# 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

रमण/Daman

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 CERTIFICATIONS WHITE UP TO THREE YEARS FROM THE DATE OF ISSUE.

(DR. V. K. DAS)

DIRECTOR,

MEDICAL & HEALTH SERVICES

DRUGS LICENSING AUTHORITY,

UT OF DAMAN & DIU,

DAMAN.

| No o    | f Certificate: DD/793/11B/2020-1-211-1  | Valid Up to: 04/01/2        | 2022                                      |
|---------|---|-----------------------------|---|
| Expo    | rting (Certifying) Country  | ; India                     |   |
| Impo    | rling (Requesting) Country  | : As per Annexure           | s-2                                       |
| 1       | Name and dosage form of Product   | : Lomustine Capsi           |   |
| 11      | Active ingredient(s)2 and amount(s) per unit dose3  | : Composition:              | ore est to mg                             |
|         | ·   | Each capsule con            | itains:                                   |
|         |   | Lomustine USP.              | 40mg                                      |
|         |   | Excipients                  | color used in capsule shells.             |
|         | For complete qualitative composition including excipient  | ts, see attached! Annex     | ure - I                                   |
| 1.2     | Is this product licensed to be placed on the market for use   | e in the exporting country? | Yes                                       |
| 13      | Is this product actually on the market in the exporting con   |                             | : Yes                                     |
|         | If the answer to 12 is yes, continue with section 2 A and   |                             |   |
|         | If the answer to 1 2 is no, omit section 2 A and continue s   | section 2 B <sup>6</sup>    |   |
| 2 A I   | Number of product licence <sup>7</sup> 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, 1.39/1, 190/2 to 4 |
|         |   |                             | Atiyawad, Dabhel, Daman - 396210          |
| 2 A 3   | Status of product licence holder 8  |                             |   |
| 2 A.3 1 | For categories b and c the name and address of the manufidosage form is?                                      | acturer producing the       | : Not applicable                          |
| 2.A.4   | Is a summary basis for approval appended?10   |                             | SING AUTO                                 |
| 2 A 5   | Is the attached, officially approved product information or with the licence? 11                              | emplete and consonant       | Ser regions (1)                           |
| 2.A 6   | Applicant for certificate, if different from licence holder (i  | name and address)12         | Nor Associated                            |
| 2 B I   | Applicant for certificate (Name & Address)  |                             |   |
| 2 B 2   | Status of applicant   |                             | NA. 0094 3002                             |
| 2B21    | For categories (b) and (c) the name and address of the mandosage form is: 9                                   | nufacturer producing the    | NE THUI COMMA                             |
| 2 B 3   | Why is marketing authorization lacking?   |                             | Nor and the second                        |
| 2 B 4   | Remark 13   |                             | UAMAN                                     |
| _       |   |                             |   |
| 3       | Does the certifying authority arrange for periodic inspectio<br>form is produced? (yes/no/not applicable) 14  | n of the manufacturing pla  | ant in which the dosage : 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 inspe  | ected?                      | : Yes                                     |
| 3 3     | Do the facilities and operation confirm to GMP as recomme Organization ? <sup>15</sup>                        | ended by World Health       | : Yes                                     |
| ļ       | Does the information submitted by the applicant satisfy the all aspects of the manufacture of the product ?16 | certifying authority on     | : Yes                                     |
|         | If No, exptain  |                             | : Not Applicable                          |
|         | Address of certifying authority Drug Licensing Authority,   |                             |   |
|         | Administration of Daman & Diu, Drugs Control Dept   |                             | gr.                                       |
|         | Frimary Health Center, Daman (UT) = 396 220.  |                             | · interest in the second                  |
|         | Telephone No. : 0091 0260 2230470<br>Fax No. : 0091 0260 2230570  |                             |   |
|         | Out out - Aurig/U   | Name of Authori             | zed Person: Dr. V.K. DAS                  |
|         |   |                             | DELICE LICENSING ALTOLOGOPH               |

Signature Stamp and Date

भीषमी लाईहेंस प्रतिकारी DRUGS CONTROL DEPARTMENT

্রীষ্টা নির্মাস রিমাস 1 5 JUN 20 UT OF DAMAN & DIU, DAMAN

- 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.
- 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 posted 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.
  - 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).
- 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/793/11B/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            | #30 Myanmar                                | 173. Sri Lanka               |
| 4 Angola             | 47. Czechoslovakia     | 88 Israel             | 131 Namibia                                | 174 Sudan                    |
| 5 Argentina          | 48 Democratic Republic | 89 Italy              | 132 Nepal                                  | 175 Suriname                 |
| 6 Amenia             | of Congo               | 90 Ivory Coast        | \$33 Netherlands Antilles                  | 176 Swaziland                |
| 7 Aruba              | 49 Denmark             | 91 Jamaica            | 134 Netherlands                            | 177 Sweden                   |
| 8 Australia          | 50 Diibouti            | 92 Japan              | 135. New Zcaland                           | 178 Switzerland              |
| 9 Austria            | 51 Dominica            | 93 Jordan             | 136 Nicaragua                              | 179 Syria                    |
| 10 Azerbaijan        | 52 Dominican Republic  | 94 Kazakhstan         | 137 Niger                                  | 180 Tadzhikistan             |
| 11 Baharnas          | 53 Ecuador             | 95 Kenya              | 138 Nigeria                                | 181 Таіwал                   |
| 12, Bahrain          | 54 Egypt               | 96 Kingdom of Tonga   | 139. North Korea                           | #82_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            | [1]] Julius                                | 186. Togo                    |
| 17 Belgium           | 59 Ethiopia            | 101 Kuwait            | 14 Maria New Maria Nation 146 Thanking 175 | 187. Tonga                   |
| 18 Belize            | 60 European Community  | 102 Kyrgyzstan        | TAR PARKE NOW HUMBY                        | 188 Trinidad                 |
| 19 Benin             | 61, Fiji               | 103 Laos              | 46 Planting/75                             | 189 Tunisia                  |
| 20. Bhutan           | 62 Finland             | 04 Latvia             | 147 Penu                                   |                              |
| 21 Bolivia           | 63 France              | 105 Lebanon           | 148 Puerto Teico                           | 91 Turkmenistan              |
| 22 Bosnia            | 64 Gabon               | 106 Lesotho           | 149 Philippines                            | )2 UAE                       |
| 23 Botswana          | 65, Gambia             | 107. Libería 💆 🛡      | \$50. Poland う                             | )3. Uganda                   |
| 24 Brazil            | 66 Guatemala           | 108. Libya            | 151 Portugal                               | 94 Ukraine                   |
| 25 Brunei            | 67 Georgia             | 109, Libyun Arab 👠    | 152 Quar                                   | 95. Liuwn of Soves           |
| 26. Bulgaria         | 68 German Democratic   | lamahiriya            | Republic of Brown                          | Socialist Republics          |
| 27. Burkina Faso     | Republic <sup>2</sup>  | 110. Liechtenstein    | SA: Republic de Ouing                      | 196 United Arab Emirates     |
| 28 Burundi           | 69. Germany Federal    | 111, Liochtonstoin    | 175. Hepublic of Mahave                    | 197 United Kingdom           |
| 29 Byelorussia       | Republic of            | 112 Lilhuania         | To MANAGATI                                | 198 United States            |
| 30 Cambodia          | 70. Germany            | 113 Luxembourg        | 157. Rively                                | 199 Uniguay                  |
| 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, Malawî           | 160, Senegai                               | 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 Indics             |
| 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 <sup>1</sup> |
| 39 Columbia          | 80. Hong Kong          | 123 Mauritius         | 166 Slovenia                               | 209, Zaire                   |
| 40 Congo             | 81. Huneary            | 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 Monaço            | 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 d

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

Signature:

जीवची लाईसेंस प्राधिकारी DRUGS CONTROL DEPARTMENT औचची नियंत्रण विभाग

UT OF DAMAN & DIU, DAMAN

Stamp and date:

सच प्रदेश दमन एवं दीव, दमन

1 5 JUN 2020

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 Name and dosage form of Product Melphalan Tablet BP 2 mg 1.1 Active ingredient(s)2 and amount(s) per unit dose3 Composition: Each film coated tablet contains: Melphalan BP......2 mg Excipients......q.s. For complete qualitative composition including excipients, see attached4. Annexure - I 1.2 Is this product licensed to be placed on the market for use in the exporting country?5 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 B6 2.A.1 Number of product licence<sup>7</sup> and date of issue : DD/793 Dated 15/05/2019 A.2 Product Licence holder (Name & Address) Bruck Pharma Pyt. 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 \* For categories b and c the name and address of the manufacturer producing the 2.A.3.1 dosage form is9 2.A.4 Is a summary basis for approval appended?10 Is the attached, officially approved product information complete and consonant 2.A.5 with the licence? 11 Applicant for certificate, if different from licence holder (name and address)12 2.A.6 2.B.1 Applicant for certificate (Name & Address) 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: 2.B.3 Why is marketing authorization lacking? 2.B.4 Remark 13 NA Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage Yes form is produced? (yes/no/not applicable) 14 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? 3.3 Do the facilities and operation confirm to GMP as recommended by World Health Organization ?15 4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?16 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

1 JUL 2020 UT OF DESTRUCT ON DAMAN

Signature

DRUGS LICENSING AUTHORITY

भौनधी साईसैंस प्रविष्कारो DRUGS CONTROL DEPARTMENT क्री-अर्थ दिल्लाम व्यवस्थ

- 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 <sup>1</sup> | 88. Israel            | 131. Namibia   | 174. Sudan                             |
| <ol><li>Argentina</li></ol>  | 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                          |
| <ol><li>Bangladesh</li></ol> | 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           |  | —————————————————————————————————————— |
| 18. Belize                   | 60. European Community          |                       | 144. Panama  | 187. Tonga                             |
| 19. Benin                    |                                 | 102. Kyrgyzstan       | 145. Papua New Guinea  | 188. Trinidad                          |
| 20. Bhutan                   | 61. Fiji                        | 103. Laos             | 146. Paraguay  | 189, Tunisia                           |
| 21. Bolivia                  | 62. Finland                     | 104. Latvia           | 146. Paraguay 147. Peru 148. Parto Rice 149 Philiphilis 10 & Saland Start Urice 152 Portugal 153. Republic of Berlin 154. Republic de Guinee | 190. Turkey                            |
| 22. Bosnia                   | 63. France                      | 105. Lebanon          | 148. Punto Rigo  | 191. Turkmenistan                      |
|                              | 64. Gabon                       | 106. Lesotho          | 149 Philippines "11/   | UAE                                    |
| 23. Botswana                 | 65. Gambia                      | 107. Liberia          | 60 doland Stall trace  | 93 Jganda                              |
| 24. Brazil<br>25. Brunei     | 66. Guatemala                   | 108. Libya            | 15 Portugal -  | 196 U craine                           |
|                              | 67. Georgia                     | 109. Libyan Arab      | 1502 Qahar   | 1495. Un on of Soviet                  |
| 26. Bulgaria                 | 68. German Democratic           | Jamahiriya            | 153. Republic of Berlin  | Socialist Republics <sup>1</sup>       |
| 27. Burkina Faso             | Republic <sup>2</sup>           | 110. Liechtenstein    |  |  |
| 28. Burundi                  | 69. Germany Federal             | 111. Liochtonstoin    | 755. Republic of Mardives  | 197. Uni ed Kingdom                    |
| 29. Byelorussia              | Republic of <sup>2</sup>        | 112. Lithuania        | 156. Romania चित्रच अवस  | 498. United States                     |
| 30. Cambodia                 | 70. Germany                     | 113. Luxembourg       | 157. Russia: 中川/Daman  | \$199. Uruguay                         |
| <ol> <li>Cameroon</li> </ol> | 71. Ghana                       | 114. Macau            | 158 Bwanda<br>19. Sandi Afabia 110 \   | . 280. VSA                             |
| 32. Canada                   | 72. Greece                      | 115. Madagascar       | 139 Sandi Arabia 11 (1)  | 201 Uzbekistan                         |
| 33.Central African           | 73. Grenada                     | 116. Malawi           | 160 Sender Danson  | 202. Vanuatu                           |
| Republic                     | 74. Guinea                      | 117. Malaysia         | 160. Sender AMAN   | 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 <sup>1</sup>           |
| 39. Columbia                 | 80. Hong Kong                   | 123. Mauritius        | 166. Slovenia  | 209. Zaire                             |
| 40. Congo                    | 81. Hungary                     | 124. Mexico           | 167. Solomon Islands   |  |
| 41. Costa Rica               | 82. Iceland                     | 125. Moldova          |  | 210. Zambia                            |
| 42. Council of Europe        | 83. India                       |                       | 168. Somalia   | 211. Zimbabwe                          |
| 43. Croatia                  |                                 | 126. Monaco           | 169. Somaliland  |  |
| rs. Civatia                  | 84. Indonesia                   | 127. Mongolia         | 170. South Africa  |  |

