन	BP BP	117.60	
11.	Dichloromethane	TOTAL SOURCE	BP	176.40	

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.: 0091-0260-2230470 Fax No. : 0091-0260-2230570

Name of Authorized Person: Dr. V.K. DAS

DRUGS LICENSING AUTHORITY

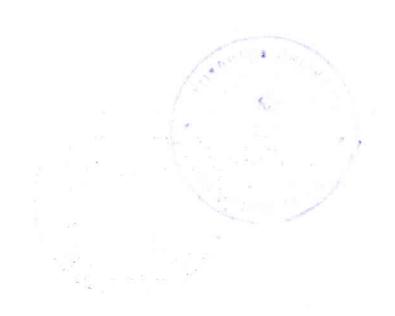
Signature

अंवर्ग सार्वित प्राविकारी DRUGS CONTROL DEPARTMENT

UT OF DAMAN & DIU, DAMAN

तथ प्रदेश काम एवं बीम, काम

Stamp & Date



ANNEXURE-II

No. of Certificate

: DD/793/21A/2022-1-211-2

Valid up to: 04/03/2025

Name of the Product : Sorafenib Tablets BP 200mg

List of countries / Institution to which the above product will be Exported / Locally supplied.

1. Afghanistan	44. Cuba	85. Iran	128. Morocco	171. South Korea
2. Albania	45. Cyprus	86. Iraq	129. Mozambique	172. Spain
3. Algeria	46. Czech Republic	87. Ireland	130. Myanmar	173. Sri Lanka
4. Angola	47. Czechoslovakia1	88. Israel	131. Namibia	174, Sudan
5. Argentina	40 Damasastia	89. Italy	132. Nepal	175. Suriname
6. Armenia	48. Democratic Republic of Congo	90. Ivory Coast	133. Netherlands Antilles	176. Swaziland
7. Aruba	49. Denmark	91. Jamaica	134. Netherlands	177. Sweden
8. Australia	50. Djibouti	92. Japan	135. New Zealand	178. Switzerland
9. Austria	51. Dominica	93. Jordan	136. Nicaragua	179. Syria
10. Azerbaijan	52. Dominican Republic	94. Kazakhstan	137. Niger	180. Tadzhikistan
11. Bahamas	53. Ecuador	95. Kenya	138. Nigeria	181. Taiwan
12. Bahrain	54. Egypt	96. Kingdom of Tonga	139. North Korea	182. Tajikistan
13. Baltic	55. El Salvador	97. Kiribati	140. Norway	183. Tanzania
14. Bangladesh	56. Equatorial Guinea	98. Korea	141. Oman	184. Thailand
15. Barbados	57. Eritrea	99. Korea Republic of	142. Pakistan	185. Tobago
16. Belarus	58. Estonia	100. Kosova	143. Palau	186. Togo
17. Belgium	59. Ethiopia	101. Kuwait	144. Panama	187. Tonga
11111	60. European	101. Kuwait	144. Panama	167. Toriga
18. Belize	Community	102. Kyrgyzstan	145. Papua New Guinea	188. Trinidad
19. Benin	61. Fiji	103. Laos	146. Paraguay	189. Tunisia
20. Bhutan	62. Finland	104. Latvia	147. Peru	190. Turkey
21. Bolivia	63. France	105. Lebanon	148. Puerto Rico	191. Turkmenistan
22. Bosnia	64. Gabon	106. Lesotho	149. Philippines	192. UAE
23. Botswana	65. Gambia	107. Liberia	150. Poland	193. Uganda
24. Brazil	66. Guatemala	108. Libya	151. Portugal	194. Ukraine
25. Brunei	67. Georgia	109. Libyan Arab	152. Qatar	195. Union of Soviet
26. Bulgaria	68. German Democratic	Jamahiriya	153. Republic of Benin	Socialist Republics ¹
27. Burkina Faso	Republic ²	110. Liechtenstein	154. Republic de Guinee	196.United Arab
28. Burundi	69. Germany Federal	111. Liochtonstoin	Guinee 155. Cepublic of Maldives	197 United Kingdom
29. Byelorussia	Republic of ²	112. Lithuania	156. Romania	188. United States
30. Cambodia	70. Germany	113. Luxembourg	1.7. Rusela	199 Uruguy
31. Cameroon	71. Ghana	114. Macau	158. Rwanda	200. USA
32. Canada	72. Greece	115. Madagascar	1596Saudi Arabia	201. Uzbek stan
33.Central African	73. Grenada	116. Malawi	160. Senegal	202. Vanuaru
Republic	74. Guinea	117. Malaysia	161. Serbid and m/Dama	203 Venet tela
34. Chad	75. Guinea Equatorial	118. Maldives	Montenegro	20% Mietram
35. Chile	76. Guyana	119. Mali	162. Se chelles	204 Viet am 205 Vest Indies
36. China	77. Haiti	120. Malta	163 Serra Mone	106 World
37. Cook Islands	78. Holland	121. Marshall Islands	163. Sierra Leone 164. Singapore DAMA	201. Yemen
38. Colombia	79. Honduras	121. Marshall Islands	165. Slovakia	208. Yugoslavia ¹
39. Columbia	80. Hong Kong	123. Mauritius	166. Slovenia	209. Zaire
40. Congo	81. Hungary	123. Mauritius 124. Mexico		
11. Congo			167. Solomon Islands	210. Zambia
	82. Iceland	125. Moldova	168. Somalia	211. Zimbabwe
42. Council of Europe	83. India	126. Monaco	169. Somaliland	
43. Croatia	84. Indonesia	127. Mongolia	170. South Africa	

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.: 0091-0260-2230470

Fax No.

