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

No. DCD / D&D / LA / 2018-2019 /224 *Dated: - 05/01/2019.*

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, Athiyawad, 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 ***THREE YEARS*** *from the date of issue.*

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

(Dr. V. K. DAS)
Director,
Medical & Health Services
Drugs Licensing Authority,
UT of Daman & Diu,
Daman.

CERTIFICATE OF PHARMACEUTICAL PRODUCTS[1]

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

No of Certificate: **DD/793/11B/2020-1-211-1** — **Valid Up to: 04/01/2022**

Exporting (Certifying) Country		:	**India**
Importing (Requesting) Country		:	**As per Annexure-2**
1	Name and dosage form of Product	:	**Lomustine Capsule USP 40 mg**
1 1	Active ingredient(s)[2] and amount(s) per unit dose[3]	:	**Composition:** **Each capsule contains:** **Lomustine USP .....40mg** **Excipients.....q.s.** **Color: Approved color used in capsule shells.**
	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 2 A and omit section 2 B

If the answer to 1 2 is no, omit section 2 A and continue section 2 B[6]

2 A 1	Number of product licence[7] and date of issue	:	**DD/793 Dated 05/08/2019**
2 A 2	Product Licence holder (Name & Address)	:	**Bruck Pharma Pvt. Ltd.** **Survey No. 188/1 to 6, 189/1, 190/2 to 4,** **Atiyawad, Dabhel, Daman - 396210**
2 A 3	Status of product licence holder [8]	:	**a**
2 A 3 1	For categories b and c the name and address of the manufacturer producing the dosage form is[9]	:	**Not applicable**
2 A 4	Is a summary basis for approval appended?[10]	:	**No**
2 A 5	Is the attached, officially approved product information complete and consonant with the licence? [11]	:	**Not required**
2 A 6	Applicant for certificate, if different from licence holder (name and address)[12]	:	**Not Applicable**
2 B 1	Applicant for certificate (Name & Address)	:	**NA**
2 B 2	Status of applicant	:	**NA**
2 B 2 1	For categories (b) and (c) the name and address of the manufacturer producing the dosage form is: [9]	:	**NA**
2 B 3	Why is marketing authorization lacking?	:	**NA**
2 B 4	Remark [13]	:	**NA**

LICENSING AUTHORITY U.T. OF DAMAN

3	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable) [14]	:	**Yes**

If Not or Not applicable proceed to question 4

3 1	Periodicity of routine inspection (years)	:	**Yearly**
3 2	Has the manufacture of this type of dosage form been inspected ?	:	**Yes**
3 3	Do the facilities and operation confirm to GMP as recommended by 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	:	**Not Applicable**

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 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

15 JUN 2020

Explanatory notes:

1. This certificates 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 form 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 licence holder.

5 When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved

8. Specify whether the person responsible for placing the product on the market:

   a) Manufactures the dosage form,
   b) Packages and / or labels a dosage form manufactured by an independent company, or
   c) Is involved in none of the above.

9. The information can be provided only with the consent of the product licence holder or, in the case of non-registered products, the applicant. non-completion of the 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 licence. If the production site is changed, the licence must be updated or it is no longer valid.

10 This refers to the documents, 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 Product Characteristics (SPC).

12 In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to 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 the 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 product in the country of import;
   d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient
   e) Any other reason, please specify

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15 The requirement 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 Preparation, WHO Technical Report Series No. 823,1992 Annex 1 Recommendation specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series No. 822,1992 Annex 1).

16 This section is to be completed when the product- licence holder or applicant conforms to status (b) and (c) as described in the 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 exercise over each of these parties

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ANNEXURE-II

No. of Certificate : DD/793/11B/2020-1-211-I **Valid up to: 04/01/2022**

Name of the Product: Lomustine Capsule USP 40 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 of Guinea	196 United Arab Emirates
28 Burundi	69 Germany Federal Republic of[2]	111 Liechtonstoin	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:

Director Medical and Health Services,
Drugs Licensing Authority,
Administration of Daman and Diu.
DAMAN – 396 220.

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

Name of the 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

15 JUN 2020

CERTIFICATE OF PHARMACEUTICAL PRODUCTS[1]

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

No. of Certificate: **DD/793/24A/2020-1-211-I** — **Valid Up to: 04/01/2022**

Exporting (Certifying) Country		:	**India**
Importing (Requesting) Country		:	**As per Annexure-2**
1.	Name and dosage form of Product	:	**Melphalan Tablet BP 2 mg**
1.1	Active ingredient(s)[2] and amount(s) per unit dose[3]	:	**Composition:** **Each film coated tablet contains:** **Melphalan BP.....2 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 2 A and omit section 2 B		
	If the answer to 1.2 is no, omit section 2 A and continue section 2 B[6]		
2.A.1	Number of product licence[7] and date of issue	:	**DD/793 Dated 15/05/2019**
A.2	Product Licence holder (Name & Address)	:	**Bruck Pharma Pvt. Ltd.** **Survey No. 188/1 to 6, 189/1, 190/2 to 4,** **Atiyawad, Dabhel, Daman - 396210**
2.A.3	Status of product licence holder [8]	:	**a**
2.A.3.1	For categories b and c the name and address of the manufacturer producing the dosage form is[9]	:	**Not applicable**
2.A.4	Is a summary basis for approval appended?[10]	:	**No**
2.A.5	Is the attached, officially approved product information complete and consonant with the licence? [11]	:	**Not Provided**
2.A.6	Applicant for certificate, if different from licence holder (name and address)[12]	:	**Not Applicable**
2.B.1	Applicant for certificate (Name & Address)		**NA**
2.B.2	Status of applicant		**NA**
2.B.2.1	For categories (b) and (c) the name and address of the manufacturer producing the dosage form is: [9]	:	**NA**
2.B.3	Why is marketing authorization lacking?	:	**NA**
2.B.4	Remark [13]	:	**NA**

DRUGS LICENSING AUTHORITY ... U.T. OF DAMAN & DIU

	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable) [14]	:	**Yes**
	If Not or Not applicable proceed to question 4		
3.1	Periodicity of routine inspection (years)	:	**Yearly**
3.2	Has the manufacture of this type of dosage form been inspected ?	:	**Yes**
3.3	Do the facilities and operation confirm to GMP as recommended by 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	:	**Not Applicable**

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 and Date

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

0 1 JUL 2020

Explanatory notes:

1. This certificates 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 form 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 licence holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:

    a) Manufactures the dosage form;
    b) Packages and / or labels a dosage form manufactured by an independent company, or
    c) Is involved in none of the above.

