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

==========

NO. DCD/D&D/LA/2022-2023/7091 DATED: 04/07/2022.

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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 VALID UP TO 04/03/2025.

LICENSING AUTHORITY
लाइसन्सिंग प्राधिकारी
दमण/Daman
संघ प्रदेश दमण एवं दीव
U.T. OF DAMAN & DIU

(DR. V. K. DAS)
DIRECTOR,
MEDICAL & HEALTH SERVICES
DRUGS LICENSING AUTHORITY,
UT OF DNH, DAMAN & DIU,
DAMAN.

Digitally signed by Dicusar Vladimir
Date: 2022.09.20 10:21:49 EEST
Reason: MoldSign Signature
Location: Moldova

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

Certificate of a Pharmaceutical Product[1]

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**
1. Name and dosage form of product : **Epirubicin Hydrochloride for Injection 10mg/vial**

1.1 Active ingredient (s)[2] and amount (s) per unit dose[3] : **Composition :**
Each Lyophilized Vial Contains:
Epirubicin hydrochloride USP.....10mg
Lactose monohydrate NF.....50mg

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 A

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]

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 lacking? : **Not applicable**

Required Requested Consideration

B.4 Remark : [13] -(**Not applicable.**)

LICENSING AUTHORITY
लाइसेन्सिंग प्राधिकारी
दमण/Daman
ADMN. OF DAMAN & DIU

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? **Yes**

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

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]
Yes If no, explain

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

Signature:

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एवं दीव, दमण

Stamp and date: 12 APR 2022

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

ANNEXURE - I

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

Sr. No.	Ingredients	Specifications	Quantity Input (mg / ml)
1.	Epirubicin Hydrochloride	USP	8.334
2.	Lactose Monohydrate	NF	41.666
3.	Methyl Paraben	USP	1.667
4.	Water for injection	USP	q.s.

DRUG LICENSING AUTHORITY
दमण, Daman
U.T. OF DAMAN & DIU

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
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एवं दीव, दमण

12 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.

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. Czechoslovakia[1]	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic Republic of Congo	89. Italy	132. Nepal	175. Suriname
6. Armenia		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 Jamahiriya	152. Qatar	195. Union of Soviet Socialist Republics[1]
26. Bulgaria	68. German Democratic Republic[2]		153. Republic of Benin	
27. Burkina Faso		110. Liechtenstein	154. Republic de Guinee	196.United Arab Emirates
28. Burundi	69. Germany Federal Republic of[2]	111. Liochtonstoin	155. Republic of Maldives	197. United Kingdom
29. Byelorussia		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 Republic	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
34. Chad	74. Guinea	117. Malaysia	161. Serbia and Montenegro	203. Venezuela
35. Chile	75. Guinea Equatorial	118. Maldives	162. Seychelles	204. Vietnam
36. China	76. Guyana	119. Mali	163. Sierra Leone	205. West Indies
37. Cook Islands	77. Haiti	120. Malta	164. Singapore	206. World
38. Colombia	78. Holland	121. Marshall Islands	165. Slovakia	207. Yemen
39. Columbia	79. Honduras	122. Mauritania	166. Slovenia	208. Yugoslavia
40. Congo	80. Hong Kong	123. Mauritius	167. Solomon Islands	209. Zaire
41. Costa Rica	81. Hungary	124. Mexico	168. Somalia	210. Zambia
42. Council of Europe	82. Iceland	125. Moldova	169. Somaliland	211. Zimbabwe
43. Croatia	83. India	126. Monaco	170. South Africa	
	84. Indonesia	127. Mongolia		

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
औषधि लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एवं दीव, दमण

12 APR 2022

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

Certificate of a Pharmaceutical Product[1]

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
Excipients .....q.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 A

A.1 Number of product license[7] : **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 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 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.**)

DRUGS LICENSING AUTHORITY औषधी लाईसेंस प्राधिकारी DRUGS CONTROL DEPARTMENT औषधी नियंत्रण विभाग UT OF DAMAN & DIU, DAMAN संघ प्रदेश दमण एवं दीव, दमण

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? **Yes**

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

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

Yes 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:

Stamp and date:

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एवं दीव, दमण

23 MAY 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.
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.
15. 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/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
Excipients .....q.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 water.