0091-0260-2230570

Name of Authorized Person: Dr. V.K. DAS

BRUGG LICENSING AUTHORITY

अवेषणी राज्यीत प्राणिकारी DRUGS CONTROL DEPARTMENT

Signature

जीवची नियंत्रन विमान UT OF BAMAN & DIU, DAMAN

Stamp & Date

2 3 MAY 2022

राम प्रवेश काम का क्रीय, काम



Administration of Daman & Diu, Drugs Licensing Authority, **Drugs Control Department,** Primary Health Centre, Daman - 396220.

Certificate of a Pharmaceutical Product¹

This certificate conforms to the format recommended by the World Health Organization (General instructions and explanatory notes attached)

No. of Certificate

: DD/793/15B/2022-1-211-2

Valid up to: 04/03/2025

: INDIA

Exporting (Certifying) Country

: As per Annexure-II

Importing (Requesting) Country 1. Name and dosage form of product

: Temozolomide Capsules USP 20 mg

1.1 Active ingredient (s)² and amount (s) per unit dose³: Composition:

Each Hard Gelatin Capsule contains:

Temozolomide USP20 mg

Approved colors used in capsule shell.

For complete qualitative composition including Excipients, see attached 4: Annexure - I

- Is this product licensed to be placed on the market for use in the exporting country?⁵ Yes
- Is this product actually on the market in the exporting country? Yes

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue section 2B 6.

A.1 Number of product license⁷: DD/793 And date of issue : 05/08/2019

A.2 Product license holder: Bruck Pharma Pvt. Ltd. Survey No. 188/1 to 6, 189/1, 190/2 to 4, Atiyawad, Dabhel, Daman - 396210

A.3 Status of product license holder 8: a

Manufacturing of Dosage forms

A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are : Not applicable

A.4 Is summary basis of Approval appended? 10

A.5 Is the attached, officially approved product information complete and consonant with the license?¹¹

Not provided

A.6 Applicant for certificate if different from license

holder: 12 : Not applicable.

2 B

Not applicable.

B.1 Application for certificate: (Not applicable.)

(Name and address)

- B.2 Status of applicant (Not applicable.)
- B.2.1 For categories b and c the name and address of the Manufacturer producing the dosage form are 9 Not applicable
- B. 3 Why is marketing authorization lacking?

: Not applicable

Required Requested Consider

B.4 Remark: 13 -(Not applicable.)

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage Yes If no or not applicable proceed to question 4.

- 3.1 Periodicity of routine inspections (years): Yearly
- 3.2 Has the manufacture of this type of dosage form been inspected?
- 3.3 Do the facilities and operations conform to GMP as recommended by Yes the World Health Organization ?¹⁵
- Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? 16

Yes If no, explain

Address of certifying authority:

Drugs Licensing Authority, Administration of Daman & Diu. **Drugs Control Department,** Primary Health Centre, Daman - 396220.

Telephone Number: (0260) 2230470 Fax Number: (0260) 2230570

Name of authorized person: Dr. V.K. DAS

DRUGS LICENSING AUTHORITY

Signature:

Stamp and date:

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the scheme. The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheet 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, whenever possible, international Nonproprietary Names (INNs) or National Nonproprietary names.
- 3. The formula (Complete composition) of the dosage form should be given on the certificate or be appended.
- Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license 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 license.
- 6. Sections 2A and 2B are mutually exclusive.
- Indicate, when applicable, if the license 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 labels 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-license 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 license. If the production site is changed, the license has to be updated or it is no longer valid.
- 10. This refers to the document, prepared by some national regulatory authori-ties 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-license 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 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.
- The requirements for good practice 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 completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 8 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.

The layout for Model Certificate is available on diskette in World Perfect from the Division of Drug Management and policies, World Health Organization, 1211 Geneva 27, Switzerland.

ANNEXURE - I

CERTIFICATE NO. DD/793/15B/2022-1-211-2

VALID UPTO- 04/03/2025

ACTIVE AND INACTIVE COMPOSITION – QUALITATIVE AND QUANTITATIVE

Name of Product

Temozolomide Capsules USP 20 mg

Composition

Each Hard Gelatin Capsule Contains:

Temozolomide USP20 mg Excipients......q.s.

Approved colors used in capsule shell.

Sr. No.	Ingredients	Specifications	Quantity Input Mg/Capsule	
1.	Temozolomide	USP	20.000	
2.	Anhydrous lactose	USP	218.20	
3.	Sodium starch glycollate	USP	12.000	
4.	L (+) Tartaric acid	USP	3.600	
5.	Hydrophobic Colloidal silicon dioxide	USP	0.200	
6.	Stearic acid	SING WIND USP	6.000	
7.	Empty hard gelatin capsule (size 2)	All Miles WH	q.s.	

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.: 0091-0260-2230470

Fax No.

: 0091-0260-2230570

Name of Authorized Person: Dr. V.K. DAS

DRUGS LICENSING AUTHORITY

जीवर्ष साहित प्रात्मिकी DRUGS CONTROL DEPARTMENT

Signature जीवधी नियंत्रय विमान

UT OF DAMAN & DIU, DAMAN

तब प्रवेश काम एवं बीम, काम

Stamp & Date



ANNEXURE-II

No. of Certificate

: DD/793/15B/2022-1-211-2

Valid up to: 04/03/2025

Name of the Product : Temozolomide Capsules USP 20 mg

List of countries / Institution to which the above product will be Exported / Locally supplied.