9. The information can be provided only with the consent of the product licence holder or, in the case of non-registered products, the applicant, non-completion of the 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 licence. If the production site is changed, the licence must be updated or it is no longer valid.

10. This refers to the documents, 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 Product Characteristics (SPC).

12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to 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 the 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 product in the country of import;
    d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.
    e) Any other reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirement 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 Preparation, WHO Technical Report Series No. 823,1992 Annex 1. Recommendation specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series No. 822,1992 Annex 1).

16. This section is to be completed when the product- licence holder or applicant conforms to status (b) and (c) as described in the 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 exercise over each of these parties.

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ANNEXURE-II

No. of Certificate : DD/793/24A/2020-1-211-I **Valid up to: 04/01/2022**

Name of the Product: Melphalan Tablet BP 2 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. Uraine
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

0 1 JUL 2020

CERTIFICATE OF PHARMACEUTICAL PRODUCTS[1]

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

No. of Certificate: **DD/793/15B/2020-1-211-I** — **Valid Up to: 04/01/2022**

Exporting (Certifying) Country		:	**India**
Importing (Requesting) Country		:	**As per Annexure-2**
1.	Name and dosage form of Product	:	**Thalidomide Capsule USP 100 mg**
1.1	Active ingredient(s)[2] and amount(s) per unit dose[3]	:	**Composition:** **Each hard gelatin capsule contains:** **Thalidomide USP .....100mg** **Excipients.....q.s.** **Color: Approved color used in capsule shells.**
	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 2 A and omit section 2 B		
	If the answer to 1.2 is no, omit section 2 A and continue section 2 B[6]		
2.A.1	Number of product licence[7] and date of issue	:	**DD/793 Dated 14/10/2019**
2.A.2	Product Licence holder (Name & Address)	:	**Bruck Pharma Pvt. Ltd.** **Survey No. 188/1 to 6, 189/1, 190/2 to 4,** **Atiyawad, Dabhel, Daman - 396210**
2.A.3	Status of product licence holder [8]	:	**a**
2.A.3.1	For categories b and c the name and address of the manufacturer producing the dosage form is[9]	:	**Not applicable**
2.A.4	Is a summary basis for approval appended?[10]	:	**NO**
2.A.5	Is the attached, officially approved product information complete and consonant with the licence? [11]	:	**Not Provided**
2.A.6	Applicant for certificate, if different from licence holder (name and address)[12]	:	**Not Applicable**
2.B.1	Applicant for certificate (Name & Address)	:	**NA**
2.B.2	Status of applicant	:	**NA**
2.B.2.1	For categories (b) and (c) the name and address of the manufacturer producing the dosage form is: [9]	:	**NA**
2.B.3	Why is marketing authorization lacking?	:	**NA**
2.B.4	Remark [13]	:	**NA**
3	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable) [14]	:	**Yes**
	If Not or Not applicable proceed to question 4		
3.1	Periodicity of routine inspection (years)	:	**Yearly**
3.2	Has the manufacture of this type of dosage form been inspected ?	:	**Yes**
3.3	Do the facilities and operation confirm to GMP as recommended by 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	:	**Not Applicable**

LICENSING AUTHORITY — 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 and Date

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

15 JUN 2020

Explanatory notes:

1. This certificates 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 form 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 licence holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:

    a) Manufactures the dosage form;
    b) Packages and / or labels a dosage form manufactured by an independent company, or
    c) Is involved in none of the above.

9. The information can be provided only with the consent of the product licence holder or, in the case of non-registered products, the applicant, non-completion of the 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 licence. If the production site is changed, the licence must be updated or it is no longer valid.

10. This refers to the documents, 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 Product Characteristics (SPC).

12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to 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 the 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 product in the country of import;
    d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.
    e) Any other reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirement 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 Preparation, WHO Technical Report Series No. 823,1992 Annex 1. Recommendation specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series No. 822,1992 Annex 1).

16. This section is to be completed when the product- licence holder or applicant conforms to status (b) and (c) as described in the 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 exercise over each of these parties.

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ANNEXURE- II

No. of Certificate : DD/793/14B/2020-1-211-I **Valid up to: 04/01/2022**

Name of the Product: Thalidomide Capsule USP 50 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. Liechtonstoin	155. Republic of Maldives	197. United Kingdom
29. Byelorussia		112. Lithuania	156. Rumania	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	125. 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:

Director Medical and Health Services,
Drugs Licensing Authority,
Administration of Daman and Diu.
DAMAN – 396 220.