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

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

Telephone No. : 0091-0260-2230470

Fax No.

: 0091-0260-2230570

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

DRUGS LICENSING AUTHORITY

औषधी लाईसेंस प्राधिकारी

Signature

Stamp & Date

DRUGS CONTROL DEPARTMENT औषशी नियंत्रण विपाग

UT OF DAMAN & DIU DAMAN

सभ प्रदेश रमण एव तीव, रमण

0 1 JUL 2020

| Atiyawad, Dabhel, Daman - 35  2.A.3. Status of product licence holder *  |              | i Certificate: DD/793/15B/2020-1-211-I  | 1      | Valid Up to: 04/01/ | /202   | 2  |
|--|--------------|---|--------|---------------------|--------|--|
| 1. Name and dosage form of Product  Active ingredient(s) <sup>2</sup> and amount(s) per unit dose <sup>3</sup> Composition:  Each and gelatin capsule contains: Thalldomide USP  |              |   | :      | India               |        |  |
| Active ingredient(s)² and amount(s) per unit dose²  Each hard gelatin capsule contains: Thatlidonial is ISP  | Impor        | ting (Requesting) Country   | :      | As per Annexur      | e-2    |  |
| Active ingredient(s)² and amount(s) per unit dose² : Composition:  Each hard gelutin capsule contains: Thalidomide USP   | 1.           | Name and dosage form of Product   | :      | Thalidomide Ca      | apsu   | ile USP 100 mg   |
| Thatidomide USP  | 1.1          | Active ingredient(s) <sup>2</sup> and amount(s) per unit dose <sup>3</sup>  | :      |                     | •      |  |
| Thatidomide USP  |              |   |        | Each hard gelati    | in ca  | apsule contains:   |
| For complete qualitative composition including excipients, see attached. Annexure 1  12 Is this product licensed to be placed on the market for use in the exporting country?  13 Is this product licensed to be placed on the market for use in the exporting country?  14 If the answer to 1.2 is yes, continue with section 2 A and omit section 2 B  15 If the answer to 1.2 is no, omit section 2 A and omit section 2 B  16 If the answer to 1.2 is no, omit section 2 A and continue section 2 B  17 If the answer to 1.2 is no, omit section 2 A and continue section 2 B  18 If the answer to 1.2 is no, omit section 2 A and continue section 2 B  2.4.1 Number of product licence' and date of issue  2.5.2 Product Licence holder (Name & Address)  2.6.3 Status of product licence holder.  2.6.4 Is a summary basis for approval appended?  2.6.4 Is a summary basis for approval appended?  2.6.5 Is the attached, officially approved product information complete and consonant with the licence?  2.6.6 Applicant for certificate, if different from licence holder (name and address)  2.6.7 Applicant for certificate (Name & Address)  2.6.8 Applicant for certificate (Name & Address)  2.7 Status of applicant  2.8.1 For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:  2.8.2 Status of applicant  2.8.3 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which address  2.8.4 Remark D  2.8.5 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which address  2.8.6 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?  2.8.7 Periodicity of routine inspection (years)  2.8.8 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?  2.8.9 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?  2.9 Does the in |              |   |        | Thalidomide US      | P      |  |
| 1.2 Is this product licence to be placed on the market for use in the exporting country?   |              |   |        | Color: Approve      | d col  | or used in capsule shalls  |
| 1.3 Is this product actually on the market in the suporting country?  1.4 If the answer to 1.2 is yes, continue with section 2 A and omit section 2 B  1.5 If the answer to 1.2 is yes, continue with section 2 A and omit section 2 B  1.6 If the answer to 1.2 is yes, continue with section 2 A and continue section 2 B  1.7 If the answer to 1.2 is yes, continue with section 2 A and continue section 2 B  1.8 If the answer to 1.2 is yes, continue with section 2 A and continue section 2 B  1.8 If the answer to 1.2 is no, omit section 2 A and continue section 2 B  1.8 If the answer to 1.2 is no, omit section 2 A and continue section 2 B  1.8 If the answer to 1.2 is no, omit section 2 A and continue section 2 B  1.8 If the answer to 1.2 is no, omit section 2 A and continue section 2 B  1.8 If the answer to 1.2 is no, omit section 2 A and continue section 2 B  1.8 If the answer to 1.2 is no, omit section 2 A and continue section 2 B  1.8 If the answer to 1.2 is no, omit section 2 A and continue section 2 B  1.8 If the answer to 1.2 is no, omit section 2 A and continue section 2 B  1.8 If the answer to 1.2 is no, omit section 2 A and continue section 2 B  1.8 If the answer to 1.2 is no, omit section 2 A and continue section 2 B  1.8 If the answer to 1.2 is no, omit section 2 B  1.8 If the answer to 1.2 is no, omit section 2 B  1.8 If the answer to 1.2 is no, omit section 2 B  1.8 If the answer to 1.2 is no, omit section 2 B  1.8 If the answer to 1.2 is no, omit section 2 B  1.8 If the answer to 1.2 is no, omit section 2 B  1.8 If the answer to 1.2 is no, omit section 2 B  1.8 If the answer to 1.2 is no, omit section 2 B  1.8 If the answer to 1.2 is no, omit section 2 B  1.8 If the answer to 1.2 is no, omit section 2 B  1.8 If the answer to 1.2 is no, omit section 2 B  1.9 If the answer to 1.2 is no, omit section 2 B  1.9 If the answer to 1.2 is no, omit section 2 B  1.9 If the answer to 1.2 is no, omit section 2 B  1.9 If the answer to 1.2 is no, omit section 2 B  1.9 If the answer to 1.2 is no, in the answer to 1.2 is no  |              | For complete qualitative composition including excipients   | , see  | attached4. Anne:    | xure   | e - I  |
| 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  If the answer to 1.2 is no, omit section 2 A and continue section 2 B  If the answer to 1.2 is no, omit section 2 A and continue section 2 B  If the answer to 1.2 is no, omit section 2 A and continue section 2 B  If the answer to 1.2 is no, omit section 2 A and continue section 2 B  If the answer to 1.2 is no, omit section 2 A and continue section 2 B  If the answer to 1.2 is no, omit section 2 A and continue section 2 B  If the answer to 1.2 is no, omit section 2 A and continue section 2 B  If the answer to 1.2 is no, omit section 2 A and continue section 2 B  If the answer to 1.2 is no, omit section 2 A and continue section 2 B  If the answer to 1.2 is no, omit section 2 A and continue section 2 B  If the answer to 1.2 is no, omit section 2 B  If the answer to 1.2 is no of the manufacture producing the dosage form is no of the manufacture of the product 1 in section 2 B  If the answer to 1.2 is no of the answer to 1  |              | Is this product licensed to be placed on the market for use   | in th  | e exporting country | /?5    | : Yes  |
| If the answer to 1.2 is no, omit section 2 A and continue section 2 B6  2.A.1 Number of product licence* and date of issue  Product Licence holder (Name & Address)  2.A.2 Product Licence holder (Name & Address)  2.A.3 Status of product licence holder *  2.A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is *  2.A.3.1 Is a summary basis for approval appended?**  2.A.4 Is a summary basis for approval appended?**  2.A.5 Is the attached, officially approved product information complete and consonant with the licence?**  2.A.6 Applicant for certificate, if different from licence holder (name and address)**  2.B.1 Applicant for certificate (Name & Address)  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: *  2.B.3 Why is marketing authorization lacking?  2.B.4 Remark *  2.B.5 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which code *  2.B.3 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which code *  2.B.4 Periodicity of routine inspection (years)  2.B.5 Does the amounfacture of this type of dosage form been inspected ?  2.B.6 Periodicity of routine inspection (years)  2.B.7 Primary Primary Health Center, Damma (UT) - 396 220.  2.B.8 Telephone No.: 0091 - 0260 - 2220470  Pare of Authorized Personal Cuts of Pare of Authorized Personal Research and the uniform them of Authorized Personal Research and the uniform them of the product of the primary Health Center, Damma (UT) - 396 220.  2.B.8 Name of Authorized Personal Research and the uniform them of the product primary Health Center, Damma (UT) - 396 220.  2.B.7 Telephone No.: 0091 - 0260 - 2220470  2.B.8 Name of Authorized Personal Research and the uniform them of the product primary that the center of the product primary that the center of the product primary them of the primary that the primary thealth Center Damma (UT) - 396 220.  2.B.8 Name of Au | 1.3          |   |        |                     |        | : Yes  |
| 2.A.1 Number of product licence* and date of issue  2.A.2 Product Licence holder (Name & Address)  2.A.3 Status of product licence holder *  2.A.3 Status of product licence holder *  2.A.3 For categories b and c the name and address of the manufacturer producing the dosage form is *  2.A.4 Is a summary basis for approval appended?*  2.A.5 Is the attached, officially approved product information complete and consonant with the licence?**  2.A.6 Applicant for certificate, if different from licence holder (name and address)**  2.B.1 Applicant for certificate (Name & Address)  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 *  2.B.3 Why is marketing authorization lacking?  2.B.3 Why is marketing authorization lacking?  2.B.3 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which address of the manufacture of the produced? (yes/no/not applicable)**  If Not or Not applicable proceed to question 4  2.B.2 Has the manufacture of this type of dosage form been inspected?  2.B.3 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?**  3. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?**  3. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?**  3. If No. explain : Not Applicable  2. Not Applicable  2. Not Applicable  2. Yes  3. Not Applicable  4. Yes  4. Y |              | If the answer to 1.2 is yes, continue with section 2 A and o  | mit s  | section 2 B         |        |  |
| Product Licence holder (Name & Address)  Bruck Pharma Pvt. Ltd. Survey No. 188/1 to 6, 189/1, I Atiyawad, Dabhel, Daman - 35  2.A.3. Status of product licence holder *  2.A.3. For categories b and c the name and address of the manufacturer producing the dosage form is *  2.A.4 Is a summary basis for approval appended *  2.A.5 Is the attached, officially approved product information complete and consonant with the licence *  2.A.6 Applicant for certificate, if different from licence holder (name and address)*  2.A.6 Applicant for certificate, (Name & Address)  2.B.1 Applicant for certificate (Name & Address)  2.B.2 Status of applicant  2.B.2. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is: *  2.B.3 Why is marketing authorization lacking?  2.B.4 Remark *  2.B.5 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which address of the periodicity of routine inspection (years)  3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which address of the periodicity of routine inspection (years)  3. Does the certifying authority periodicity of routine inspection (years)  3. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?  3. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?  3. If No. explain  3. Not Applicable  Address of certifying authority  4. Primary Health Center, Daman (UT) - 396 220.  1. Telephone No.: 9091 - 0260 - 2230470  1. Fax No.: 9091 - 0260 - 2230570  1. Not Authorized Person Routing Authority and entitled unformation information complete and consonant information information information information complete and consonant i |              | If the answer to 1.2 is no, omit section 2 A and continue se  | ction  | 1 2 B <sup>6</sup>  |        |  |
| Product Licence holder (Name & Address)  Bruck Pharma Pvt. Ltd. Survey No. 188/1 to 6, 189/1, 1 Atiyawad, Dabhel, Daman - 39  2.A.3.1  For categories b and c the name and address of the manufacturer producing the dosage form is?  2.A.4 Is a summary basis for approval appended?  2.A.5 Is the attached, officially approved product information complete and consonant with the licence?  2.A.6 Applicant for certificate, if different from licence holder (name and address)  2.B.1 Applicant for certificate (Name & Address)  2.B.2 Status of applicant  2.B.3.1 For categories (b) and (c) the name and address of the manufacturer producing the dosage form is?  2.B.3.1 For categories (b) and (c) the name and address of the manufacturer producing the dosage form is?  3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which address of the manufacturer of the product (vestor)  3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which address of the manufacture of this type of dosage form been inspected?  3. Periodicity of routine inspection (years)  3. Do the facilities and operation confirm to GMP as recommended by World Health  3. Organization?  3. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?  4. If No. explain  4. Not Applicable  Address of certifying authority  4. Periodicity of routine inspection (Panan & Diu, Drugs Control Dept., Perimary Health Center, Daman (UT) – 396 220.  1. Telephone No.: 0091 – 0260 – 2230470  1. Fax No.: 0091 – 0260 – 2230570  1. Not Applicable and constant and address of the manufacture of the product?  1. Not Applicable and constant and address of the manufacture of the product?  1. Not Applicable and constant and address of the manufacture of the product? | 2.A.1        | Number of product licence <sup>7</sup> and date of issue  |        |                     | :      | DD/793 Dated 14/10/2019  |
| Survey No. 188/1 to 6, 189/1, I Adiyawad, Dabhel, Daman - 35  2.A.3. Status of product licence holder 1  2.A.3. For categories b and c the name and address of the manufacturer producing the dosage form is 2  2.A.4 Is a summary basis for approval appended 1 No Not applicable 2  2.A.5 Is the attached, officially approved product information complete and consonant with the licence? 11  2.A.6 Applicant for certificate, if different from licence holder (name and address) 2 No Not Provided with the licence? 11  2.A.6 Applicant for certificate (Name & Address) Not Applicable Not Not Applicable Not Address of certifying authority or not product (Name & Address of certifying authority or not product (Name & Address of certifying authority Not Applicable Not Address of certifying authority Drug Licensing Authority  Address of certifying authority  Address of certifying authority  Pure Licensing Authority  Address of certifying authority  Pure Licensing Authority  Not Applicable  Not Applicable  Not Applicable  Not Applicable  Not Applicable   | 2.A.2        | Product Licence holder (Name & Address)   |        |                     |        |  |