1. Afghanistan	44. Cuba	85. Iran	128. Morocco	171. South Korea
2. Albania	45. Cyprus	86. Iraq	129. Mozambique	172. Spain
3. Algeria	46. Czech Republic	87. Ireland	130. Myanmar	173. Sri Lanka
4. Angola	47. Czechoslovakia¹	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic	89. Italy	132. Nepal	175. Suriname
6. Armenia	Republic of Congo	90. Ivory Coast	133. Netherlands Antilles	176. Swaziland
7. Aruba	49. Denmark	91. Jamaica	134. Netherlands	177. Sweden
8. Australia	50. Djibouti	92. Japan	135. New Zealand	178. Switzerland
9. Austria	51. Dominica	93. Jordan	136. Nicaragua	179. Syria
10. Azerbaijan	52. Dominican Republic	94. Kazakhstan	137. Niger	180. Tadzhikistan
11. Bahamas	53. Ecuador	95. Kenya	138. Nigeria	181. Taiwan
12. Bahrain	54. Egypt	96. Kingdom of Tonga	139. North Korea	182. Tajikistan
13. Baltic	55. El Salvador	97. Kiribati	140. Norway	183. Tanzania
14. Bangladesh	56. Equatorial Guinea	98. Korea	141. Oman	184. Thailand
15. Barbados	57. Eritrea	99. Korea Republic of	142. Pakistan	185. Tobago
16. Belarus	58. Estonia	100. Kosova	143. Palau	186. Togo
17. Belgium	59. Ethiopia	101. Kuwait	144. Panama	187. Tonga
18. Belize	60. European Community	102. Kyrgyzstan	145. Papua New Guinea	188. Trinidad
19. Benin	61. Fiji	103. Laos	146. Paraguay	189. Tunisia
20. Bhutan	62. Finland	104. Latvia	147. Peru	190. Turkey
21. Bolivia	63. France	105. Lebanon	148. Puerto Rico	191. Turkmenistan
22. Bosnia	64. Gabon	106. Lesotho	149. Philippines	192. UAE
23. Botswana	65. Gambia	107. Liberia	150. Poland	193. Uganda
24. Brazil	66. Guatemala	108. Libya	151. Portugal	194. Ukraine
25. Brunei	67. Georgia	109. Libyan Arab	152. Qatar	195. Union of Soviet
26. Bulgaria	68. German Democratic	Jamahiriya	153. Republic of Benin	Socialist Republics ¹
27. Burkina Faso	Republic ²	110. Liechtenstein	154. Republic de Guinee	196 United Arab Emirates
28. Burundi	69. Germany Federal Republic of ²	111. Liochtonstoin	155. Republic of Maldives	Emirates 197. United Mingulom 198. United States
29. Byelorussia		112. Lithuania	156. Romania	198 United States
30. Cambodia	70. Germany	113. Luxembourg	156. Romania 157. Russia 158. Rwanda	199 Atruguay
31. Cameroon	71. Ghana	114. Macau	158. Rwanda 🕟	200 USA
32. Canada	72. Greece	115. Madagascar	159. Saudi Arabia	200 Luzbekistan
33.Central African	73. Grenada	116. Malawi	160. Senegal	29% Vanuatu
Republic	74. Guinea	117. Malaysia	161. Serbia and	1-293. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives	Monten egro 🐧 🕏	T200 Mesham
35. Chile	76. Guyana	119. Mali	161. Serbia and Montenegro 77	205. West Indies
36. China	77. Haiti	120. Malta	103. Siella Leone	205 World
37. Cook Islands	78. Holland	121. Marshall Islands	164. Singapore	207 Yeman
38. Colombia	79. Honduras	122. Mauritania	165. Slovakia	208. Yugoslavia¹
39. Columbia	80. Hong Kong	123. Mauritius	166. Slovenia	209. Zaire
40. Congo	81. Hungary	124. Mexico	167. Solomon Islands	210. Zambia
41. Costa Rica	82. Iceland	125. Moldova	168. Somalia	211. Zimbabwe
42. Council of Europe	83. India	126. Monaco	169. Somaliland	
43. Croatia	84. Indonesia	127. Mongolia	170. South Africa	

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.:

0091-0260-2230470

Fax No. : 0091-0260-2230570

Name of Authorized Person: Dr. V.K. DAS

DRUGS LICENSING AUTHORITY

व्यक्ति स्वर्धित प्रक्रियती DRUGS CONTROL DEPARTMENT

जीवयी नियंत्रय विमान

UT OF DAMAN & DIU, DAMAN तम प्रवेश समय एवं रीम, समय

2 3 MAY 2022

Signature

Stamp & Date



Administration of Daman & Diu, Drugs Licensing Authority, **Drugs Control Department,** Primary Health Centre, Daman - 396220.

Certificate of a Pharmaceutical Product¹

This certificate conforms to the format recommended by the World Health Organization

(General instructions and explanatory notes attached)

No. of Certificate

: DD/793/19B/2022-1-211-2

Valid up to: 04/03/2025

Exporting (Certifying) Country

: INDIA

Importing (Requesting) Country

: As per Annexure-II

1. Name and dosage form of product

: Thalidomide Capsules USP 100 mg

1.1 Active ingredient (s)² and amount (s) per unit dose³: Composition:

Each hard gelatin capsule contains:

Thalidomide USP100 mg

Approved colors used in capsule shell.