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

Name of the 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

15 JUN 2020

CERTIFICATE OF PHARMACEUTICAL PRODUCTS[1]

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

No. of Certificate: **DD/794/82C/2020-1-211-1** — **Valid Up to: 04/01/2022**

Exporting (Certifying) Country		:	**India**
Importing (Requesting) Country		:	**As per Annexure-II**
1.	Name and dosage form of Product	:	**MESNA INJECTION 400MG/4ML**
1.1	Active ingredient(s)[2] and amount(s) per unit dose[3]	:	**Composition:** **Each ml contains:** **Mesna USP.....100mg** **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 2 A and omit section 2 B

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

2.A.1	Number of product licence[7] and date of issue	:	**DD/794 Dated 09/10/2019**
2.A.2	Product Licence holder (Name & Address)	:	**Bruck Pharma Pvt. Ltd.** **Survey No. 188/1 to 6, 139/1, 190/2 to 4,** **Atiyawad, Dabhel, Daman - 396210**
2.A.3	Status of product licence holder [8]	:	**a**
2.A.3.1	For categories b and c the name and address of the manufacturer producing the dosage form is[9]	:	**Not applicable**
2.A.4	Is a summary basis for approval appended?[10]	:	**NO**
2.A.5	Is the attached, officially approved product information complete and consonant with the licence? [11]	:	**Not Provided**
2.A.6	Applicant for certificate, if different from licence holder (name and address)[12]	:	**Not Applicable**
2.B.1	Applicant for certificate (Name & Address)	:	**NA**
2.B.2	Status of applicant		
2.B.2.1	For categories (b) and (c) the name and address of the manufacturer producing the dosage form is: [9]	:	**NA**
2.B.3	Why is marketing authorization lacking?	:	**NA**
2.B.4	Remark [13]	:	**NA**

DRUG LICENSING AUTHORITY औषधि लाईसेंस प्राधिकारी DAMAN दमण UT OF DAMAN & DIU

3	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable) [14]	:	**Yes**

If Not or Not applicable proceed to question 4

3.1	Periodicity of routine inspection (years)	:	**Yearly**
3.2	Has the manufacture of this type of dosage form been inspected ?	:	**Yes**
3.3	Do the facilities and operation confirm to GMP as recommended by 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	:	**Not Applicable**

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 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

25 MAR 2021

Explanatory notes:

1. This certificates 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 form 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 licence holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:

    a) Manufactures the dosage form;
    b) Packages and / or labels a dosage form manufactured by an independent company, or
    c) Is involved in none of the above.

9. The information can be provided only with the consent of the product licence holder or, in the case of non-registered products, the applicant, non-completion of the 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 licence. If the production site is changed, the licence must be updated or it is no longer valid.

10. This refers to the documents, 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 Product Characteristics (SPC).

12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to 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 the 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 product in the country of import;
    d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.
    e) Any other reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirement 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 Preparation, WHO Technical Report Series No. 823,1992 Annex 1. Recommendation specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series No. 822,1992 Annex 1).

16. This section is to be completed when the product- licence holder or applicant conforms to status (b) and (c) as described in the 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 exercise over each of these parties

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ANNEXURE-II

No. of Certificate : DD/794/82C/2020-1-211-I **Valid up to: 04/01/2022**

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[1]
26. Bulgaria	68. German Democratic Republic[2]		153. Republic of Benin	
27. Burkina Faso		110. Liechtenstein	154. Republic of 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
दमण प्रदेश दमण एवं दीव, दमण

25 MAR 2021

CERTIFICATE OF PHARMACEUTICAL PRODUCTS[1]

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

No. of Certificate: **DD/794/14C/2020-1-211-I** — **Valid Up to: 04/01/2022**

Exporting (Certifying) Country		:	**India**
Importing (Requesting) Country		:	**As per Annexure-2**
1.	Name and dosage form of Product	:	**Vincristine sulphate Injection USP 1mg/1 ml**
1.1	Active ingredient(s)[2] and amount(s) per unit dose[3]	:	**Composition:** **Each ml contains:** **Vincristine sulphate 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 2 A and omit section 2 B

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

2.A.1	Number of product licence[7] and date of issue	:	**DD/794 Dated 16/08/2019**
2.A.2	Product Licence holder (Name & Address)	:	**Bruck Pharma Pvt. Ltd.** **Survey No. 188/1 to 6, 189/1, 190/2 to 4,** **Atiyawad, Dabhel, Daman - 396210**
2.A.3	Status of product licence holder [8]	:	**a**
2.A.3.1	For categories b and c the name and address of the manufacturer producing the dosage form is[9]	:	**Not applicable**
2.A.4	Is a summary basis for approval appended?[10]	:	**NO**
2.A.5	Is the attached, officially approved product information complete and consonant with the licence? [11]	:	**Not Provided**
2.A.6	Applicant for certificate, if different from licence holder (name and address)[12]	:	**Not Applicable**
2.B.1	Applicant for certificate (Name & Address)	:	**NA**
2.B.2	Status of applicant	:	**NA**
2.B.2.1	For categories (b) and (c) the name and address of the manufacturer producing the dosage form is: [9]	:	**NA**
2.B.3	Why is marketing authorization lacking?	:	**NA**
2.B.4	Remark [13]	:	**NA**

LICENSING AUTHORITY — 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/no/not applicable) [14]		**Yes**

If Not or Not applicable proceed to question 4

3.1	Periodicity of routine inspection (years)	:	**Yearly**
3.2	Has the manufacture of this type of dosage form been inspected ?	:	**Yes**
3.3	Do the facilities and operation confirm to GMP as recommended by 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	:	**Not Applicable**

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 and Date

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

15 JUN 2020

Explanatory notes:

1. This certificates 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 form 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 licence holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:

    a) Manufactures the dosage form;
    b) Packages and / or labels a dosage form manufactured by an independent company, or
    c) Is involved in none of the above.

9. The information can be provided only with the consent of the product licence holder or, in the case of non-registered products, the applicant, non-completion of the 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 licence. If the production site is changed, the licence must be updated or it is no longer valid.

10. This refers to the documents, 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 Product Characteristics (SPC).

12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to 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 the 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 product in the country of import;
    d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.
    e) Any other reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirement 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 Preparation, WHO Technical Report Series No. 823,1992 Annex 1. Recommendation specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series No. 822,1992 Annex 1).