LICENSING AUTHORITY लाइसन्सिंग प्राधिकारी सत्यमेव जयते दमण/Daman संघप्रदेश दमण तथा दीव U.T. OF DAMAN & DIU

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

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
U.T OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एवं दीव, दमण

Stamp & Date 23 MAY 2022

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. Czechoslovakia[1]	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic Republic of Congo	89. Italy	132. Nepal	175. Suriname
6. Armenia		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 Jamahiriya	152. Qatar	195. Union of Soviet Socialist Republics[1]
26. Bulgaria	68. German Democratic Republic[2]		153. Republic of Benin	
27. Burkina Faso		110. Liechtenstein	154. Republic de Guinee	196. United Arab Emirates
28. Burundi	69. Germany Federal Republic of[2]	111. Liochtonstoin	155. Republic of Maldives	197. United Kingdom
29. Byelorussia		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 Republic	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
	74. Guinea	117. Malaysia	161. Serbia and Montenegro	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives		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

Signature

Stamp & Date

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एवं दीव, दमण
23 MAY 2022

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

Certificate of a Pharmaceutical Product[1]

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** **Valid up to: 04/03/2025**
Exporting (Certifying) Country : **INDIA**
Importing (Requesting) Country : **As per Annexure-II**
1. Name and dosage form of product : **MESNA INJECTION 400 MG/4ML**

1.1 Active ingredient (s)[2] and amount (s) per unit dose[3] : **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**

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 A

A.1 Number of product license[7] : **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 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.)

LICENSING AUTHORITY
लाइसेंस प्राधिकारी
मान्यकृत प्रयत
दमण/Daman
U.T. OF DAMAN & DIU

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? **Yes**

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

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]
Yes 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:

Stamp and date:
DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एवं दीव, दमण

20 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.
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.
15. 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/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	USP	q.s.

LICENSING AUTHORITY
लाइसन्सिंग प्राधिकारी
सत्यमेव जयते
दमण/Daman
U.T. OF DAMAN & DIU

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

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
दमण एवं दीव, दमण

Stamp & Date 20 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. Czechoslovakia[1]	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic Republic of Congo	89. Italy	132. Nepal	175. Suriname
6. Armenia		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 Jamahiriya	152. Qatar	195. Union of Soviet Socialist Republics
26. Bulgaria	68. German Democratic Republic[2]		153. Republic of Benin	
27. Burkina Faso		110. Liechtenstein	154. Republic de Guinea	196.United Arab Emirates
28. Burundi	69. Germany Federal Republic of[2]	111. Liochtonstoin	155. Republic of Maldives	197. United Kingdom
29. Byelorussia		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 Republic	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
	74. Guinea	117. Malaysia	161. Serbia and Montenegro	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives		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

Signature

Stamp & Date

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एवं दीव, दमण

20 JUN 2022

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

Certificate of a Pharmaceutical Product[1]

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**
1. Name and dosage form of product :**Sorafenib Tablets BP 200mg**
1.1 Active ingredient (s)[2] and amount (s) per unit dose[3] : **Composition :**
Each film coated tablet contains:
Sorafenib Tosilate BP
Equivalent to Sorafenib ..... 200 mg
Excipients ..... q.s.
Color: Titanium Dioxide & Ferric Oxide Red.