For complete qualitative composition including Excipients, see attached ⁴: Annexure - I

- Is this product licensed to be placed on the market for use in the exporting country?⁵ Yes 1.2
- Is this product actually on the market in the exporting country? Yes

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue section 2B 6.

2 A

A.1 Number of product license⁷: DD/793 And date of issue : 14/10/2019

A.2 Product license holder:

Bruck Pharma Pvt. Ltd.

Survey No. 188/1 to 6, 189/1, 190/2 to 4, Atiyawad, Dabhel, Daman - 396210

A.3 Status of product license holder 8: a

Manufacturing of Dosage forms

A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are 9

: Not applicable

A.4 Is summary basis of Approval appended? 10

A.5 Is the attached, officially approved product information complete and consonant with the license?¹¹

A.6 Applicant for certificate if different from license

holder: 12 : Not applicable.

2 B

Not applicable.

B.1 Application for certificate: (Not applicable.)

(Name and address)

B.2 Status of applicant (Not applicable.)

B.2.1 For categories b and c the name and address of the

Manufacturer producing the dosage for

: Not applicable

B. 3 Why is marketing aut

: Not applicable

onsideration गलामच जयत Required Requested

B.4 Remark: 13 -(Not app

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes If no or not applicable proceed to question 4

3.1 Periodicity of routine inspections (years): Yearly

3.2 Has the manufacture of this type of dosage form been inspected?

3.3 Do the facilities and operations conform to GMP as recommended by Yes the World Health Organization ?¹⁵

Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? 16

Yes If no, explain

Address of certifying authority:

Drugs Licensing Authority, Administration of Daman & Diu, **Drugs Control Department,** Primary Health Centre, Daman - 396220. Telephone Number: (0260) 2230470 Fax Number: (0260) 2230570

Name of authorized person: Dr. V.K. DAS
DRUGS LICENSING AUTHORITY

Signature:

औषधी लाईलेंस प्राधिकारी DRUGS CONTROL DEPARTMENT

औषधी नियंत्रण विभाग

UT OF DAMAN & DIU, DAMAN Stamp and date:

संघ प्रदेश दमण एवं दीव, दमण

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the scheme. The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheet 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, whenever possible, international Nonproprietary Names (INNs) or National Nonproprietary names.
- 3. The formula (Complete composition) of the dosage form 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-license 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 license.
- Sections 2A and 2B are mutually exclusive.
- Indicate, when applicable, if the license is provisional, or the product has not yet been approved.
- Specify whether the person responsible for placing the product on the market.
 - (a) manufactures the dosage form:
 - (b) Packages and/or labels a dosage form manufactured by an independent company; or
 - (c) is involved in none of the above.
- This information can be provided only with the consent of the product-license 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 license. If the production site is changed, the license has to be updated or it is no longer valid.
- 10. This refers to the document, prepared by some national regulatory authori-ties 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).
- In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission must be provided to the authority by the applicant.
- 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 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.
- The requirements for good practice 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).
- This section is to completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 8 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.

The layout for Model Certificate is available on diskette in World Perfect from the Division of Drug Management and policies, World Health Organization, 1211 Geneva 27, Switzerland.

ANNEXURE - I

CERTIFICATE NO.: DD/793/19B/2022-1-211-2

VALID UPTO 04/03/2025

ACTIVE AND INACTIVE COMPOSITION – QUALITATIVE AND QUANTITATIVE

Name of Product

Thalidomide Capsules USP 100 mg

Composition

Each hard gelatin capsule contains:

Thalidomide USP100mg Excipients......q.s.

Approved colors used in capsule shell.

Sr. No.	Ingredients	Specifications	Quantity Input Mg/Capsule
1.	Thalidomide	USP	100.00
2.	Maize starch	USP	342.00
3.	Cross povidone	USP	12.00
4.	Colloidal silicon dioxide	USP	2.00
5.	Magnesium stearate	AUTHOUSP	4.0
6.	Empty hard gelatin capsule (size 0)	ATTE TO THE	q.s.

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.: 0091-0260-2230470 Fax No.

: 0091-0260-2230570

Name of Authorized Person: Dr. V.K. DAS
DRUGS LICENSING AUTHORITY

औषधी लाईसेंस प्राधिकारी DRUGS CONTROL DEPARTMENT औषधी नियंत्रण विभाग

UT OF DAMAN & DIU, DAMAN सध प्रदेश दमण एव दीव, दमण

Stamp & Date

Signature

ANNEXURE-II

No. of Certificate

: DD/793/19B/2022-1-211-2

Valid up to: 04/03/2025

Name of the Product : Thalidomide Capsules USP 100 mg

List of countries / Institution to which the above product will be Exported / Locally supplied.