| 2.A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is?  2.A.4 Is a summary basis for approval appended?  2.A.5 Is the attached, officially approved product information complete and consonant with the licence?  2.A.6 Applicant for certificate, if different from licence holder (name and address)  2.B.1 Applicant for certificate (Name & Address)  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:  2.B.3 Why is marketing authorization lacking?  2.B.4 Remark   3 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which address of form is produced? (yes/no/not applicable)  11 Fixed or Not applicable proceed to question 4  Periodicity of routine inspection (years)  12 Has the manufacture of this type of dosage form been inspected?  2.B.2 Dothe facilities and operation confirm to GMP as recommended by World Health  2.B.3 Operation of the manufacture of the product?  3.B.4 Manufacture of the product?  3.B.5 Periodicity of routine inspection (years)  4.C.7 Periodicity of routine inspection (years)  5.C.7 Periodicity of routine inspection (years)  5.C.7 Periodicity of routine inspection (years)  6.C.7 Periodicity of routine inspection (years)  7.T.10  8.C.7 Periodicity of routine inspection (years)  7.T.10  8.C.7 Periodicity of routine inspection (years)  8.C.7 Periodicity of routine inspection (years)  9.C.7 Periodicity of rou |              |   |        |                     |        | Survey No. 188/1 to 6, 189/1, 190/2 to 4,<br>Afiyawad, Dabhel, Daman - 396210  |
| 2.A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is?  2.A.4 Is a summary basis for approval appended?¹¹⁰  2.A.5 Is the attached, officially approved product information complete and consonant with the licence?¹¹¹  2.A.6 Applicant for certificate, if different from licence holder (name and address)¹²  2.B.1 Applicant for certificate (Name & Address)  2.B.2.1 For categories (h) and (c) the name and address of the manufacturer producing the dosage form is?  2.B.2.2 For categories (h) and (c) the name and address of the manufacturer producing the dosage form is?  2.B.3 Why is marketing authorization lacking?  2.B.4 Remark ¹¹  3 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which address of the manufacture of the special plant in which address of the manufacture of the product ?? Yes  2.B.2 Production ?? Yes  2.B.3 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?? Yes  2.B.3 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?? Yes  2.B.3 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?? Yes  | 2.A.3        | Status of product licence holder 8  |        |                     | •      | s  |
| State attached, officially approved product information complete and consonant with the licence?   Not Applicant with the licence?   Not Applicant for certificate, if different from licence holder (name and address)   Not Applicant   Not Applicant for certificate (Name & Address)   Not Applicant for certificate (Name & Address)   Not Applicant for certificate (Name & Address)   Name of Authorized Personal Polynomeros   Not Applicable   Not Not Applicable   Not   | 2.A.3.1      | For categories b and c the name and address of the manufactorage form is 9  | cture  | r producing the     | :      |  |
| Is the attached, officially approved product information complete and consonant with the licence?\(^{11}\)  2.A.6 Applicant for certificate, if different from licence holder (name and address)\(^{12}\): Not Applicant for Applicant for certificate (Name & Address)  2.B.1 Applicant for certificate (Name & Address)  2.B.2.1 For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:\(^{13}\)  2.B.3 Why is marketing authorization lacking?  2.B.4 Remark \(^{12}\)  3 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which address of the manufacture of this type of dosage form been inspected?  3.1 Periodicity of routine inspection (years)  3.2 Has the manufacture of this type of dosage form been inspected?  3.3 Do the facilities and operation confirm to GMP as recommended by World Health  3.4 Yes  3.5 Do the facilities and operation confirm to GMP as recommended by World Health  3.6 Priodicity of routine inspection to generate the product \(^{16}\)  3.7 Yes  3.6 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product \(^{16}\)  3.6 If No, explain  3.7 Yes  3.7 Yes  4. Not Applicable  Address of certifying authority  4. Prior Prio | 2.A.4        | Is a summary basis for approval appended?10   |        |                     |        | NO   |
| 2.B.1 Applicant for certificate (Name & Address)  Status of applicant  For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:  2.B.2.1 For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:  Why is marketing authorization lacking?  Remark 19  Does the certifying authority arrange for periodic inspection of the manufacturing plant in which and the form is produced? (yes/no/not applicable) 14  If Not or Not applicable proceed to question 4  Periodicity of routine inspection (years)  Has the manufacture of this type of dosage form been inspected?  Yes  Do the facilities and operation confirm to GMP as recommended by World Health  Organization ?15  Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?  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, Desired Person, Desired Person, Desired Person, United United United Person (UT)  Signature   | 2.A.5        | Is the attached, officially approved product information con<br>with the licence? 11                                      | nplet  | e and consonant     | _      |  |
| 2.B.1 Applicant for certificate (Name & Address)  Status of applicant  For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:  2.B.2.1 For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:  Why is marketing authorization lacking?  Remark 19  Does the certifying authority arrange for periodic inspection of the manufacturing plant in which and the form is produced? (yes/no/not applicable) 14  If Not or Not applicable proceed to question 4  Periodicity of routine inspection (years)  Has the manufacture of this type of dosage form been inspected?  Yes  Do the facilities and operation confirm to GMP as recommended by World Health  Organization ?15  Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?  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, Desired Person, Desired Person, Desired Person, United United United Person (UT)  Signature   | 2.A.6        | Applicant for certificate, if different from licence holder (na   | ame :  | and address)12      |        | Not Applicated G Alle.   |
| 2.B.2.1 For categories (h) and (c) the name and address of the manufacturer producing the dosage form is:   2.B.3 Why is marketing authority arrange for periodic inspection of the manufacturing plant in which address form is produced? (yes/no/not applicable)   3 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which address form is produced? (yes/no/not applicable)   If Not or Not applicable proceed to question 4  Periodicity of routine inspection (years) : Yearly  Has the manufacture of this type of dosage form been inspected? : Yes  Do the facilities and operation confirm to GMP as recommended by World Health : Yes  Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?   If No, explain : Not Applicable  Address of certifying authority, Administration of Daman & Diu, Drugs Control Dept., Primary Health Center, Daman (UT) – 396 220.  Telephone No.: 0991 – 0260 – 2230470  Fax No.: 0991 – 0260 – 2230470  Name of Authorized Person Research and Control Dept., Primary Health Center, Daman (UT) – 396 220.  Signature  | 2.B.1        | Applicant for certificate (Name & Address)  |        | ,                   | •      | 135  |
| dosage form is:  2.B.3 Why is marketing authorization lacking?  Remark 19  Does the certifying authority arrange for periodic inspection of the manufacturing plant in which form is produced? (yes/no/not applicable) 14  If Not or Not applicable proceed to question 4  Periodicity of routine inspection (years) : Yearly  Has the manufacture of this type of dosage form been inspected? : Yes  Do the facilities and operation confirm to GIMP as recommended by World Health : Yes  Organization? 15  Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? 16  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- Residue and a surfacturing plant in which which the manufacture primary Health under  | 2.B.2        | Status of applicant   |        |                     | •      |  |
| 2.B.4 Remark D  Does the certifying authority arrange for periodic inspection of the manufacturing plant in which reduced form is produced? (yes/no/not applicable) D  If Not or Not applicable proceed to question 4  Periodicity of routine inspection (years) : Yearly  But the manufacture of this type of dosage form been inspected? : Yes  Do the facilities and operation confirm to GMP as recommended by World Health : Yes  Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? Health Certifying authority Drug Licensing Authority  Address of certifying authority  Drug Licensing Authority  Administration of Daman & Diu, Drugs Control Dept., Primary Health Center, Daman (UT) – 396 220.  Telephone No.: 0091 – 0260 – 2230470  Fax No.: 0091 – 0260 – 2230570  Name of Authorized Person Debt Certifying Authority Interest in their interest interest in their interest interest.   | 2.B.2.1      | For categories (b) and (c) the name and address of the manu dosage form is: 9   | factu  | arer producing the  | :      | The second   |
| Does the certifying authority arrange for periodic inspection of the manufacturing plant in which and the DAMAN  If Not or Not applicable proceed to question 4  Periodicity of routine inspection (years)  But the manufacture of this type of dosage form been inspected?  Do the facilities and operation confirm to GMP as recommended by World Health  Organization?  Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?  If No, explain  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: 15 18 18 18 18 18 18 18 18 18 18 18 18 18  | 2.B.3        |   |        |                     | :      | *  |
| If Not or Not applicable proceed to question 4  Periodicity of routine inspection (years)  Has the manufacture of this type of dosage form been inspected?  Yes  Do the facilities and operation confirm to GMP as recommended by World Health  Yes  Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?  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: Disk Certifying Authority Interests of Control Dept.,  Signature  | 2.B.4        |   |        |                     | ;      | 🔥 🛠 समाग Daman 🔊   |
| Periodicity of routine inspection (years)  Has the manufacture of this type of dosage form been inspected?  Do the facilities and operation confirm to GMP as recommended by World Health Organization?  Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?  If No, explain  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: Primary Health Centers and interest interest interest interest interest interest.  Signature   | 3            | Does the certifying authority arrange for periodic inspection form is produced? (yes/no/not applicable) 14                | of th  | ne manufacturing pl | lant i | in which to do the DAMAN the   |
| Has the manufacture of this type of dosage form been inspected?  Do the facilities and operation confirm to GMP as recommended by World Health Organization?  Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?  If No, explain  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: Research and an interest under  | <b>L</b> . ' | If Not or Not applicable proceed to question 4  |        |                     |        | The same of the sa |
| Has the manufacture of this type of dosage form been inspected?  Do the facilities and operation confirm to GMP as recommended by World Health  Organization?  Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?  If No, explain  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: Control Dept.,  Signature   | 3.1          | Periodicity of routine inspection (years)   |        |                     | :      | Yearly   |
| Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?  If No, explain : Not Applicable  Address of certifying authority  Drug Licensing Authority,  Administration of Daman & Diu, Brugs Control Dept.,  Primary Health Center, Daman (UT) – 396 220.  Telephone No.: 0091 – 0260 – 2230470  Fax No.: 0091 – 0260 – 2230570  Name of Authorized Person: Desk Centrol Dept.,  Signature  | 3.2          | Has the manufacture of this type of dosage form been inspec   | ted?   | •                   | :      | -  |
| 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: Cost Canada (UT) Signature   | 3.3          | Do the facilities and operation confirm to GMP as recommer Organization ? <sup>15</sup>                                   | nded   | by World Health     | :      | Yes  |
| 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: Post Centrol Dept. Signature  |              | Does the information submitted by the applicant satisfy the call aspects of the manufacture of the product? <sup>16</sup> | ertify | ving authority on   | :      | Yes  |
| 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: Dick CENSING AUT Signature  |              |   |        |                     | :      | Not Applicable   |
| 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: Possible Canal Signature  |              |   |        |                     |        | 2 <del>-</del>   |
| Primary Health Center, Daman (UT) = 396 220. Telephone No. : 0091 = 0260 = 2230470 Fax No. : 0091 = 0260 = 2230570  Name of Authorized Person: Possible CentsING AUT  Signature  | ]            | Drug Licensing Authority,<br>Administration of Daman & Div. Drugs Control Dept  |        |                     |        |  |
| Fax No. : 0091 – 0260 – 2230570  Name of Authorized Person: Dick CENSING AUT  Signature  |              | rimary Health Center, Daman (IIT) - 396 220   |        |                     |        |  |
| Signature अनिवासी लाईसेंस प्राप्तिय  | 1            | Fax No. : 0091 - 0260 - 2230570   |        |                     |        | 1  |
| Signature अनिवासी लाईसेंस प्राप्तिय  |              |   |        | Name of Authori     | ized   | Person: Dr. Velk Designing Authority   |
| Stamp and Date Division in the state of the  |              |   |        |                     |        | अनियों लाईसेंस प्रधिकारी DRUGS CONTROL DEPARTMENT  |