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 A

A.1 Number of product license[7] : **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]

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 lacking?
: **Not applicable**

Required Requested Consideration

B.4 Remark : [13] -(**Not applicable.**)

LICENSING AUTHORITY
U.T. OF DAMAN & DIU
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? **Yes**

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

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

Yes 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:

DRUGS LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
UT OF DAMAN & DIU, DAMAN

Stamp and date:

2 3 MAY 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.
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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 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.
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.
15. 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/793/21A/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
Excipients .....q.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	BP	13.72
6.	Croscarmellose sodium	BP	17.28
7.	Microcrystalline cellulose	BP	35.00
8.	Magnesium stearate	BP	11.00
9.	Opadry Brown	IH	14.70
10.	Isopropyl alcohol	BP	117.60
11.	Dichloromethane	BP	176.40

LICENSING AUTHORITY

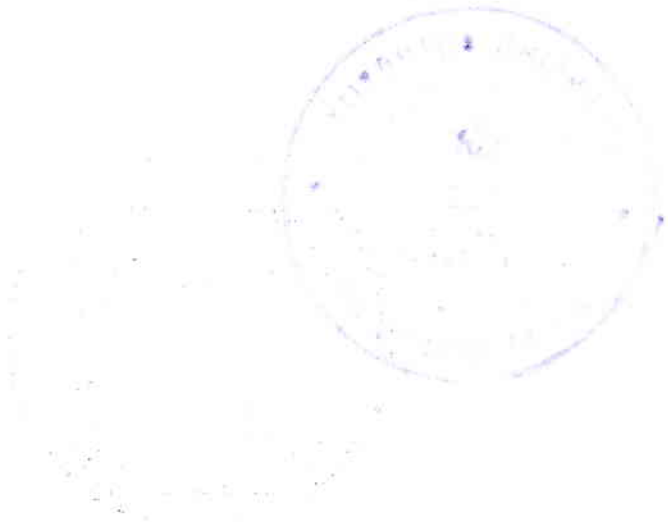
Address of Certifying Authority:
Drug Licensing Authority,
Administration of Daman & Diu, Drugs Control Dept.,
Primary Health Center, Daman (UT) – 396 220.
Telephone No. : 0091–0260–2230470
Fax No. : 0091–0260–2230570

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

Signature

DRUGS LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
UT OF DAMAN & DIU, DAMAN

Stamp & Date 23 MAY 2022



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. Czechoslovakia[1]	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic Republic of Congo	89. Italy	132. Nepal	175. Suriname
6. Armenia		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 Jamahiriya	152. Qatar	195. Union of Soviet Socialist Republics[1]
26. Bulgaria	68. German Democratic Republic[2]		153. Republic of Benin	
27. Burkina Faso		110. Liechtenstein	154. Republic de Guinee	196.United Arab Emirates
28. Burundi	69. Germany Federal Republic of[2]	111. Liochtonstoin	155. Republic of Maldives	197. United Kingdom
29. Byelorussia		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 Republic	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
	74. Guinea	117. Malaysia	161. Serbia and Montenegro	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives		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

Signature

Stamp & Date

DRUGS LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
UT OF DAMAN & DIU, DAMAN

23 MAY 2022

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

Certificate of a Pharmaceutical Product[1]

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**
Exporting (Certifying) Country : **INDIA**
Importing (Requesting) Country : **As per Annexure-II**
1. Name and dosage form of product : **Temozolomide Capsules USP 20 mg**

1.1 Active ingredient (s)[2] and amount (s) per unit dose[3] : **Composition :**
Each Hard Gelatin Capsule contains:
Temozolomide USP .....20 mg
Excipients..... q.s.
Approved colors used in capsule shell.

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 A

A.1 Number of product license[7] : **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[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 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.)**

LICENSING AUTHORITY
लाइसन्सिंग प्राधिकारी
सत्यमेव जयते
दमण/Daman
U.T. OF DAMAN & DIU

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? **Yes**

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

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

Yes 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:

DRUGS LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
UT OF DAMAN & DIU, DAMAN

Stamp and date:

2 3 MAY 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.
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.
15. 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 USP .....20 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	USP	6.000
7.	Empty hard gelatin capsule (size 2)	IH	q.s.