1. Afghanistan	44. Cuba	85. Iran	128. Morocco	171. South Korea
2. Albania	45. Cyprus	86. Iraq	129. Mozambique	172. Spain
3. Algeria	46. Czech Republic	87. Ireland	130. Myanmar	173. Sri Lanka
4. Angola	47. Czechoslovakia¹	88. Israel	131. Namibia	174. Sudan
5. Argentina		89. Italy	132. Nepal	175. Suriname
6. Armenia	48. Democratic Republic of Congo	90. Ivory Coast	133. Netherlands Antilles	176. Swaziland
7. Aruba	49. Denmark	91. Jamaica	134. Netherlands	177. Sweden
8. Australia	50. Diibouti	92. Japan	135. New Zealand	178. Switzerland
9. Austria	51. Dominica	93. Jordan	136. Nicaragua	179. Syria
10. Azerbaijan	52. Dominican Republic	94. Kazakhstan	137. Niger	180. Tadzhikistan
11. Bahamas	53. Ecuador	95. Kenya	138. Nigeria	181. Taiwan
12. Bahrain	54. Egypt	96. Kingdom of Tonga	139. North Korea	182. Tajikistan
13. Baltic	55. El Salvador	97. Kiribati	140. Norway	183. Tanzania
14. Bangladesh	56. Equatorial Guinea	98, Korea	141. Oman	184. Thailand
15. Barbados	57. Eritrea	99. Korea Republic of	142. Pakistan	185. Tobago
16. Belarus	58. Estonia	100. Kosova	143. Palau	186. Togo
17. Belgium	59. Ethiopia	101. Kuwait	144. Panama	187. Tonga
18. Belize	60. European Community	102. Kyrgyzstan	145. Papua New Guinea	188. Trinidad
19. Benin	61. Fiji	103. Laos	146. Paraguay	189. Tunisia
20. Bhutan	62. Finland	104. Latvia	147. Peru	190 Turkey
21. Bolivia	63. France	105. Lebanon	148. Puerto Rico M G	191/Turkmenistan
22. Bosnia	64. Gabon	106. Lesotho	148. Puerto Rico NG 149. Philippines	192. UAE
23. Botswana	65. Gambia	107. Liberia	150. Poland	193. Uganda
24. Brazil	66. Guatemala	108. Libya	151. Portugal	M94. Ukraine
25. Brunei	67. Georgia	109. Libyan Arab	152. Qatar 🚫	6.7 (12)
26. Bulgaria	68. German Democratic	Jamahiriya	153. Republic of Benin *	Socialist Republics ¹
27. Burkina Faso	Republic ²	110. Liechtenstein	154. Republic de Guinee ्रे.	Emirates
28. Burundi	69. Germany Federal Republic of ²	111. Liochtonstoin	155. Republic of Maldives	197. United Kingdom
29. Byelorussia	Republic of	112. Lithuania		198. United States
30. Cambodia	70. Germany	113. Luxembourg	157. Russia	199 Uruguay
31. Cameroon	71. Ghana	114. Macau	158. Rwanda	200 USA
32. Canada	72. Greece	115. Madagascar	159. Saudi Arabia	201. Uzbekistan
33.Central African	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
Republic	74. Guinea	117. Malaysia	161. Serbia and	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives	Montenegro	204. Vietnam
35. Chile	76. Guyana	119. Mali	162. Seychelles	205. West Indies
36. China	77. Haiti	120. Malta	163. Sierra Leone	206. World
37. Cook Islands	78. Holland	121. Marshall Islands	164. Singapore	207. Yemen
38. Colombia	79. Honduras	122. Mauritania	165. Slovakia	208. Yugoslavia ¹
39. Columbia	80. Hong Kong	123. Mauritius	166. Slovenia	209. Zaire
40. Congo	81. Hungary	124. Mexico	167. Solomon Islands	210. Zambia
41. Costa Rica	82. Iceland	125. Moldova	168. Somalia	211. Zimbabwe
42. Council of Europe	83. India	126. Monaco	169. Somaliland	
43. Croatia	84. Indonesia	127. Mongolia	170. South Africa	

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.: 0091-0260-2230470

Fax No.

0091-0260-2230570

Name of Authorized Person: Dr. V.K. DAS DRUGS LICENSING AUTHORITY

औषधी लाईसेंस प्राधिकारी DRUGS CONTROL DEPARTMENT

Signature

Stamp & Date

औषधी नियंत्रण विभाग UT OF DAMAN & DIU, DAMAN मध प्रदेश दमण एवं दीव, दमण

Administration of Daman & Diu, Drugs Licensing Authority, **Drugs Control Department,** Primary Health Centre, Daman - 396220.

Valid up to: 04/03/2025

Certificate of a Pharmaceutical Product¹

This certificate conforms to the format recommended by the World Health Organization

(General instructions and explanatory notes attached)

No. of Certificate : DD/794/67C/2022-1-211-2 **Exporting (Certifying) Country** : INDIA : As per Annexure-II Importing (Requesting) Country

: Vinblastine Sulfate Injection BP 10mg/10ml 1. Name and dosage form of product

1.1 Active ingredient (s)² and amount (s) per unit dose³: Composition: Each ml Contains:

Vinblastine sulfate BP1 mg

For complete qualitative composition including Excipients, see attached ⁴: Annexure - I

- Is this product licensed to be placed on the market for use in the exporting country?⁵ Yes 1.2
- Is this product actually on the market in the exporting country? Yes

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue section 2B 6.

2 A

A.1 Number of product license⁷: DD/794 And date of issue : 05/08/2019

A.2 Product license holder: Bruck Pharma Pvt. Ltd. Survey No. 188/1 to 6, 189/1, 190/2 to 4, Atiyawad, Dabhel, Daman - 396210

A.3 Status of product license holder 8: a

Manufacturing of Dosage forms

A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are 9 : Not applicable

A.4 Is summary basis of Approval appended? 10

A.5 Is the attached, officially approved product information complete and consonant with the license?¹¹

Not provided

A.6 Applicant for certificate if different from license

holder: 12 : Not applicable.

2 B

Not applicable.

B.1 Application for certificate: (Not applicable.)