16. This section is to be completed when the product- licence holder or applicant conforms to status (b) and (c) as described in the 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 exercise over each of these parties.

****

NNEXURE-II

No. of Certificate : DD/794/14C/2020-1-211-I **Valid up to: 04/01/2022**

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

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[3]
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
दमण एवं दीव, दमण

15 JUN 2020

CERTIFICATE OF PHARMACEUTICAL PRODUCTS[1]

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

No. of Certificate: **DD/793/12B/2020-1-211-I** — **Valid Up to: 04/01/2022**

Exporting (Certifying) Country		:	**India**
Importing (Requesting) Country		:	**As per Annexure-2**
1	Name and dosage form of Product	:	**Procarbazine Hydrochloride Capsule USP 50 mg**
1 1	Active ingredient(s)[2] and amount(s) per unit dose[3]	:	**Composition:** **Each capsule contains:** **Procarbazine hydrochloride USP equivalent to Procarbazine .....50mg** **Excipients.....q.s.** **Color: Approved color used in capsule shells.**
	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 2 A and omit section 2 B

If the answer to 1 2 is no, omit section 2 A and continue section 2 B[6]

2.A.1	Number of product licence[7] and date of issue	:	**DD/793 Dated 19/01/2019**
..A.2	Product Licence holder (Name & Address)	:	**Bruck Pharma Pvt. Ltd.** **Survey No. 188/1 to 6, 189/1, 190/2 to 4,** **Atiyawad, Dabhel, Daman - 396210**
2 A 3	Status of product licence holder [8]	:	**a**
2 A 3 1	For categories b and c the name and address of the manufacturer producing the dosage form is[9]	:	**Not applicable**
2 A 4	Is a summary basis for approval appended?[10]	:	**NO**
2.A 5	Is the attached, officially approved product information complete and consonant with the licence? [11]	:	**Not Provided**
2 A 6	Applicant for certificate, if different from licence holder (name and address)[12]	:	**Not Applicable**
2 B 1	Applicant for certificate (Name & Address)	:	**NA**
2 B 2	Status of applicant	:	**NA**
2 B 2 1	For categories (b) and (c) the name and address of the manufacturer producing the dosage form is: [9]	:	**NA**
2.B 3	Why is marketing authorization lacking?	:	**NA**
2.B 4	Remark [13]	:	**NA**

LICENSING AUTHORITY ... U.T. OF DAMAN & DIU

Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable) [14] : **Yes**

If Not or Not applicable proceed to question 4

3 1	Periodicity of routine inspection (years)	:	**Yearly**
3 2	Has the manufacture of this type of dosage form been inspected ?	:	**Yes**
3 3	Do the facilities and operation confirm to GMP as recommended by 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	:	**Not Applicable**

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

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

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

15 JUN 2020

Explanatory notes:

1. This certificates 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 form 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 licence holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:

   a) Manufactures the dosage form;
   b) Packages and / or labels a dosage form manufactured by an independent company, or
   c) Is involved in none of the above.

9. The information can be provided only with the consent of the product licence holder or, in the case of non-registered products, the applicant, non-completion of the 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 licence. If the production site is changed, the licence must be updated or it is no longer valid.

10. This refers to the documents, 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 Product Characteristics (SPC).

12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to 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 the 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 product in the country of import;
   d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.
   e) Any other reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirement 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 Preparation, WHO Technical Report Series No. 823,1992 Annex 1. Recommendation specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series No. 822,1992 Annex 1).

16. This section is to be completed when the product- licence holder or applicant conforms to status (b) and (c) as described in the 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 exercise over each of these parties.

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ANNEXURE- II

No. of Certificate : DD/793/12B/2020-1-211-I **Valid up to: 04/01/2022**

Name of the Product: Procarbazine Hydrochloride Capsule USP 50 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	89. Italy	132. Nepal	175. Suriname
6. Armenia	of Congo	90. Ivory Coast	133. Netherlands Antilles	176. Swaziland
7. Aruba	49. Denmark	91. Jamaica	134. Netherlands	177. Sweden
8. Australia	50. Djibouti	92. Japan	135. New Zealand	178. Switzerland
9. Austria	51. Dominica	93. Jordan	136. Nicaragua	179. Syria
10. Azerbaijan	52. Dominican Republic	94. Kazakhstan	137. Niger	180. Tadzhikistan
11. Bahamas	53. Ecuador	95. Kenya	138. Nigeria	181. Taiwan
12. Bahrain	54. Egypt	96. Kingdom of Tonga	139. North Korea	182. Tajikistan
13. Baltic	55. El Salvador	97. Kiribati	140. Norway	183. Tanzania
14. Bangladesh	56. Equatorial Guinea	98. Korea	141. Oman	184. Thailand
15. Barbados	**57. Eritrea**	99. Korea Republic of	142. Pakistan	185. Tobago
16. Belarus	**58. Estonia**	100. Kosova	143. Palau	186. Togo
17. Belgium	59. Ethiopia	101. Kuwait	144. Panama	187. Tonga
18. Belize	60. European Community	102. Kyrgyzstan	145. Papua New Guinea	188. Trinidad
19. Benin	61. Fiji	103. Laos	146. Paraguay	189. Tunisia
20. Bhutan	62. Finland	104. Latvia	147. Peru	190. Turkey
21. Bolivia	63. France	105. Lebanon	148. Puerto Rico	191. Turkmenistan
22. Bosnia	64. Gabon	106. Lesotho	149. Philippines	192. UAE
23. Botswana	65. Gambia	107. Liberia	150. Poland	193. Uganda
24. Brazil	66. Guatemala	108. Libya	151. Portugal	194. Ukraine
25. Brunei	67. Georgia	109. Libyan Arab	152. Qatar	195. Union of Soviet
26. Bulgaria	68. German Democratic	Jamahiriya	153. Republic of Benin	Socialist Republics[1]
27. Burkina Faso	Republic[2]	110. Liechtenstein	154. Republic de Guin	[illegible]ited Arab Emirates
28. Burundi	69. Germany Federal	111. Liechtenstein	155. Republic of [illegible]	197. United Kingdom
29. Byelorussia	Republic of[2]	112. Lithuania	156. Romania	198. United States
30. Cambodia	70. Germany	113. Luxembourg	157. Russia	199. Uruguay
31. Cameroon	71. Ghana	114. Macau	158. Rwanda	200. USA
32. Canada	72. Greece	115. Madagascar	159. Saudi Arabia	201. Uzbekistan
33. Central African	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
Republic	74. Guinea	117. Malaysia	161. Serbia and	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives	Montenegro	204. Vietnam
35. Chile	76. Guyana	119. Mali	162. Seychelles	205. West Indies
36. China	77. Haiti	120. Malta	163. Sierra Leone	206. World
37. Cook Islands	78. Holland	121. Marshall Islands	164. Singapore	207. Yemen
38. Colombia	79. Honduras	122. Mauritania	165. Slovakia	208. Yugoslavia
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:

Director Medical and Health Services,
Drugs Licensing Authority,
Administration of Daman and Diu.
DAMAN – 396 220.

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

Name of the 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

15 JUN 2020

CERTIFICATE OF PHARMACEUTICAL PRODUCTS[1]

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

No. of Certificate: **DD/793/29A/2020-1-211-I** — **Valid Up to: 04/01/2022**

Exporting (Certifying) Country		:	India
Importing (Requesting) Country		:	As per Annexure-II
1.	Name and dosage form of Product	:	SORAFENIB TABLET 200MG
1.1	Active ingredient(s)[2] and amount(s) per unit dose[3]	:	Composition: Each film coated tablet contains: Sorafenib Tosylate Eq. to Sorafenib.....200mg Excipients..... q.s. Colors: 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 2 A and omit section 2 B

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

2.A.1	Number of product licence[7] and date of issue	:	DD/793 Dated 21/03/2020
2.A.2	Product Licence holder (Name & Address)	:	Bruck Pharma Pvt. Ltd. Survey No. 188/1 to 6, 189/1, 190/2 to 4, Atiyawad, Dabhel, Daman - 396210
2.A.3	Status of product licence holder [8]	:	a
2.A.3.1	For categories b and c the name and address of the manufacturer producing the dosage form is[9]	:	Not applicable
2.A.4	Is a summary basis for approval appended?[10]	:	NO
2.A.5	Is the attached, officially approved product information complete and consonant with the licence? [11]	:	Not Provided
2.A.6	Applicant for certificate, if different from licence holder (name and address)[12]		Not Applicable
2.B.1	Applicant for certificate (Name & Address)		NA
2.B.2	Status of applicant		NA
2.B.2.1	For categories (b) and (c) the name and address of the manufacturer producing the dosage form is: [9]	:	NA
2.B.3	Why is marketing authorization lacking?	:	NA
2.B.4	Remark [13]	:	NA

LICENSING AUTHORITY ... 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/no/not applicable) [14]	:	Yes

If Not or Not applicable proceed to question 4

3.1	Periodicity of routine inspection (years)	:	Yearly
3.2	Has the manufacture of this type of dosage form been inspected ?	:	Yes
3.3	Do the facilities and operation confirm to GMP as recommended by 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	:	Not Applicable

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

25 MAR 2021

Name of Authorized: DRUGS LICENSING AUTHORITY

Signature
Stamp and Date: DRUGS CONTROL DEPARTMENT ... UT OF DAMAN & DIU DAMAN

Explanatory notes:

1. This certificates 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 form 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 licence holder.

5. When applicable, append details of any restriction applied to the sale. distribution or administration of the product that is specified in the product licence.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:

   a) Manufactures the dosage form;
   b) Packages and / or labels a dosage form manufactured by an independent company, or
   c) Is involved in none of the above.

9. The information can be provided only with the consent of the product licence holder or, in the case of non-registered products, the applicant, non-completion of the 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 licence. If the production site is changed, the licence must be updated or it is no longer valid.

10. This refers to the documents, 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 Product Characteristics (SPC).

12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to 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 the 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 product in the country of import;
    d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.
    e) Any other reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirement 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 Preparation, WHO Technical Report Series No. 823,1992 Annex 1. Recommendation specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series No. 822,1992 Annex 1).

16. This section is to be completed when the product- licence holder or applicant conforms to status (b) and (c) as described in the 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 exercise over each of these parties.

***

ANNEXURE-II

No. of Certificate : DD/793/29A/2020-1-211-I **Valid up to: 04/01/2022**

Name of the Product: SORAFENIB TABLET 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. Swazilanc
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 of 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

25 MAR 2021

CERTIFICATE OF PHARMACEUTICAL PRODUCTS[1]