Page 1 of 3

औत्रदी नियंत्रण विभाग UT OF DAMAN & DIU, DAMAN - ःसब क्रेश शमक एव दीव,,दमकः

1 5 JUN 2020

- 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.
- Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
- Specify whether the person responsible for placing the product on the market:
  - a) Manufactures the dosage form;
  - b) Packages and / or labels a dosage form manufactured by an independent company, or
  - c) Is involved in none of the above.
- 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
  - 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/793/14B/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.

| I. Afghanistan                | T 44. Cuba                       | 85. Iran                               | 128. Morocco  | 171. South Korea                   |
|-------------------------------|----------------------------------|--|---|------------------------------------|
| 2. Albania                    | 45. Cyprus                       | 86. Iraq                               | 129. Mozambique   | 172. Spain                         |
| 3. Algeria                    | 46. Czech Republic               | 87. Ireland                            | 130. Myanmar  | 173. Sri Lanka                     |
| 4. Angola                     | 47. Czechoslovakia¹              | 88. Israel                             | 131. Namibia  | 174. Sudan                         |
| 5. Argentina                  | 48. Democratic 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: Diibouti                     | 92. Japan                              | 135. New Zealand  | 178. Switzerland                   |
| 9. Austria                    | 51. Dominica                     | 93. Jordan                             | 136. Nicaragua  | 179. Syria                         |
| 10. Azerbaijan                | 52. Dominican Republic           | 94. Kazakhstan                         | 137. Niger  | 180. Tadzhikistan                  |
| 11. Bahamas                   | 53. Ecuador                      | 95. Kenya                              | 138. Nigeria  | 181. Taiwan                        |
| 12. Bahrain                   | 54. Egypt                        | 96. Kingdom of Tonga                   | 139. North Korea  | 182. Tajikistan                    |
|                               | 55. El Salvador                  | 97. Kiribati                           | 140. Norway   | 183, Tanzania                      |
| 13. Baltic<br>14. Bangladesh  | 56. Equatorial Guinea            | 98. Korea                              | 141. Oman   | 184, Thailand                      |
| ,                             | 50. Equatorial Gamea             | ······································ |   | 185. Tobago                        |
| 15. Barbados                  |                                  | 99. Korea Republic of                  | 142. Pakistan   |                                    |
| 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 149. Philippines 150. Poland 151. Portuge 152. Qara 153. Republic de Suine | 101 Turkmenistan                   |
| 22. Bosnia                    | 64. Gabon                        | 106, Lesotho                           | 149. Philippines  | 192.UAS                            |
| 23. Botswana                  | 65. Gambia                       | 107. Liberia                           | 150, Poland   | 199. Diamia                        |
| 24. Brazil                    | 66. Guatemala                    | 108. Libya                             | 151. Portugal Co. St.   | 194. Ukrand<br>195. Urion of Sovet |
| 25. Brunei                    | 67. Georgia                      | 109, Libyan Arab                       | 152. Qafa   | 195. Urtion of Covet               |
| 26. Bulgaria                  | 68. German Democratic            | Jamahiriya                             | 153. Rep blie of Binin  | Socialist Republics                |
| 27. Burkina Faso              | Republic <sup>2</sup>            | 110, Liechtenstein                     |   |                                    |
| 28. Burundi                   | 69. Germany Federal              | 111. Liochtonstoin                     | 155. Re ublic of Maldives   | 4 197. United Kingdom              |
| 29. Byelorussia               | Republic of <sup>2</sup>         | 112. Lithuania                         | 156. Rt nama  | 198, United States                 |
| 30. Cambodia                  | 70. Germany                      | 113. Luxembourg                        | 157. Ruisia 103   | 1997 Uruguay                       |
| 31. Cameroon                  | 71, Ghana                        | 114. Macau                             | 158. Rwarda 💫 उभग   | Damausas                           |
| 32. Canada                    | 72. Greece                       | 115, Madagascar                        |   | 201. Uzbeki tan                    |
| 33.Central African            | 73. Grenada                      | 116, Malawi                            | 159. Saudi Arabia   | 71202. Vandab                      |
| 1                             | 74. Guinea                       | 117. Malaysia                          | 161. Serbia and UF  | - 363.Velezaria                    |
| Republic                      | 75. Guinea Equatorial            | 118. Maldives                          | Montenegro  | Volezuela<br>2012 - Lemam          |
| 34. Chad                      | 75. Guinea Equatorial 76. Guvana | 119. Mali                              | 162. Scychelles   | 205, West Indies                   |
| 35. Chile                     | 76. Guyana<br>77. Haiti          | 120. Malta                             | 163. Sierra Leone   | 206. World                         |
| 36. China<br>37. Cook Islands | 78. Holland                      | 121. Marshall Islands                  | 164. Singapore  | 207. Yemen                         |
|                               | 79. Honduras                     | 121. Mauritania                        | 165, Slovakia   | 208. Yugoslavia <sup>1</sup>       |
| 38. Colombia                  | 80. Hong Kong                    | 123. Mauritius                         | 166. Slovenia   | 209. Zaire                         |
| 39. Columbia                  | 81. Hungary                      | 124. Mexico                            | 167, Solomon Islands  | 210. Zambia                        |
| 40; Congo                     |                                  | 125. Moldova                           | 168. Somalia  | 211, Zimbabwe                      |
| 41. Costa Rica                | 82. Iceland                      |  | 169. Somaliland   | ZII. ZIIIIDabwe                    |
| 42. Council of Europe         | 83. India                        | 126. Monaco                            |   |                                    |
| 43. Croatia                   | 84. Indonesia                    | 127. Mongolia                          | 170, South Africa   | 1                                  |

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 DRUGS LICENSING AUTHORITY

भीवधी लाईसेंस प्रश्चिकारी

Signature:

DRUGS CONTROL DEPARTMENT

औषधी नियंत्रण विभाग UT OF DAMAN & DIU, DAMAM

Stamp and date:

T OF DAMAN & DIU, DAM संघ प्रदेश उमन एवं दीव, दमन

1 5 JUN 2020

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 dose3 Composition: Each ml contains: Mesna USP......100mg Water for Injection USP......q.s. For complete qualitative composition including excipients, see attached. Annexure - 1 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<sup>7</sup> 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 2.A.3.1 For categories b and c the name and address of the manufacturer producing the Not applicable dosage form is9 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 Not Provided with the licence? 1 2.A.6 Applicant for certificate, if different from licence holder (name and address)12 2.B.1 Applicant for certificate (Name & Address) 2.B.2 Status of applicant 2.8.2.1For categories (b) and (c) the name and address of the manufacturer producing the dosage form is: 2.B.3 Why is marketing authorization lacking? 2.B.4 Remark B Does the certifying authority arrange for periodic inspection of the manufacturing plant in v 3 form is produced? (yes/no/not applicable) 1-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 4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?16 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

: 0091 - 0260 - 2230570

Fax No.