(Name and address)

- B.2 Status of applicant (Not applicable.)
- B.2.1 For categories b and c the name and address of the Manufacturer producing the dosage

: Not applicable

B. 3 Why is marketing authorization lacking? : Not applicable

Consideration Required Requested गन्त्रस्य तस्त

B.4 Remark: 13 -(Not applicable.)

ट्रमण/Daman

- 3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes If no or not applicable proceed to question 4
- 3.1 Periodicity of routine inspections (years): Yearly
- 3.2 Has the manufacture of this type of dosage form been inspected?
- 3.3 Do the facilities and operations conform to GMP as recommended by Yes the World Health Organization ?¹⁵
- 4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? 16

Yes If no, explain

Address of certifying authority:

Drugs Licensing Authority, Administration of Daman & Diu, Drugs Control Department. Primary Health Centre, Daman - 396220.

Telephone Number: (0260) 2230470 Fax Number: (0260) 2230570

Name of authorized person: Dr. V.K. DAS

DRUGS LICENSING AUTHORITY

Signature:

औषधी लाईसेंस प्राधिकारी DRUGS CONTROL DEPARTMENT

औषधी नियंत्रण विभाग UT OF DAMAN & DIU, DAMAN

Stamp and date: मध प्रदेश दमण एव दीव, दमण

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the scheme. The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten

Additional sheet 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, whenever possible, international Nonproprietary Names (INNs) or National Nonproprietary names.
- 3. The formula (Complete composition) of the dosage form should be given on the certificate or be appended.
- Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license 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 license.
- Sections 2A and 2B are mutually exclusive.
- 7. Indicate, when applicable, if the license 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 labels 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-license 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 license. If the production site is changed, the license has to be updated or it is no longer valid.
- 10. This refers to the document, prepared by some national regulatory authori-ties 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-license 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 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.
- The requirements for good practice 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).
- This section is to completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 8 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.

The layout for Model Certificate is available on diskette in World Perfect from the Division of Drug Management and policies, World Health Organization, 1211 Geneva 27, Switzerland.

ANNEXURE-I

No. of Certificate

: DD/794/67C/2022-1-211-2

Valid up to: 04/03/2025

Name of the Product : Vinblastine Sulfate Injection BP 10mg/ 10ml

List of countries / Institution to which the above product will be Exported / Locally supplied.

1. Afghanistan	44. Cuba	85. Iran	128. Morocco	171. South Korea
2. Albania	45. Cyprus	86. Iraq	129. Mozambique	172. Spain
3. Algeria	46. Czech Republic	87. Ireland	130. Myanmar	173. Sri Lanka
4. Angola	47. Czechoslovakia¹	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic	89. Italy	132, Nepal	175. Suriname
6. Armenia	Republic of Congo	90. Ivory Coast	133. Netherlands Antilles	176. Swaziland
7. Aruba	49. Denmark	91. Jamaica	134. Netherlands	177. Sweden
8. Australia	50. Diibouti	92. Japan	135. New Zealand	178. Switzerland
9. Austria	51. Dominica	93. Jordan	136. Nicaragua	179. Syria
10. Azerbaijan	52. Dominican Republic	94. Kazakhstan	137. Niger	180. Tadzhikistan
11. Bahamas	53. Ecuador	95. Kenya	138. Nigeria	181. Taiwan
12. Bahrain	54. Egypt	96. Kingdom of Tonga	139. North Korea	182. Tajikistan
13. Baltic	55. El Salvador	97. Kiribati	140. Norway	183. Tanzania
14. Bangladesh	56. Equatorial Guinea	98. Korea	141. Oman	184. Thailand
15. Barbados	57. Eritrea	99. Korea Republic of	142. Pakistan	185. Tobago
16. Belarus	58. Estonia	100. Kosova	143. Palau	186. Togo
17. Belgium	59. Ethiopia	101. Kuwait	144. Panama	187. Tonga
18. Belize	60. European Community	102. Kyrgyzstan	AAF D	400 Taimided
19. Benin	61. Fiji	103. Laos	146. Paraguay U	189. Tunisia
20. Bhutan	62. Finland	104. Latvia	147 Peru	190. Turkey
21. Bolivia	63. France	105. Lebanon	48. Ruerto Rico	491. Turkmenistan
22. Bosnia	64. Gabon	106. Lesotho	1492 Philippines	192 UAE
23. Botswana	65. Gambia	107. Liberia	150 Poland	
24. Brazil	66. Guatemala	108. Libya	151. Portugal	194. Ukraine
25. Brunei	67. Georgia	109. Libyan Arab		195. Union of Soviet
26. Bulgaria	68. German Democratic	Jamahiriya	158 Republic of Benin	Socialist Regublics ¹
27. Burkina Faso	Republic ²	110. Liechtenstein	154. Republic de Guinee	196.United Arab
28. Burundi	69. Germany Federal Republic of ²	111. Liochtonstoin	155. Republic of Mandives	197. United Kingdom
29. Byelorussia	Kebublic of	112. Lithuania	156. Romania	198. United States
30. Cambodia	70. Germany	113. Luxembourg	157. Russia	199. Uruguay
31. Cameroon	71. Ghana	114. Macau	158. Rwanda	200. USA
32. Canada	72. Greece	115. Madagascar	159. Saudi Arabia	201. Uzbekistan
33.Central African	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
Republic	74. Guinea	117. Malaysia	161. Serbia and	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives	Montenegro	204. Vietnam
35. Chile	76. Guyana	119. Mali	162. Seychelles	205. West Indies
36. China	77. Haiti	120. Malta	163. Sierra Leone	206. World
37. Cook Islands	78. Holland	121. Marshall Islands	164. Singapore	207. Yemen
38. Colombia	79. Honduras	122. Mauritania	165. Slovakia	208. Yugoslavia ¹
39. Columbia	80. Hong Kong	123. Mauritius	166. Slovenia	209. Zaire
40. Congo	81. Hungary	124. Mexico	167. Solomon Islands	210. Zambia
41. Costa Rica	82. Iceland	125. Moldova	168. Somalia	211. Zimbabwe
42. Council of Europe	83. India	126. Monaco	169. Somaliland	

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.:

0091-0260-2230470

Fax No.