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

No. of Certificate: **DD/793/15A/2020/-1-211-I** — Valid Up to: **04/01/2022**

	Exporting (Certifying) Country	:	**India**
	Importing (Requesting) Country	:	**As per Annexure-2**
1	Name and dosage form of Product	:	**Chlorambucil Tablet BP 2 mg**
1.1	Active ingredient(s)[2] and amount(s) per unit dose[3]	:	**Composition:** **Each film coated tablet contains:** **Chlorambucil BP .....2mg** **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 2 A and omit section 2 B		
	If the answer to 1.2 is no, omit section 2 A and continue section 2 B[6]		
2.A.1	Number of product licence[7] and date of issue	:	**DD/793 Dated 15/05/2019**
2.A.2	Product Licence holder (Name & Address)	:	**Bruck Pharma Pvt. Ltd.** **Survey No. 188/1 to 6, 189/1, 190/2 to 4,** **Atiyawad, Dabhel, Daman - 396210**
2.A.3	Status of product licence holder [8]	:	**a**
2.A.3.1	For categories b and c the name and address of the manufacturer producing the dosage form is[9]	:	**Not applicable**
2.A.4	Is a summary basis for approval appended?[10]	:	**NO**
2.A.5	Is the attached, officially approved product information complete and consonant with the licence? [11]	:	**Not applicable**
2.A.6	Applicant for certificate, if different from licence holder (name and address)[12]	:	**Not Applicable**
2.B.1	Applicant for certificate (Name & Address)	:	**NA**
2.B.2	Status of applicant	:	**NA**
2.B.2.1	For categories (b) and (c) the name and address of the manufacturer producing the dosage form is: [9]	:	**NA**
2.B.3	Why is marketing authorization lacking?	:	**NA**
2.B.4	Remark [13]	:	**NA**
3	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable)[14]	:	**Yes**
	If Not or Not applicable proceed to question 4		
3.1	Periodicity of routine inspection (years)	:	**Yearly**
3.2	Has the manufacture of this type of dosage form been inspected ?	:	**Yes**
3.3	Do the facilities and operation confirm to GMP as recommended by 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	:	**Not Applicable**

LICENSING AUTHORITY ... 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 and Date

15 JUN 2020

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

Explanatory notes:

1. This certificates 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 form 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 licence holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:

    a) Manufactures the dosage form;
    b) Packages and / or labels a dosage form manufactured by an independent company, or
    c) Is involved in none of the above.

9. The information can be provided only with the consent of the product licence holder or, in the case of non-registered products, the applicant, non-completion of the 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 licence. If the production site is changed, the licence must be updated or it is no longer valid.

10. This refers to the documents, 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 Product Characteristics (SPC).

12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to 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 the 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 product in the country of import;
    d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.
    e) Any other reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirement 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 Preparation, WHO Technical Report Series No. 823,1992 Annex 1. Recommendation specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series No. 822,1992 Annex 1).

16. This section is to be completed when the product- licence holder or applicant conforms to status (b) and (c) as described in the 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 exercise over each of these parties.

****

ANNEXURE- II

No. of Certificate : DD/793/15A/2020-1-211-1 **Valid up to: 04/01/2022**

Name of the Product: Chlorambucil Tablet BP 2 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. Philippines	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 Albania	
27 Burkina Faso		110. Liechtenstein	154. Republic of Guinea	196 United Arab Emirates
28 Burundi	69 Germany Federal Republic of[2]	111. Liechtonstoin	155. Republic of Kazakhstan	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:

Director Medical and Health Services,
Drugs Licensing Authority,
Administration of Daman and Diu.
DAMAN – 396 220.

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

Name of the authorized person: Dr. S. S. 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

15 JUN 2020

CERTIFICATE OF PHARMACEUTICAL PRODUCTS[1]

This certificate conforms to the format recommended by the World Health Organizat on

No. of Certificate: **DD/794/44C/2020-1-211-I** — **Valid Up to: 04/01/2022**

Exporting (Certifying) Country		:	**India**
Importing (Requesting) Country		:	**As per Annexure-2**
1	Name and dosage form of Product	:	**Cytarabine Injection BP 1000mg/10 ml**
1.1	Active ingredient(s)[2] and amount(s) per unit dose[3]	:	**Composition:** **Each ml contains:** **Cytarabine BP 100mg**
	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 2.A and omit section 2.B		
	If the answer to 1.2 is no, omit section 2.A and continue section 2.B[6]		
2.A.1	Number of product licence[7] and date of issue	:	**DD/794 Dated 05/08/2019**
2.A.2	Product Licence holder (Name & Address)	:	**Bruck Pharma Pvt. Ltd.** **Survey No. 188/1 to 6, 189/1, 190/2 to 4,** **Atiyawad, Dabhel, Daman - 396210**
2.A.3	Status of product licence holder [8]	:	**a**
2.A.3.1	For categories b and c the name and address of the manufacturer producing the dosage form is[9]	:	**Not applicable**
2.A.4	Is a summary basis for approval appended?[10]	:	**NO**
2.A.5	Is the attached, officially approved product information complete and consonant with the licence? [11]	:	**Not Provided**
2.A.6	Applicant for certificate, if different from licence holder (name and address)[12]	:	**Not Applicable**
2.B.1	Applicant for certificate (Name & Address)	:	**NA**
2.B.2	Status of applicant	:	**NA**
2.B.2.1	For categories (b) and (c) the name and address of the manufacturer producing the dosage form is: [9]	:	**NA**
2.B.3	Why is marketing authorization lacking?	:	**NA**
2.B.4	Remark [13]	:	**NA**
3	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable) [14]	:	**Yes**
	If Not or Not applicable proceed to question 4		
3.1	Periodicity of routine inspection (years)	:	**Yearly**
3.2	Has the manufacture of this type of dosage form been inspected ?	:	**Yes**
3.3	Do the facilities and operation confirm to GMP as recommended by 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	:	**Not Applicable**

LICENSING AUTHORITY
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 and Date

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

15 JUN 2020

Explanatory notes:

1. This certificates which is in the formal 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 form 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 apperided.

4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product licence holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:

    a) Manufactures the dosage form;
    b) Packages and / or labels a dosage form manufactured by an independent company, or
    c) Is involved in none of the above.

9. The information can be provided only with the consent of the product licence holder or, in the case of non-registered products, the applicant, non-completion of the 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 licence. If the production site is changed, the licence must be updated or it is no longer valid.

10. This refers to the documents, 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 Product Characteristics (SPC).

12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to 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 the 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 product in the country of import;
    d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.
    e) Any other reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture

15. The requirement 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 Preparation, WHO Technical Report Series No. 823,1992 Annex 1. Recommendation specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series No. 822,1992 Annex 1).