LICENSING AUTHORITY
दमण/Daman
U.T. OF DAMAN & DIU

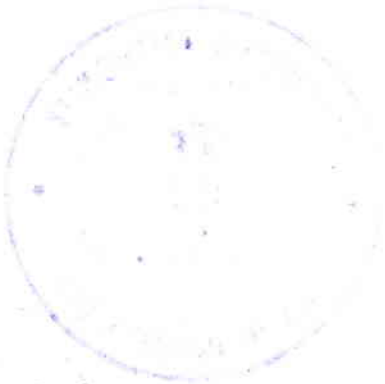
Address of Certifying Authority:
Drug Licensing Authority,
Administration of Daman & Diu, Drugs Control Dept.,
Primary Health Center, Daman (UT) – 396 220.
Telephone No. : 0091–0260–2230470
Fax No. : 0091–0260–2230570

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

Signature

DRUGS LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
UT OF DAMAN & DIU, DAMAN

Stamp & Date 23 MAY 2022



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. Czechoslovakia[1]	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic Republic of Congo	89. Italy	132. Nepal	175. Suriname
6. Armenia		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 Jamahiriya	152. Qatar	195. Union of Soviet Socialist Republics[1]
26. Bulgaria	68. German Democratic Republic[2]		153. Republic of Benin	
27. Burkina Faso		110. Liechtenstein	154. Republic de Guinee	196 United Arab Emirates
28. Burundi	69. Germany Federal Republic of[2]	111. Liochtonstoin	155. Republic of Maldives	197. United Kingdom
29. Byelorussia		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 Republic	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
	74. Guinea	117. Malaysia	161. Serbia and Montenegro	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives		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

Signature

Stamp & Date

DRUGS LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
UT OF DAMAN & DIU, DAMAN
23 MAY 2022

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

Certificate of a Pharmaceutical Product[1]

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 dose[3] : **Composition :**
Each hard gelatin capsule contains:
Thalidomide USP .....100 mg
Excipients..... q.s.
Approved colors used in capsule shell.

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 A

A.1 Number of product license[7] : **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]

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 lacking?
: **Not applicable**

Required Requested Consideration

B.4 Remark : [13] **-(Not applicable.)**

LICENSING AUTHORITY औषधी लाईसेंस प्राधिकारी दमण/Daman U.T. OF DAMAN & DIU

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? **Yes**

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

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

Yes If no, explain

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

Signature:

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एवं दीव, दमण

Stamp and date:

2 3 MAY 2022

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

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.
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.
15. 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/793/19B/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 USP 100mg
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	USP	4.0
6.	Empty hard gelatin capsule (size 0)	IH	q.s.

LICENSING AUTHORITY
लाइसेंस प्राधिकारी
सत्यमेव जयते
दमण/Daman
संघप्रदेश दमण एवं दीव
U.T. OF DAMAN & DIU

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

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
मध प्रदेश दमण एव दीव, दमण

Stamp & Date 23 MAY 2022

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. Czechoslovakia[1]	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic Republic of Congo	89. Italy	132. Nepal	175. Suriname
6. Armenia		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 Jamahiriya	152. Qatar	195. Union of Soviet Socialist Republics[1]
26. Bulgaria	68. German Democratic Republic[2]		153. Republic of Benin	
27. Burkina Faso		110. Liechtenstein	154. Republic de Guinee	196.United Arab Emirates
28. Burundi	69. Germany Federal Republic of[2]	111. Liochtonstoin	155. Republic of Maldives	197. United Kingdom
29. Byelorussia		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 Republic	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
	74. Guinea	117. Malaysia	161. Serbia and Montenegro	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives		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

Signature

Stamp & Date

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
मध्य प्रदेश दमण एव दीव, दमण
23 MAY 2022

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

Certificate of a Pharmaceutical Product[1]