0091-0260-2230570

Name of Authorized Person: Drugs LICENSING AUTHORITY

औषधी लाईसेंस प्राधिकारी DRUGS CONTROL DEPARTMENT

Signature

Stamp & Date

औषधी नियंत्रण विभाग UT OF DAMAN & DIU, DAMAN सघ प्रदेश दमण एव दीव, दमण

Administration of Daman & Diu, Drugs Licensing Authority, **Drugs Control Department,** Primary Health Centre, Daman - 396220.

Certificate of a Pharmaceutical Product¹

This certificate conforms to the format recommended by the World Health Organization (General instructions and explanatory notes attached)

No. of Certificate

: DD/794/68C/2022-1-211-2 : INDIA

Valid up to: 04/03/2025

Exporting (Certifying) Country Importing (Requesting) Country

: As per Annexure-II

1. Name and dosage form of product

: Vincristine Sulfate Injection USP 1 mg/ ml

1.1 Active ingredient (s)² and amount (s) per unit dose³ : Composition :

Each ml contains:

Vincristine sulfate USP1mg Water for Injection USPq.s.

For complete qualitative composition including Excipients, see attached ⁴ : Annexure - I

- Is this product licensed to be placed on the market for use in the exporting country?⁵ Yes
- Is this product actually on the market in the exporting country? Yes

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue section 2B 6.

A.1 Number of product license7: DD/794 And date of issue : 16/08/2019

A.2 Product license holder: Bruck Pharma Pvt. Ltd. Survey No. 188/1 to 6, 189/1, 190/2 to 4. Atiyawad, Dabhel, Daman - 396210

A.3 Status of product license holder 8: a

Manufacturing of Dosage forms

A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are 9 : Not applicable

A.4 Is summary basis of Approval appended? 10

A.5 Is the attached, officially approved product information complete and consonant with the license?¹¹

Not provided

A.6 Applicant for certificate if different from license

holder: 12 : Not applicable.

2 B

Not applicable.

B.1 Application for certificate: (Not applicable.)

(Name and address)

- B.2 Status of applicant (Not applicable.)
- B.2.1 For categories b and c the name and address of the Manufacturer producing the desage form

: Not applicable

B. 3 Why is marketing author ation lacking : Not applicable

Required Requested consideration

B.4 Remark: 13 -(Not applicable)

दम्ण/Daman o

- 3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes If no or not applicable proceed to question 4.
- 3.1 Periodicity of routine inspections (years): Yearly
- 3.2 Has the manufacture of this type of dosage form been inspected?
- 3.3 Do the facilities and operations conform to GMP as recommended by Yes the World Health Organization?¹⁵
- Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? 16

Yes If no, explain

Address of certifying authority:

Drugs Licensing Authority, Administration of Daman & Diu, **Drugs Control Department,** Primary Health Centre, Daman - 396220.

Telephone Number: (0260) 2230470 Fax Number: (0260) 2230570

Name of authorized person: Dr. V.K. DAS

DRUGS LICENSING AUTHORITY

Signature: औषधी लाईसेंस प्राधिकारी

DRUGS CONTROL DEPARTMENT

औषधी निर्वतिष विभाग

UT OF DAMAN & DIU DAMAN Stamp and date:

सध प्रदेश उद्यक्ष एवं दीखे, दमण

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the scheme. The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheet 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, whenever possible, international Nonproprietary Names (INNs) or National Nonproprietary names.
- The formula (Complete composition) of the dosage form 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-license 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 license.
- Sections 2A and 2B are mutually exclusive.
- 7. Indicate, when applicable, if the license is provisional, or the product has not yet been approved.
- Specify whether the person responsible for placing the product on the market.
 - (a) manufactures the dosage form :
 - (b) Packages and/or labels a dosage form manufactured by an independent company; or
 - (c) is involved in none of the above.
- This information can be provided only with the consent of the product-license 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 license. If the production site is changed, the license has to be updated or it is no longer valid.
- 10. This refers to the document, prepared by some national regulatory authori-ties 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-license 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 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.
- The requirements for good practice 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).
- This section is to completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 8 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.

The layout for Model Certificate is available on diskette in World Perfect from the Division of Drug Management and policies, World Health Organization, 1211 Geneva 27, Switzerland.

ANNEXURE - I

CERTIFICATE NO.: DD/794/68C/2022-1-211-2

:

VALID UPTO 04/03/2025

ACTIVE AND INACTIVE COMPOSITION – QUALITATIVE AND QUANTITATIVE

Name of Product

Vincristine Sulfate Injection USP 1 mg/ ml

Composition

Each ml contains:

Vincristine Sulfate USP1mg Water for Injection USPq.s.