16. This section is to be completed when the product- licence holder or applicant conforms to status (b) and (c) as described in the 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 exercise over each of these parties.

****

ANNEXURE- II

No. of Certificate : DD/794/44C/2020-1-211-I **Valid up to: 04/01/2022**

Name of the Product: Cytarabine Injection BP 1000mg/10 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 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 of Guinea	196 United Arab Emirates
28 Burundi	69 Germany Federal Republic of[2]	111 Liechtenstein	155 Republic of Malawi	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:

Director Medical and Health Services,
Drugs Licensing Authority,
Administration of Daman and Diu.
DAMAN – 396 220.

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

Name of the 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

15 JUN 2020

CERTIFICATE OF PHARMACEUTICAL PRODUCTS[1]

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

No of Certificate: **DD/794/37C/2020-1-211-I** — **Valid Up to: 04/01/2022**

Exporting (Certifying) Country		:	**India**
Importing (Requesting) Country		:	**As per Annexure-2**
1	Name and dosage form of Product	:	**Doxorubicin Hydrochloride Injection USP 10mg/5 ml**
1.1	Active ingredient(s)[3] and amount(s) per unit dose[3]	:	**Composition:** **Each ml contains:** **Doxorubicin hydrochloride USP .....2mg** **Sodium Chloride USP .....9 mg** **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 2 A and omit section 2 B		
	If the answer to 1.2 is no, omit section 2 A and continue section 2 B[6]		
2.A.1	Number of product licence[7] and date of issue	:	**DD/794 Dated 16/08/2019**
2.A.2	Product Licence holder (Name & Address)	:	**Bruck Pharma Pvt. Ltd.** **Survey No. 188/1 to 6, 189/1, 190/2 to 4,** **Atiyawad, Dabhel, Daman - 396210**
2.A.3	Status of product licence holder [8]	:	**a**
2.A.3.1	For categories b and c the name and address of the manufacturer producing the dosage form is[9]	:	**Not applicable**
2.A.4	Is a summary basis for approval appended?[10]	:	**N**
2.A.5	Is the attached, officially approved product information complete and consonant with the licence? [11]	:	**Not provided**
2.A.6	Applicant for certificate, if different from licence holder (name and address)[12]	:	**Not Applicable**
2.B.1	Applicant for certificate (Name & Address)	:	**NA**
2.B.2	Status of applicant	:	**NA**
2.B.2.1	For categories (b) and (c) the name and address of the manufacturer producing the dosage form is. [9]	:	**NA**
2.B.3	Why is marketing authorization lacking?	:	**NA**
2.B.4	Remark [13]	:	**NA**

LICENSING AUTHORITY ... 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/no/not applicable) [14]	:	**Yes**
	If Not or Not applicable proceed to question 4		
3.1	Periodicity of routine inspection (years)	:	**Yearly**
3.2	Has the manufacture of this type of dosage form been inspected ?	:	**Yes**
3.3	Do the facilities and operation confirm to GMP as recommended by 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	:	**Not Applicable**

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 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

15 JUN 2020

Explanatory notes:

1. This certificates 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 form 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 licence holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:

    a) Manufactures the dosage form,
    b) Packages and / or labels a dosage form manufactured by an independent company, or
    c) Is involved in none of the above.

9. The information can be provided only with the consent of the product licence holder or, in the case of non-registered products, the applicant, non-completion of the 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 licence. If the production site is changed, the licence must be updated or it is no longer valid.

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11. This refers to product information approved by the competent national regulatory authority, such as a Summary Product Characteristics (SPC).

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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 the 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 product in the country of import;
    d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.
    e) Any other reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirement 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 Preparation, WHO Technical Report Series No. 823,1992 Annex 1. Recommendation specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series No. 822,1992 Annex 1).

16. This section is to be completed when the product- licence holder or applicant conforms to status (b) and (c) as described in the 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 exercise over each of these parties.

****

ANNEXURE- II

No. of Certificate : DD/794/37C/2020-1-211-1 **Valid up to: 04/01/2022**

Name of the Product: Doxorubicin Hydrochloride Injection USP 10mg/5 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 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 Liechtonstoin	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:

Director Medical and Health Services,
Drugs Licensing Authority,
Administration of Daman and Diu.
DAMAN – 396 220.

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

Name of the authorized person: Dr. V. K. Jha

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

15 JUN 2020

CERTIFICATE OF PHARMACEUTICAL PRODUCTS[1]

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

No of Certificate: **DD/794/20C/2020-1-211-I** — **Valid Up to: 04/01/2022**

Exporting (Certifying) Country		:	**India**
Importing (Requesting) Country		:	**As per Annexure-2**
1	Name and dosage form of Product	:	**Eprubicin Hydrochloride for Injection 10mg/vial**
1.1	Active ingredient(s)[2] and amount(s) per unit dose[3]	:	**Composition:** **Each vial contains:** **Epirubicin hydrochloride .....10mg** **Lactose monohydrate.....50 mg**
	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 2 A and omit section 2 B		
	If the answer to 1.2 is no, omit section 2 A and continue section 2 B[6]		
2.A.1	Number of product licence[7] and date of issue	:	**DD/794 Dated 11/12/2019**
2.A.2	Product Licence holder (Name & Address)	:	**Bruck Pharma Pvt. Ltd.** **Survey No. 188/1 to 6, 189/1, 190/2 to 4,** **Atiyawad, Dabhel, Daman - 396210**
2.A.3	Status of product licence holder [8]	:	**a**
2.A.3.1	For categories b and c the name and address of the manufacturer producing the dosage form is[9]	:	**Not applicable**
2.A.4	Is a summary basis for approval appended?[10]	:	**NO**
2.A.5	Is the attached, officially approved product information complete and consonant with the licence? [11]	:	**Not applicable**
2.A.6	Applicant for certificate, if different from licence holder (name and address)[12]	:	**Not applicable**
2.B.1	Applicant for certificate (Name & Address)	:	**NA**
2.B.2	Status of applicant	:	**NA**
2.B.2.1	For categories (b) and (c) the name and address of the manufacturer producing the dosage form is: [9]	:	**NA**
2.B.3	Why is marketing authorization lacking?	:	**NA**
2.B.4	Remark: [13]	:	**NA**
3	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable) [14]	:	**Yes**
	If Not or Not applicable proceed to question 4		
3.1	Periodicity of routine inspection (years)	:	**Yearly**
3.2	Has the manufacture of this type of dosage form been inspected ?	:	**Yes**
3.3	Do the facilities and operation confirm to GMP as recommended by 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	:	**Not Applicable**