Name of Authorize BRUSS LICENSING AUTHORITY Signature औषधी लाईसेंस प्राधिकारी Stamp and Date DRUGS CONTROL DEPARTMENT ओवधी निबंजन विभाग

UT OF DAMAN & DIU DAMAN सभ प्रदेश दमण एवं दीव, दभन

2 5 MAR 2021

- 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.
- Use, whenever possible, international Nonproprietary Names (INNs) or national nonproprietary names.
- The formula (complete composition) of the dosage form should be given on the certificate or be appended.
- 4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product 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;
  - 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. Czechoslovakia¹      | 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. Diibouti             | 92 Japan              | 135. New Zealand              | 178. Switzerland   |
| 9. Austria            | 51. Dominica             | 93. Jordan            | 136. Nicaragua                | 179. Syria   |
| 10. Azerbaijan        | 52. Dominican Republic   | 94. Kazakhstan        | 137, Niger                    | 180, Tadzhikistan  |
| 11. Bahamas           | 53. Ecuador              | 95. Kenya             | 138, Nigeria                  | 181. Taiwan  |
| 12. Bahrain           | 54. Egypt                | 96. Kingdom of Tonga  | 139. North Korea              | 182. Tajikistan  |
| 13. Baltic            | 55. El Salvador          | 97. Kiribati          | 140. Norway                   | 183. Tanzania  |
| 14. Bangladesh        | 56. Equator al Guinea    | 98. Korea             | 141. Oman                     | 184. Thailand  |
| 15. Barbados          | 57. Eritrea              | 99. Korea Republic of | 142. Pakistan                 | 185. Tobago  |
| 15. Barbagos          |                          |                       |                               |  |
| 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                   | 103 Uganda   |
| 24. Brazil            | 66. Guatemala            | 108. Libya            | 151. Portugal                 | 194 Ukinse<br>194 Japan Soviet<br>Socked Resublies<br>196 Aroked Arch Entrates |
| 25. Brunei            | 67. Georgia              | 109. Libyan Arab      | 151. Portugal<br>152. Qatar   | 196 Duop of Coviet   |
| 26. Bulgaria          | 68. German Democratic    | Jamahiriya            | 153. Repub to on death co-    | Societo Resublics  |
| 27. Burkina Faso      | Republic <sup>2</sup>    | 110. Liechtenstein    | 154. Republic of Guinge       | 196 United Arge, Engrates  |
| 28. Burundi           | 69. Germany Federal      | 111. Liochtonstoin    | 155. Regulate of Mardives     | LEGI-97. United Kingdom  |
| 29. Byelorussia       | Republic of <sup>2</sup> | 112. Lithuania        | 156. Re mania 157. Ri ssia 18 | Miles Times  |
| 30. Cambodia          | 70. Germany              | 113. Luxembourg       | 157. R ssia 16                | 1) 1199. Uruguay   |
| 31. Cameroon          | 71. Ghana                | 114. Macau            | 158, R vanda                  | :200. USA  |
| 32. Canada            | 72. Greece               | 115. Madagascar       | 159. Saudi Arabia             | 20,L Uzbekiştan  |
| 33 Central African    | 73. Grenada              | 116. Malawi           | 160. Sel egal .               | 202 Vanuatur   |
| Republic              | 74. Guinea               | 117. Malaysia         | 161. Servia and               | 1 202 Vanuatu<br>Dam<br>203. Venezuela   |
| 34. Chad              | 75. Guinea Equatorial    | 118. Maldives         | Mont negro,                   | 204, Vietnath  |
| 35, Chile             | 76. Guyana               | 119. Mali             | 162. Sevcheres                | 204, Vietnatic<br>구되05: West, India  |
| 36. China             | 77. Haiti                | 120, Malta            | 163. Sierra Leon              | 7 h AAO 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. Slovenía                 | 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. Indones a            | 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. DASTHORITY

औषधी लाईतेंस प्राधिकारी DRUGS CONTROL DEPARTMENT

Signature Stamp & Date

जीतथी तिर्धप्रण विभाग UT OF DAMAN & DIU DAMAN सथ प्रदेश दशन एवं दीव, दगन

2 5 MAR 2021

Page 1 of 1

|         | Certificate: DD//94/14C/2020-1-211-1  | Va            | lid Up to: 04/01   | /2022  |
|---------|---|---------------|--------------------|--|
| Export  | ing (Certifying) Country  | : Ind         | lia                |  |
| Import  | ing (Requesting) Country  | : As          | per Annexure-2     | 2  |
| 1.      | Name and dosage form of Product   | : Vir         | ocristine sulpha   | te Injection USP 1mg/1 ml  |
| 1.1     | Active ingredient(s) <sup>2</sup> and amount(s) per unit dose <sup>3</sup>  |               | mposition:         | •  |
|         |   |               | ch ml contains:    |  |
|         |   | Vir           | scristine sulpha   | te USP1mg  |
|         |   | Wa            | iter for Injection | n USPq.s.  |
|         | For complete qualitative composition including excipient  | ts, see attac | hed4. Annexu       | re - I   |
| 1.2     | Is this product licensed to be placed on the market for use   | e in the exp  | orting country?5   | : Yes  |
| 1.3     | Is this product actually on the market in the exporting con   |               |                    | : Yes  |
|         | If the answer to 1.2 is yes, continue with section 2 A and  | omit section  | on 2 B             |  |
|         | If the answer to 1.2 is no, omit section 2 A and continue   |               |                    |  |
| 2.A.1   | Number of product licence <sup>7</sup> and date of issue  |               |                    | : DD/794 Dated 16/08/2019  |
| ?.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 manuf<br>dosage form is <sup>9</sup>   | facturer pro  | ducing the         | : Not applicable   |
| 2.A.4   | Is a summary basis for approval appended? <sup>10</sup>   |               |                    | : NO   |
| 2.A.5   | Is the attached, officially approved product information c with the licence? 11   | omplete and   | d consonant        | : Not Provided SING AUTION: Not Applicable SING AUTION: NA                 |
| 2.A.6   | Applicant for certificate, if different from licence holder (   | (name and a   | address)12         | : Not Applicable ATT HIS.  |
| 2.B.1   | Applicant for certificate (Name & Address)  |               | •                  | : NA > 20  |
| 2.B.2   | Status of applicant   |               |                    | : NA   |
| 2.B.2.1 | For categories (b) and (c) the name and address of the ma dosage form is: 9   | nufacturer    | producing the      | : NA   |
| 2.B.3   | Why is marketing authorization lacking?   |               |                    | : NA ARTHUR Daman  |
| 2.B.4   | Remark 13   |               |                    | : NA PART TO DIN   |
| 3       | Does the certifying authority arrange for periodic inspecti<br>form is produced? (yes/no/not applicable) <sup>14</sup>  | on of the m   | anufacturing pla   | ont in which the dosage  |
|         | 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 insp   | pected?       |                    | : Yes  |
| 3.3     | Do the facilities and operation confirm to GMP as recommon Organization? <sup>15</sup>  | mended by     | World Health       | : Yes  |
| 4.      | Does the information submitted by the applicant satisfy the all aspects of the manufacture of the product? <sup>16</sup>  | e certifying  | g authority on     | : 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   |               |                    |  |
|         |   | N             | ame of Authori     | zed Person: Dr. V.K. DASING AUTHORITY                                      |

Signature Stamp and Date

1 5 JUN 2020

Page 1 of 3

औषपी लाईसेंग्र प्राधिकारी DRUGS CONTROL DEPARTMENT

औषधी नियंत्रण विभान UT OF DAMAN & DIU, DAMAN

सथ ब्रदेश दमन एव दीव, दमन

- 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                             | 172. Spani<br>173. Sri Lanka    |
| 4. Angola             | 47. Czechoslovakia                     | 88. Israel                 | 131. Namibia                             | 174. Sudan                      |
| 5. Argentina          | 48. Democratic Republic                | 89. Italy                  | 131. Namioia                             | 175. Suriname                   |
| 6. Armenia            | of Congo                               | 90. Ivory Coast            | 133. Netherlands Antilles                | 176. Swaziland                  |
| 7. Aruba              | 49. Denmark                            |                            |  |                                 |
| 8. Australia          |  | 91. Jamaica                | 134. Netherlands                         | 177. Sweden<br>178. Switzerland |
| 9. Austria            | 50. Djibouti<br>51. Dominica           | 92. Japan                  | 135. New Zealand                         |                                 |
| 10. Azerbaijan        | 51. Dominica<br>52. Dominican Republic | 93. Jordan                 | 136. Nicaragua                           | 179. Syria<br>180. Tadzhikistan |
| 11. Bahamas           | 53. Ecuador                            | 94. Kazakhstan             | 137. Niger                               |                                 |
| 12. Bahrain           |  | 95. Kenya                  | 138. Nigeria                             | 181. Taiwan                     |
| 13. Baltic            | 54. Egypt                              | 96. Kingdom of Tonga       | 139. North Korea                         | 182. Tajikistan                 |
|                       | 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                               | 102 Handa                       |
| 24. Brazil            | 66. Guatemala                          | 108. Libva                 | 151. Portugal . N. C. //                 | 194 Dkraine                     |
| 25. Brunei            | 67. Georgia                            | 109. Libyan Arab           | 151. Portugal 115. 152. Ordans 5114 115. | Mon of Soviet                   |
| 26. Bulgaria          | 68. German Democratic                  | Jamahiriya                 | 153 Republic of Hamin UT                 | Union of Soviet                 |
| 27. Burkina Faso      | Republic <sup>2</sup>                  | 110. Liechtenstein         | 15. Republió de Guinee                   | 196. Carned Arab Emirates       |
| 28. Burundi           | 69. Germany Federal                    | 111. Liochtonstoin         | 15. Republic of Malaives                 | 197, United Kingdom             |
| 29. Byelorussia       | Republic of <sup>2</sup>               | 1/2. Lithuania             | 56. Romania                              | 198-United states               |
| 30. Cambodia          | 70. Germany                            | 113. Luxembourg            | 574Russia                                | 199. Urugua                     |
| 31. Cameroon          | 71. Ghana                              | 114. Macau                 | 68. Rwanda                               | 200. USA                        |
| 32. Canada            | 72. Greece                             | 115. Madagascar            | Do. Rwallua                              | 201 Uzbekistan                  |
| 33.Central African    | 73. Grenada                            | 116. Malawi                | 19. Saudi Arabia III. Oama               | 201: Uzbek man<br>202: Vanustu  |
| Republic              | 74. Guinea                             | 117. Malaysia              | 160. Senegal                             | 1 292.                          |
| 34. Chad              | 75. Guinea Equatorial                  |                            | 161 Sabia and                            | 203 Ven zuela<br>g200 Vetnam    |
| 35. Chile             | 76. Guinea Equatorial                  | 118. Maldives<br>119. Mali | 161 Schilla and 字中写                      | 1020W Victnam                   |
| 36. China             | 76. Guyana<br>77. Haiti                | 120. Malta                 | 162. Seye. 165 JAM                       | 205. West Indies<br>206. World  |
| 37. Cook Islands      |  |                            | 163. Sierra Leone                        |                                 |
|                       | 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:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

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

Telephone No. : 0091-0260-2230470

Fax No.