Sr. No.	Ingredients	Specifications	Quantity Input (mg/ml)	
1.	Vincristine sulfate	USP USP USP	1.0	
2.	Mannitol		100.0 1.3 0.2	
3.	Methyl Paraben			
4.	Propyl paraben			
5.	Sodium acetate	USP	0.8	
6.	Glacial acetic acid	USP	for pH adjustment only	
7.	Water for Injection	MGUSPIT	q. s.	

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.: 0091-0260-2230470

Fax No.

: 0091-0260-2230570

Name of Authorized Person: Dr. V.K. DAS
DRUGS LICENSING AUTHORITY

औषधी लाईसेंस प्राधिकारी DRUGS CONTROL DEPARTMENT

Signature औषधी नियंत्रण विभाग UT OF DAMAN & DIU, DAMAN

सघ प्रदेश दमण एव दीव, दमन

Stamp & Date

ANNEXURE-II

No. of Certificate

: DD/794/68C/2022-1-211-2

Valid up to: 04/03/2025

Name of the Product : Vincristine Sulfate Injection USP 1mg/ ml

List of countries / Institution to which the above product will be Exported / Locally supplied.

1. Afghanistan	44. Cuba	85. Iran	128. Morocco	171. South Korea
2. Albania	45. Cyprus	86. Iraq	129. Mozambique	172. Spain
3. Algeria	46. Czech Republic	87. Ireland	130. Myanmar	173. Sri Lanka
4. Angola	47. Czechoslovakia1	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic	89. Italy	132. Nepai	175. Suriname
6. Armenia	Republic of Congo	90. Ivory Coast	133. Netherlands Antilles	176. Swaziland
7. Aruba	49. Denmark	91. Jamaica	134. Netherlands	177. Sweden
8. Australia	50. Djibouti	92. Japan	135. New Zealand	178. Switzerland
9. Austria	51. Dominica	93. Jordan	136. Nicaragua	179. Syria
10. Azerbaijan	52. Dominican Republic	94. Kazakhstan	137. Niger	180, Tadzhikistan
11. Bahamas	53. Ecuador	95. Kenya	138. Nigeria	181. Taiwan
12. Bahrain	54. Egypt	96. Kingdom of Tonga	139. North Korea	182. Tajikistan
13. Baltic	55. El Salvador	97. Kiribati	140. Norway	183. Tanzania
14. Bangladesh	56. Equatorial Guinea	98. Korea	141. Oman	184. Thailand
15. Barbados	57. Eritrea	99. Korea Republic of	142. Pakistan	185. Tobago
16. Belarus	58. Estonia	100. Kosova	143. Palau	186. Togo
17. Belgium	59. Ethiopia	101. Kuwait	144. Panama	187. Tonga
18. Belize	60. European Community	102. Kyrgyzstan	145. Papua New Guinea	188. Trinidad
19. Benin	61. Fiji	103. Laos	146. Paraguay	189. Tunisia
20. Bhutan	62. Finland	104. Latvia	147. Peru	190. Turkey
21. Bolivia	63. France	105. Lebanon	148. Puerto Rico	191. Turkmenistan
22. Bosnia	64. Gabon	106. Lesotho	149 Philippines AUTU	192. UAE
23. Botswana	65. Gambia	107. Liberia	A self control of the self	/193 Uganda
24. Brazil	66. Guatemala	108. Libya	150. Roland	194 kraine
25. Brunei	67. Georgia	109. Libyan Arab	152 Qatar	195. Union of Soviet
26. Bulgaria	68. German Democratic	Jamahiriya	153. Republic of Benin	Socialist Republics¹
27. Burkina Faso	Republic ²	110. Liechtenstein	454. Republic de Guinee	196.United Arab Emirates
28. Burundi	69. Germany Federal Republic of ²	111. Liochtonstoin	155. Republic of Daman	197. United Kingdom
29. Byelorussia		112. Lithuania	166 Romatria	198 United States
30. Cambodia	70. Germany	113. Luxembourg	157 Russia	199. Uruguay
31. Cameroon	71. Ghana	114. Macau	158. Rwanda // William	200. USA
32. Canada	72. Greece	115. Madagascar	159. Saudi Arabia	201. Uzbekistan
33.Central African	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
Republic	74. Guinea	117. Malaysia	161. Serbia and	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives	Montenegro	204. Vietnam
35. Chile	76. Guyana	119. Mali	162. Seychelles	205. West Indies
36. China	77. Haiti	120. Malta	163. Sierra Leone	206. World
37. Cook Islands	78. Holland	121. Marshall Islands	164. Singapore	207. Yemen
38. Colombia	79. Honduras	122. Mauritania	165. Slovakia	208. Yugoslavia ¹
39. Columbia	80. Hong Kong	123. Mauritius	166. Slovenia	209. Zaire
10. Congo	81. Hungary	124. Mexico	167. Solomon Islands	210. Zambia
11. Costa Rica	82. Iceland	125. Moldova	168. Somalia	211. Zimbabwe
12. Council of Europe	83. India	126. Monaco	169. Somaliland	
13. Croatia	84. Indonesia	127. Mongolia	170. South Africa	

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

Primary Health Center, Daman (UT) - 396 220.

Telephone No.:

0091-0260-2230470

Fax No.

0091-0260-2230570

Name of Authorized Person: Dr. V.K. DAS
DRUGS LICENSING AUTHORITY

औषधी लाईसेंस प्राधिकारी DRUGS CONTROL DEPARTMENT

औषधी नियंत्रण विभाग

Signature

Stamp & Date

UT OF DAMAN & DIU, DAMAN सच प्रदेश दमण एव दीव, दमण

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