DRUG LICENSING AUTHORITY ... 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 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

15 JUN 2020

Explanatory notes:

1. This certificates 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 form 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 licence holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:

    a) Manufactures the dosage form;
    b) Packages and / or labels a dosage form manufactured by an independent company, or
    c) Is involved in none of the above.

9. The information can be provided only with the consent of the product licence holder or, in the case of non-registered products, the applicant, non-completion of the 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 licence. If the production site is changed, the licence must be updated or it is no longer valid.

10. This refers to the documents, 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 Product Characteristics (SPC).

12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to 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 the 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 product in the country of import;
    d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient
    e) Any other reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirement 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 Preparation, WHO Technical Report Series No. 823,1992 Annex 1. Recommendation specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series No. 822,1992 Annex 1).

16. This section is to be completed when the product- licence holder or applicant conforms to status (b) and (c) as described in the 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 exercise over each of these parties.

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ANNEXURE-II

No. of Certificate : DD/794/20C/2020-1-211-1 **Valid up to: 04/01/2022**

Name of the Product: Eprubicin 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	89. Italy	132. Nepal	175. Suriname
6. Armenia	of Congo	90. Ivory Coast	133. Netherlands Antilles	176. Swaziland
7. Aruba	49. Denmark	91. Jamaica	134. Netherlands	177. Sweden
8. Australia	50. Djibouti	92. Japan	135. New Zealand	178. Switzerland
9. Austria	51. Dominica	93. Jordan	136. Nicaragua	179. Syria
10. Azerbaijan	52. Dominican Republic	94. Kazakhstan	137. Niger	180. Tadzhikistan
11. Bahamas	53. Ecuador	95. Kenya	138. Nigeria	181. Taiwan
12. Bahrain	54. Egypt	96. Kingdom of Tonga	139. North Korea	182. Tajikistan
13. Baltic	55. El Salvador	97. Kiribati	140. Norway	183. Tanzania
14. Bangladesh	56. Equatorial Guinea	98. Korea	141. Oman	184. Thailand
15. Barbados	57. Eritrea	99. Korea Republic of	142. Pakistan	185. Tobago
16. Belarus	58. Estonia	100. Kosova	143. Palau	186. Togo
17. Belgium	59. Ethiopia	101. Kuwait	144. Panama	187. Tonga
18. Belize	60. European Community	102. Kyrgyzstan	145. Papua New Guinea	188. Trinidad
19. Benin	61. Fiji	103. Laos	146. Paraguay	189. Tunisia
20. Bhutan	62. Finland	104. Latvia	147. Peru	190. Turkey
21. Bolivia	63. France	105. Lebanon	148. Puerto Ri[illegible]	191. Turkmenistan
22. Bosnia	64. Gabon	106. Lesotho	149. Philip[illegible]	[illegible]
23. Botswana	65. Gambia	107. Liberia	150. Pol[illegible]	[illegible]
24. Brazil	66. Guatemala	108. Libya	151. [illegible]	[illegible]
25. Brunei	67. Georgia	109. Libyan Arab	152. [illegible]	193. Union of Soviet
26. Bulgaria	68. German Democratic	Jamahiriya	153. Republic of Benin	Socialist Republics[1]
27. Burkina Faso	Republic[2]	110. Liechtenstein	154. Republic de Guinee	196. United Arab Emirates
28. Burundi	69. Germany Federal	111. Liechtonstoin	155. Republic of Maldive	197. United Kingdom
29. Byelorussia	Republic of[2]	112. Lithuania	156. Romania	198. United States
30. Cambodia	70. Germany	113. Luxembourg	157. Russia	199. Uruguay
31. Cameroon	71. Ghana	114. Macau	158. Rwanda	200. USA
32. Canada	72. Greece	115. Madagascar	159. Saudi Arabia	201. Uzbekistan
33. Central African	73. Grenada	116. Malawi	160. Sene[illegible]	202. Vanuatu
Republic	74. Guinea	117. Malaysia	161. Serbia and	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives	Montenegro	204. Vietnam
35. Chile	76. Guyana	119. Mali	162. Seychelles	205. West Indies
36. China	77. Haiti	120. Malta	163. Sierra Leone	206. World
37. Cook Islands	78. Holland	121. Marshall Islands	164. Singapore	207. Yemen
38. Colombia	79. Honduras	122. Mauritania	165. Slovakia	208. Yugoslavia[1]
39. Columbia	80. Hong Kong	123. Mauritius	166. Slovenia	209. Zaire
40. Congo	81. Hungary	124. Mexico	167. Solomon Islands	210. Zambia
41. Costa Rica	82. Iceland	125. Moldova	168. Somalia	211. Zimbabwe
42. Council of Europe	83. India	126. Monaco	169. Somaliland	
43. Croatia	84. Indonesia	127. Mongolia	170. South Africa	

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

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

Signature
Stamp & Date

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
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15 JUN 2020