: 0091-0260-2230570

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

**DRUGS LICENSING AUTHORITY** 

औषधी लाईसिस प्राधिकारी

Signature

Stamp & Date

DRUGS CONTROL DEPARTMENT

औषधी निशंत्रण विभाग UT OF DAMAN & DIU, DAMAM

सब प्रदेश अधल एवं दीव, दमब

1 5 JUN 2020

| No. o   | f Certificate: DD/793/12B/2020-1-211-I   | Valid Up to: 04/01       | 2022  |
|---------|--|--------------------------|---|
| Expor   | ting (Certifying) Country  | : India                  | 12022   |
| Impor   | ting (Requesting) Country  | : As per Annexus         | u. ?  |
| 1       | Name and dosage form of Product  |                          | lydrochloride Capsule USP 50 mg                                       |
| 11      | Active ingredient(s)2 and amount(s) per unit dose3   | : Composition:           | symbolinde Capsule OSP 50 mg  |
|         | •  | Each capsule co          | entains:  |
|         |  | Procarbazine hy          | ydrochloride USP equivalent to  |
|         |  | Procarbazine             | 50mg  |
|         | ******   | Color: Approve           | d color used in cancule shells  |
| 1.2     | For complete qualitative composition including excipients,   | see attached . Anne      | xure - I  |
| 13      | Is this product licensed to be placed on the market for use i  | in the exporting country | Y <sup>5</sup> : Yes  |
| **      | Is this product actually on the market in the exporting coun   |                          | : Yes   |
|         | If the answer to 1.2 is yes, continue with section 2 A and of  |                          |   |
|         | If the answer to 1.2 is no, omit section 2 A and continue sec  | ction 2 B <sup>6</sup>   |   |
| 2.A.L   | Number of product licence <sup>7</sup> and date of issue   |                          | DD 703 Date 3 10 Mt most  |
| A.2     | Product Licence holder (Name & Address)  |                          | : DD/793 Dated 19/01/2019   |
|         | ,  |                          | : Bruck Pharma Pvt. Ltd.<br>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   |                          |   |
| 2 A 3 I | For categories b and c the name and address of the manufactor dosage form is 9   | turer producing the      | Not applicable  |
| 2.A.4   | Is a summary basis for approval appended?10  |                          | : NO  |
| 2.A 5   | Is the attached, officially approved product information con with the licence? 11  | iplete and consonant     | : NO : Not Provided AII.  |
| 2 A 6   | Applicant for certificate, if different from licence holder (na  | me and address)12        | No. and Still U.S. O.   |
| 2 B 1   | Applicant for certificate (Name & Address)   | the and adoless).        | Not Applied SAVE SIZE   |
| 2 B 2   | Status of applicant  |                          | NA / TO THE TAIL  |
| 2B21    | For categories (b) and (c) the name and address of the manu-   | facturer producing the   | NA B  |
|         | dosage form is:  | nationer producing inc   | क्रांच राज्य  |
| 2,B.3   | Why is marketing authorization lacking?  |                          | : NA SHITT Daman SS   |
| 2.B 4   | Remark 13  |                          | : NA CAPTO OF AND   |
| (       |  |                          | OF DOLLAN &   |
|         | Does the certifying authority arrange for periodic inspection form is produced? (yes/no/not applicable) 14   | of the manufacturing p   | lant in which the dosage  |
|         | If Not or Not applicable proceed to question 4   |                          |   |
| 3 1     | Periodicity of routine inspection (years)  |                          | : Yearly  |
| 32      | Has the manufacture of this type of dosage form been inspect   |                          | : Yes   |
| 3 3     | Do the facilities and operation confirm to GMP as recommend Organization? <sup>15</sup>  | ded by World Health      | : Yes   |
| 4.      | Does the information submitted by the applicant satisfy the coall aspects of the manufacture of the product? <sup>16</sup>   | ertifying authority on   | : 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 Author           |   |

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

Signature Stamp and Date

1 5 JUN 2020

अविश्वी लासिस प्रार्थिकारी DRUGS CONTROL DEPARTMENT

औषधी नियंत्रण विभाग FUT-OF DAMAN & DIU, DAMAN

सथ प्रदेश दमण एवं दीश उपन

- 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.
- 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;
  - 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/793/12B/2020-1-211-J

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.

| I Afghanistan        | 44. Cuba                 | 85 Iran               | 128 Morocco  | 171 South Korea   |
|----------------------|--------------------------|-----------------------|--|---|
| 2 Albania            | 45. Cyprus               | 86 Iraq               | 129 Mozambique   | 172 Spain   |
| 3 Algeria            | 46 Czech Republic        | 87 Ireland            | 130 Myanmar  | 173 Sri Lanka   |
| 4 Angola             | 47 Czechoslovakia¹       | 88 Israel             | 31 Namibia   | 174 Sudan   |
| 5 Argentina          | 48 Democratic Republic   | 89 lialy              | 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 Diibouti              | 92 Japan              | 135 New Zealand  | 178 Switzerland   |
| 9 Austria            | 51. Dominica             | 93 Jordan             | 136 Nicaragua  | 179 Syria   |
| 10 Azerbajian        | 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  |
|                      |                          |                       |  | <del></del>   |
| 15. Barbados         | 57. Eritres              | 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 Tunisía   |
| 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 UAÉ   |
| 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                                       |
| 27 Burkina Faso      | Republic <sup>2</sup>    | 110 Liechtenstein     | 154 Republic de Guina  | guted Arab Emirates                                       |
| 28 Burundi           | 69 Germany Federal       | 111 Liochtonstoin     | 155 Republic of Multiple                                       | 1997 Almas Kingdom  |
| 29 Byelorussia       | Republic of <sup>2</sup> | 112. Lithuania        | 156 Romania  | 198; VA Ard States  |
| 30 Cambodia          | 70 Germany               | 113. Luxembourg       | 155 Republic of Hulling 156 Romania C. 157 Russia C. 158 Rwada | 1927 Aliyas Kingdom<br>1988 Voyad States<br>1 Sept Urings |
| 31 Cameroon          | 71. Ghana                | II4 Macau             | 158 Rwasia   | .200 USA  |
| 32 Canada            | 72. Greece               | 115 Madagascar        | 159 Sauli Acibia   | 201 Uzhoketan   |
| 33 Central African   | 73. Grenada              | 116 Malawi            | 160 Seregal  | .202. Vanuatu   |
| Republic             | 74. Guinea               | 117 Malaysia          | 161 Se na and (  | 203 Venezuela ■   |
| 34 Chad              | 75, Guinea Equatorial    | 118 Maldives          | Montebegan   | 204 Vietnam   |
| 35 Chile             | 76 Guyana                | 119 Mali              | IAC Capalialles  | 202, West Indies  |
| 36 China             | 77. Haiti                | 120 Malta             | 163. Sterin Learne   | 206. World  |
| 37 Cook Islands      | 78 Holland               | 121 Marshall Islands  | 163. Stern Lexing 164. Singapore 165. Slovakia 166. Slovenia   | 207. Yémen  |
| 38 Colombia          | 79. Honduras             | 122 Mauritania        | 165 Slovakia   | 7 408 YIMBSTOWN   |
| 39 Columbia          | 80. Hong Kong            | 123 Mauritius         | 166 Slovenia   | MANNIE  |
| 40 Congo             | 81. Hungary              | 124 Mexico            | 167 Solomon Islands  | Birthin 2011  |
| 41, Costa Rica       | 82 Iceland               | 125 Moldova           | 168 Somalia  | 211. Zimbabwe   |
| 42 Council of Europe | 83. India                | 126 Моласо            | 169. Somaliland  | -   |
| 43 Croatia           | 84 Indonesia             | 127 Mongolia          | 170 South Africa   | - <del> </del>  |

Manager and the second of the

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 persons Licensing AUTHORITY

औषणी साईसेंस प्राधिवारी Signature: DRUGS CONTROL DEPARTI

DRUGS CONTROL DEPARTMENT औषधी नियंत्रण विभाग

UT OF DAMAN & DIU, DAMAN Stamp and date: श्रष्ट प्रदेश दमण एवं दींग, दमण

1 5 JUN 2020

Page 1 of 1

| No. of  | Certificate: <b>DD/793/29A/2020-1-211-I</b>   | Valid Up to: 04/01/20                  | 22   |
|---------|---|--|--|
| Export  | ing (Certifying) Country  | : India                                |  |
| Import  | ng (Requesting) Country   | : As per Annexure-I                    | I  |
| 1.      | Name and dosage form of Product   | : SORAFENIB TAE                        | BLET 200MG                                     |
| 1.1     | Active ingredient(s) <sup>2</sup> and amount(s) per unit dcse <sup>3</sup>  | : Composition:                         |  |
|         |   | Each film coated ta                    |  |
|         |   | Sorafenib Tosylate<br>Eq. to Sorafenib | 200mg  |
|         |   | Excipients                             | Dioxide & Ferric Oxide Red.                    |
|         |   | Colors, Tramum 1                       | Sinxide & Petric Oxide Reu.                    |
|         | For complete qualitative composition including excipients, se   | e attached <sup>4</sup> . Annexu       | re - I   |
| 1.2     | Is this product licensed to be placed on the market for use in t  |  | : 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 omi  | t section 2 B                          |  |
|         | If the answer to 1.2 is no, omit section 2 A and continue section   | on 2 B <sup>6</sup>                    |  |
|         |   |  |  |
| A.I     | Number of product licence <sup>7</sup> 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 manufactu dosage form is 9   | rer producing the                      | : Not applicable                               |
| 2.A.4   | Is a summary basis for approval appended?10   |  | : NO CING AUTHO                                |
| 2.A.5   | Is the attached, officially approved product information comp with the licence? $^{\rm II}$   | lete and consonant                     | : Your Tovided 11 11/15                        |
| 2.A.6   | Applicant for certificate, if different from licence holder (nam  | e and address)12                       | Not soplicable like                            |
| 2.B.1   | Applicant for certificate (Name & Address)  |  | NA (Constant)                                  |
| 2.B.2   | Status of applicant   |  | NA Herri Sere L                                |
| 2.B.2.1 | For categories (b) and (c) the name and address of the manufadosage form is: 9  | cturer producing the                   | NA Zami/Daman &                                |
| 2.B.3   | Why is marketing authorization lacking?   |  | : भी उन्हार है                                 |
| 2.B.4   | Remark <sup>13</sup>  |  | : NA CAMAN                                     |
|         |   |  |  |
| 3       | Does the certifying authority arrange for periodic inspection of form is produced? (yes/no/not applicable) 14   | f the manufacturing pla                | int in which the dosage : 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  | ed ?                                   | : Yes  |
| 3.3     | Do the facilities and operation confirm to GMP as recommend Organization $?^{15}$   | led by World Health                    | : Yes  |
| 4.      | Does the information submitted by the applicant satisfy the ce-   | rtifying authority on                  | : Yes  |
|         | all aspects of the manufacture of the product ?16   |  |  |
|         | 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 |  | 2 5 MAR 2021                                   |
|         | Fax No. : 0091 - 0260 - 2230570   | Name of Authori                        | ZEU DRUGSDINGENSING AUTHORITY                  |
|         |   |  | औरधी लाईर्सेस प्राधिकारी                       |
|         |   | Signature<br>Stamp and Date            | DRUGS CONTROL DEPARTMENT                       |
|         |   |  | औरची नियंत्रण विभाग<br>UT OF DAMAN & DIU DAMAN |