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** **Valid up to: 04/03/2025**
Exporting (Certifying) Country : **INDIA**
Importing (Requesting) Country : **As per Annexure-II**
1. Name and dosage form of product : **Vinblastine Sulfate Injection BP 10mg/ 10ml**
1.1 Active ingredient (s)[2] and amount (s) per unit dose[3] : **Composition :**
Each ml Contains:
Vinblastine sulfate BP .....1 mg
Excipients ..... q.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 A

A.1 Number of product license[7] : **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]

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 lacking?
: **Not applicable**

Required Requested Consideration

B.4 Remark : [13] **-(Not applicable.)**

LICENSING AUTHORITY
लाइसेंसिंग प्राधिकारी
सत्यमेव जयते
दमण/Daman
U.T. OF DAMAN & DIU

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? **Yes**

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

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

Yes If no, explain

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

Signature:

Stamp and date:

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU. DAMAN
मघ प्रदेश दमण एव दीव, दमण

2 3 MAY 2022

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

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.
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.
15. 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

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. Czechoslovakia[1]	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic Republic of Congo	89. Italy	132. Nepal	175. Suriname
6. Armenia		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 Jamahiriya	152. Qatar	195. Union of Soviet Socialist Republics[1]
26. Bulgaria	68. German Democratic Republic[2]		153. Republic of Benin	
27. Burkina Faso		110. Liechtenstein	154. Republic de Guinee	196. United Arab Emirates
28. Burundi	69. Germany Federal Republic of[2]	111. Liochtonstoin	155. Republic of Maldives	197. United Kingdom
29. Byelorussia		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 Republic	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
	74. Guinea	117. Malaysia	161. Serbia and Montenegro	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives		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:
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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
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एव दीव, दमण

23 MAY 2022

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

Certificate of a Pharmaceutical Product[1]

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** **Valid up to: 04/03/2025**
Exporting (Certifying) Country : **INDIA**
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 dose[3] : **Composition :**
Each ml contains:
Vincristine sulfate USP 1mg
Water for Injection USP .....q.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 A

A.1 Number of product license[7] : **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]

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 lacking? : **Not applicable**

Required Requested Consideration

B.4 Remark : [13] **-(Not applicable.)**

LICENSING AUTHORITY
औषधि लाईसेंस प्राधिकारी
दमण/Daman
U.T. OF DAMAN & DIU

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? **Yes**

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

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

Yes If no, explain

Address of certifying authority :

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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:

Stamp and date:

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU DAMAN
संघ प्रदेश दमण एवं दीव, दमण

23 MAY 2022

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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.
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   (a) manufactures the dosage form :
   (b) Packages and/or labels a dosage form manufactured by an independent company; or
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    (b) the product has been reformulated with a view to improving its stability under tropical conditions;
    (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
    (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
    (e) any other reason, please specify.
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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 USP 1mg
Water for Injection USP .....q.s.

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

LICENSING AUTHORITY लाइसन्सिंग प्राधिकारी सत्यमेव जयते दमण/Daman संघप्रदेश दमण एवं दीव U.T. OF DAMAN & DIU

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
संघ प्रदेश दमण एवं दीव, दमण

Signature

Stamp & Date

23 MAY 2022

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. Czechoslovakia[1]	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic Republic of Congo	89. Italy	132. Nepal	175. Suriname
6. Armenia		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. Roland	193. Uganda
24. Brazil	66. Guatemala	108. Libya	151. Portugal	194. Ukraine
25. Brunei	67. Georgia	109. Libyan Arab Jamahiriya	152. Qatar	195. Union of Soviet Socialist Republics[1]
26. Bulgaria	68. German Democratic Republic[2]		153. Republic of Benin	
27. Burkina Faso		110. Liechtenstein	154. Republic de Guinee	196. United Arab Emirates
28. Burundi	69. Germany Federal Republic of[2]	111. Liochtonstoin	155. Republic of Maldives	197. United Kingdom
29. Byelorussia		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 Republic	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
	74. Guinea	117. Malaysia	161. Serbia and Montenegro	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives		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	

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

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

Signature

Stamp & Date

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
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23 MAY 2022