Page 1 of 2

सप प्रदेश दक्षण एवं दीत, प्रथम

- 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.
- 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.
- 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;
  - 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, Czechoslovakia1      | 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. 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   |
| <ol><li>Azerbaijan</li></ol>   | 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  |
| <ol> <li>Bangladesh</li> </ol> | 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. Turkev  |
| 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   | Illraina   |
| 25. Brunei                     | 67. Georgia              | 109, Libyan Arab      | 152. Oatar   | IP Units of Soviet  Project Republics  1176 Unit of Arb Emirates  197 Spite Princiom |
| 26. Bulgaria                   | 68. German Democratic    | Jamahiriya            | 153. Republic of Schim   | Asoialis Republics!  |
| 27. Burkina Faso               | Republic <sup>2</sup>    | 110. Liechtenstein    | 154 Re ublic le Guinte   | U156.Unit d Ar b Emirates  |
| 28. Burundi                    | 69. Germany Federal      | 111. Liochtonstoin    | 154. Roubbase Guined<br>155. Reputs of Maldives-<br>156. Romania   | 197 United Kin clom  |
| 29. Byelorussia                | Republic of <sup>2</sup> | 112. Lithuania        | 156 Comadia 20   | 198 United State   |
| 30. Cambodia                   | 70. Germany              | 113. Luxembourg       | 157 Russia   | 199 Urueliav   |
| 31. Cameroon                   | 71. Ghana                | 114. Macau            |  |  |
| 32. Canada                     | 72. Greece               | 115. Madagascar       | 159 Sattli Arabia  | 201. Uzbekistan  |
| 33.Central African             | 73. Grenada              | 116. Malawi           | 160 Compani  | · xxxxx Vanuatu  |
| Republic Republic              | 74. Guinea               | 117. Malaysia         | 161 Jerbia and Tarrit!   | namanVenezuela I   |
| 34. Chad                       | 75. Guinea Equatorial    | 118, Maldives         | Montenegro   | 204. Xietnasn  |
| 35. Chile                      | 76. Guyana               | 119. Mali             | 162 Sexheres   | - 205 West indes   |
| 36. China                      | 77. Haiti                | 120, Malta            | 161 terbia and Funt 161 terbia and Funt 161 terbia and Funt 161 terbia and Funt 161 Service of 163 Signary | 206. World   |
| 37. Cook Islands               | 78. Holland              | 121, Marshall Islands | 164, Singapore   | M207 Yanen   |
| 38. Colombia                   | 79. Honduras             | 122. Mauritania       | 165. Slovakia  | 206. 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          | 82. Iceland<br>83. India | 126. Monaco           | 169. Somaliland  | 211. Zimodowe  |
| 43. Croatia                    | 84. Indonesia            | 126. Mongolia         | 170. South Africa  |  |
| 43. Croatia                    | 1 84. Indonesia          | 127. Mongoita         | 1 170. 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: Druger Bris AUTHORITY

औषधी लाईसेंस प्राधिकारी DRUGS CONTROL DEPARTMENT

Signature:

Stamp & Date:

अरेक्सी नियंगण विभाग UT OF DAMAN 3 DIU DAMAN

सथ प्रदेश दमन एवं दीव, दनन

2 5 MAR 2021

Page I of I

|         | Certificate: DD/793/15A/2020/-1-211-1  | Va         | lid Up to: 04/01/20            | 22   |
|---------|--|------------|--------------------------------|--|
|         | ling (Certifying) Country  | :          | India                          |  |
| Import  | ing (Requesting) Country   | <b>:</b> . | As per Annexure-2              | 2  |
| 1       | Name and dosage form of Product  | :          | Chlorambucil Tab               | elet BP 2 mg   |
| 11      | Active ingredient(s) <sup>2</sup> and amount(s) per unit dose <sup>3</sup>   | :          | Composition:                   |  |
|         |  |            | Each film coated to            |  |
|         |  |            | Chlorambuen BP .<br>Excipients | 2mg  |
|         | Parameters 1973  |            |                                |  |
|         | For complete qualitative composition including excipients  |            |                                |  |
| 1.2     | Is this product licensed to be placed on the market for use  |            | exporting country?5            | : Yes  |
| 13      | Is this product actually on the market in the exporting coul   |            |                                | : Yes  |
|         | If the answer to 1.2 is yes, continue with section 2 A and o   |            |                                |  |
|         | If the answer to 1.2 is no, omit section 2.A and continue st   | ection 2   | 2 B*                           |  |
| 2 A I   | Number of product licence <sup>7</sup> and date of issue   |            |                                | T 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   |            |                                | : 9  |
| 2.A.3.1 | For categories b and c the name and address of the manufa dosage form is?  | acturer p  | producing the                  | : Not applicable   |
| 2.A.4   | Is a summary basis for approval appended?10  |            |                                | : NO SING AUTHO  |
| 2.A.5   | Is the attached, officially approved product information co with the licence? 11                                     | mplete     | and consonant                  | : Number of the state of the st |
| 2 A 6   | Applicant for certificate, if different from licence holder (n   | tante ar   | nd address)13                  | : ot Appurable City  |
| 2 B:1   | Applicant for certificate (Name & Address)   |            |                                | : W. **  |
| 2 B 2   | Status of applicant  |            |                                |  |
| 2.B.2.1 | For categories (b) and (c) the name and address of the man dosage form is: 9   | ıu factor  | er producing the               | : N Sy contidens of  |
| 2:B.3   | Why is marketing authorization lacking?  |            |                                | : NA   |
| 2-B-4   | Remark <sup>13</sup>   |            |                                | : NA   |
| 3       | Does the certifying authority arrange for periodic inspectio form is produced? (yes/no/not applicable) <sup>14</sup> | or of the  | e manufactoring pla            | nt in which the dosage T Yes   |
|         | If Not or Not applicable proceed to question 4   |            |                                |  |
| 31      | Periodicity of routine inspection (years)  |            |                                | : Yearly   |
| 3.2     | Has the manufacture of this type of dosage form been inspe   | ected?     |                                | : Yes  |
| 3 3     | Do the facilities and operation confirm to GMP as recommon Organization ? <sup>15</sup>                              | ended l    | oy World Health                | : Yes  |
| 4       | Does the information submitted by the applicant satisfy the all aspects of the manufacture of the product ?16        | certify    | ing authority on               | : Yes  |
|         | If No, explain   |            |                                | : Not Applicable   |
|         | Address of certifying authority Drug Licensing Authority,  |            |                                | e e  |
|         | Administration of Daman & Diu, Drugs Control Dept.   |            |                                | . <i>f</i>   |
|         | Primary Health Center, Daman (UT) - 396 220.<br>Telephone No.: 0091 - 0260 - 2230470                                 |            |                                | <b>X</b> /   |
|         | Fax No. : 0091 - 0260 - 2230570  |            |                                | <i>v</i> -   |
|         |  |            | Name of Authoria               | red Person: Dr. V.K. DAS DRUGS LICENSING AUTHORITY   |

Stamp and Trate
DRUGS CONTROL DEPARTMENT
1 5 JUN 2020 প্রতির বিশেষত কি

सम प्रदेश हमण एवं हीता, हमण

- 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.
- 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 Merocco                   | 1 171 6                     |
|-----------------------|-------------------------|---------------------------|-------------------------------|-----------------------------|
| 2 Albania             | 45 Cyprus               | 86 Iraq                   | 129 Mozambique                | 171 South Korea             |
| 3 Algeria             | 46 Czech Republic       | 87 Ireland                | 130, Myanmar                  | 172. Spain                  |
| 4. Angola             | 47 Czechoslovakia       | 88 Israel                 | 130, Myanmar<br>131, Namibia  | 173. Sri Lanka              |
| 5 Argentina           | 48. Democratic Republic | 89 Italy                  | 132 Nepal                     | 174. Sudan<br>175. Suriname |
| 6. Armenia            | of Congo                | 90. Ivory Coast           |                               |                             |
| 7. Aruba              | 49 Denmark              | 91 Jamaica                | 133. Netherlands Antilles     | 176 Swaziland               |
| 8. Australia          | 50 Djibouti             | 92 Japan                  | 134. Netherlands              | 177 Sweden                  |
| 9 Austria             | 51 Dominica             |                           | 135. New Zealand              | 178. Switzerland            |
| 10 Azerbaijan         | 52 Dominican Republic   | 93 Jordan                 | 136. Nicaragua                | 179 Syria                   |
| 11 Bahamas            | 53 Ecuador              | 94 Kazakhstan             | 137. Niger                    | 180 Tadzhikistan            |
| 12 Bahrain            | 54 Egypt                | 95 Kenya                  | 138. Nigeria                  | 181. Taiwan                 |
| 13. Baltic            | 55 El Salvador          | 96 Kingdom of Tonga       | 139. North Korea              | 182. Tajikistan             |
| 14 Bangladesh         | 56 Equatorial Guinea    | 97. Kiribati<br>98. Korea | 140. Norway                   | 183 Tanzania                |
| 15 Barbados           | 57. Eritrea             |                           | I#1 Oman                      | 184 Thailand                |
|                       |                         | 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. Panage                   | Ja Vonga                    |
| 18 Belize             | 60. European Community  | 102 Kyrgyzstan            | 144. Panta 144. Militea       | 16 In jidad                 |
| 19 Benin              | 61. Piji                | 103 Laos                  | 146. Marie 145 1171 7         | 1 89 Aepina                 |
| 20 Bhutan             | 62 Finland              | 104 Latvia                |                               | 490 1 400                   |
| 21 Bolivia            | 63. France              | 105 Lebanon               | 14 Photo Cox                  | 191/Teneme istan            |
| 22 Bosnia             | 64 Gabon                | 106 Lesotho               | 1.0. Philippines              | 192 JAAE                    |
| 23 Botswana           | 65 Gambia               | 107 Libena                | 1 0. Poland                   | 192 ASAE<br>193 Ugarda      |
| 24 Brazil             | 66 Guatemala            | 108 Libya                 | l L Portugal                  | 194 Ukraine                 |
| 25 Brunei             | 67 Georgia              | 109 Libyan Arab           | 12. Qatara                    | 195. Sprion of Govies       |
| 26 Bulgaria           | 68 German Democratic    | Jamahiriya                | IS Republic of the in Daniel  | The Consisting Countries    |
| 27 Burkina Faso       | Republic <sup>2</sup>   | 110. Liechtenstein        | 154 Capplic Cas (Juinee       | -156 Que Arab Emirates      |
| 28 Burundi            | 69 Germany Federal      | 111 Liochtonstoin         | 155 20                        | 197 and Kingdom             |
| 29 Byelorussia        | Republic of             | 12 Lithuania              | 155. Kin older of Alessifus I | Red Kinedom                 |
| 30 Cambodia           | 70 Germany              |                           | 156. Rom DAMA                 | 198 mited States            |
| 31 Cameroon           | 71 Ghana                | 113 Luxembourg            | 157 Russia                    | Uruguay                     |
| 32 Canada             |                         | 114. Macau                | 158. Rwanda                   | 200 USA                     |
| 33 Central African    | 72 Greece               | 115. Madagascar           | 159. Saudi Arabia             | 201 Uzbekistan              |
| Republic              | 73 Grenada              | 116. Malawi               | 160. Senegal                  | 202 Vanuatu                 |
| 34 Chad               | 74. Guinea              | 117. Malaysia             | 161 Serbia and                | 203, Venezuela              |
| 35. Chile             | 75 Guinea Equatorial    | 118. Maldives             | Montenegro                    | 204 Vietnam                 |
| 36 China              | 76 Guyana               | 119. Mali                 | 162. Seychelles               | 205, West Indies            |
| 37 Cook Islands       | 77 Haiti                | 20. Malta                 | 163. Sierra Leone             | 206 World                   |
| 38. Colombia          | 78 Holland              | (2), Marshall Islands     | 164 Singapore                 | 207 Yemen                   |
|                       | 79 Honduras             | 122 Mauritania            | 165. Slovakia                 | 208 Yugoslavia'             |
| 39. Columbia          | 80 Hong Kong            | #23 Mauritius             | 166, Slovenia                 | 209. Zaire                  |
| 40 Congo              | 81 Hungary              | 124 Mexico                | 167. Solomon Islands          | 210. Zambia                 |
| 41. Costa Rica        | 82 Iceland              | \$25 Moldova              | 168 Somalia                   | 211 Zimbabwe                |
| 42. Council of Europe | 83 India                | \$26. Monaco              | 169. Somaliland               |                             |
| 43. Croatia           | 84 Indonesia            | \$27 Mongotia             | 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 persuarity CENSING AUTHORITY

औषयी साइंसेंस प्रतिकारी !GS CONTROL SCENETTS

DRUGS CONTROL DEPARTMENT

औरपी नियंत्रण विभाग UT OF DAMAN & DIU, DAMAN

Stamp and date: संध प्रदेश दमण एवं दीव, दमण

1 5 JUN 2020

Signature:

| No. of  | Сепіficate: DD/794/44C/2020-1-211-I  | 'alid Up to: 04/01/2022                               |
|---------|--|---|
| Export  | ing (Certifying) Country ;   | India   |
| lmport  | ing (Requesting) Country   | As per Annexure-2                                     |
| 1:      | Name and dosage form of Product :  | Cytarabine Injection BP 1000mg/10 m!                  |
| 11      | Active ingredient(s) <sup>2</sup> and amount(s) per unit dose <sup>3</sup> :   | Composition:  |
|         |  | Each ml contains:                                     |
|         |  | Cytarabine BP100mg                                    |
|         | For complete qualitative composition including excipients, see   | attached Annexure - I                                 |
| 12      | Is this product licensed to be placed on the market for use in the   |   |
| 13      | Is this product actually on the market in the exporting country?   |   |
|         | If the answer to 1.2 is yes, continue with section 2. A and ornit s  |   |
|         | If the answer to 1.2 is no, omit section 2 A and continue section  | 12 B <sup>6</sup>                                     |
|         |  |   |
| 2.A.1   | Number of product licence <sup>7</sup> 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   | 3 #   |
| 2.A.3.1 | For categories b and c the name and address of the manufacture   | r producing the ; Nut applicable                      |
| 2.A.4   | dosage form is9  Is a summary basis for approval appended?10   | ISING AUTHO   |
| 2.A.5   | Is the attached, officially approved product information comple  | No Asia Mariana                                       |
| 2010    | with the licence? 11   | te and consonant . Natt Paville                       |
| 2.A.6   | Applicant for certificate, if different from licence holder (name  | and address)12 Not policable                          |
| 2.B.1   | Applicant for certificate (Name & Address)   | : NA  |
| 2 B:2   | Status of applicant  | : NA September (*)                                    |
| 2 B.2.1 | For categories (b) and (c) the name and address of the manufact dosage form is: 9  | urer producing the : NA                               |
| 2 B 3   | Why is marketing authorization lacking?  | : NA DAMAN  |
| 2.B.4   | Remark <sup>17</sup>   | : NA  |
| 3       | Does the certifying authority arrange for periodic inspection of form is produced? (yes/no/not applicable) 14  | the manufacturing plant in which the dosage : 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 Organization ? <sup>15</sup>   | d by World Health : Yes                               |
| 4       | Does the information submitted by the applicant satisfy the certiall aspects of the manufacture of the product ? <sup>16</sup>   | fying authority on : 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. E. DAS NO AUTHORITY |
|         |  | Parfector Paris paris and a second                    |

Signature
Stamp and Date

1 5 JUN 2020

औषपी लाईसैंत प्रतिषक्षारी DRUGS CON'ROL DEPARTMENT औषपी निवंत्रण विमाल UT OF DAMAN & DIU, DAMAN सब प्रदेश रमन एश दीन, रमन

- 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.
- 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
- 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;
  - 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              | 28 Morocco                 | 171 South Korea  |
|----------------------|--------------------------------|----------------------|----------------------------|--|
| 2. Albania           | 45 Cyprus                      | 86 Iraq              | 29 Mozambique              | 172 Spain  |
| 3 Algena             | 46 Czech Republic              | 87 Ireland           | \$30 Myanmar               | 173 Sri Lanka  |
| 4 Angola             | 47 Czechoslovakia <sup>1</sup> | 88 Israel            | 131 Namibia                | 174 Sudan  |
| 5 Argentina          | 48. Democratic Republic        | 89. Italy            | 132 Nepal                  | 175 Sunname  |
| 6 Armenia            | of Congo                       | 90 Ivory Coast       | 133. Netherlands Antilles  | 176 Swaziland  |
| 7. Aruba             | 49. Denmark                    | 91 Jamaica           | 34 Netherlands             | 177 Sweden   |
| 8 Australia          | 50 Djibouti                    | 92 Japan             | 35 New Zealand             | 178 Switzerland  |
| 9. Austria           | 51 Dominica                    | 93 Jordan            | 136 Nicaragua              | 179 Syma   |
| 10 Azerbaijan        | 52 Dominican Republic          | 94 Kazakhstan        | 137 Niger                  | 180 Tadzhikistan   |
| 11 Bahamas           | 53 Ecuador                     | 95, Kenva            | 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                    | 7                    |                            | <del></del>  |
| 13 Darbagos          |                                | 99 Korea Republic of | 142 Pakistan               | 185 Tobago   |
| 16 Belarus           | 58. Estonia                    | 100 Kosova           | 143 Palau                  | 186. Togo  |
| 17 Belgium           | 59 Ethiopia                    | J01 Kuwait           | 144 Proposition (147)      | 1 tinga  |
| 18 Belize            | 60 European Community          | 102 Kyrgyzstan       | 145 Programme Citingea     | 1 Invidad  |
| 19 Benin             | 61 Fiji                        | 103 Laos             | 146 Pagingray > 5/(111 5/) | F. 1894 Planting   |
| 20 Bhutan            | 62 Finland                     | 104 Latvia           | 14 . 3 6 Line              | 190. Tarke   |
| 21 Bolivia           | 63 Гталсе                      | ₹05. Lebanon         | U 8 Puerta Rico Ch. Re     | 19t Turkmenistan   |
| 22 Bosnia            | 64 Gabon                       | 106 Lesotho          | 19. Philippines            | 192: UAE   |
| 23. Botswana         | 65 Gambia                      | 107 Liberia          | 50MPoland                  | 193 Uganda   |
| 24 Brazil            | 66. Guatemala                  | 108. Libva           | 51. Portugal               | 194. Ukraino   |
| 25 Brunei            | 67 Georgia                     | 109 Libyan Arab      | IV Catara                  | The second secon |
| 26. Bulgaria         | 68 German Democratic           | Jamahiriya           | 5 Republic of Benin        | 3. Social It Republics1  |
| 27 Burkina Faso      | Republic <sup>2</sup>          | 110 Liechtenstein    | 154. Re Slic We Guinee     | 1 % Dait of Arab Emirates  |
| 28 Burundi           | 69 Germany Federal             | 111 Liochtonstoin    | 155 Remedigat Manufels     | c199. United Kingdom   |
| 29 Byelorussia       | Republic of <sup>2</sup>       | 112 Lithuania        | 156 Roma in LAWAY          | Inited States  |
| 30 Cambodia          | 70 Germany                     | 113 Luxemboure       | 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          | 117 Maldives         | Montenegro                 | 204 Vietnam  |
| 35 Chile             | 76 Guyana                      | 119 Mali             | 162 Sevehelles             | 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 Mauntius         | 166 Slovenia               |  |
| 40. Congo            | 81 Hungary                     | ·                    | <del></del>                | 209 Zaire  |
| 41 Costa Rica        |                                | 124 Mexico           | 167. Solomon Islands       | 210 Zambia   |
|                      | 82 Iceland                     | 125 Moldova          | 168 Somalia                | 211 Zimbabwe   |
| 42 Council of Europe | 83. India                      | 126 Monaco           | 169, Somaliland            | <u> </u>   |
| 43 Croatia           | 84, Indonesia                  | 127 Mongolia         | 170 South Africa           | 5  |

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

DRUGS LICENSING AUTHORITY

सीवधी साईसेंस प्रापिकारी DRUGS CON₹ROL DEPARTMENT

Stamp and date:

उरीषधी नियंत्रण विभाग UT OF DAMAN 3 DIU, DAMAN संघ प्रदेश दमण एवं दीत, टमण

1 5 JUN 2020

Signature:

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 Name and dosage form of Product Doxorubicin Hydrochloride Injection USP 10mg/5 ml 1.1 Active ingredient(s)1 and amount(s) per unit dose3 Composition: Each ml contains: Doxorubicin hydrochloride USP ......2mg Water for Injection USP......q.s. For complete qualitative composition including excipients, see attached. Annexure - I 12 Is this product licensed to be placed on the market for use in the exporting country?5 Yes Is this product actually on the market in the exporting country? 1.3 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 B6 2.A I Number of product licence<sup>7</sup> and date of issue d DD/794 Dated 16/08/2019 ?A2 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 For categories b and c the name and address of the manufacturer producing the 2 A 3.1 dosage form is5 2.A.4 Is a summary basis for approval appended?10 2 A 5 Is the attached, officially approved product information complete and consonant with the licence? 11 2 A 6 Applicant for certificate, if different from licence holder (name and address)12 2B1 Applicant for certificate (Name & Address) 2 B 2 Status of applicant 2 B 2 I For executives (b) and (c) the name and address of the manufacturer producing the dos form is. 2.B 3 Why is marketing authorization lacking? 2.B4 Remark 13 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage Yes form is produced? (yes/no/not applicable) 1 If Not or Not applicable proceed to question 4 31 Periodicity of routine inspection (years) Yearly 3.2 Has the manufacture of this type of dosage form been inspected? Yes 33 Do the facilities and operation confirm to GMP as recommended by World Health Organization ?15 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product  $?^{16}$ 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

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

Name of Authorized Person: Dr VK DAS

Signature Stamp and Date DRUGS LICENSING AUTHORITY औषपी लाईसँस प्राधिकारी DRUGS CONTROL DEPARTMENT

JUN 2020 औरपमी रियंत्रण निपान UT OF DAMAN & DIU, DAMAN

संघ प्रदेश दण्ण एवं दीव, रूपण

Page 1 of 3

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  - 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.
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  - d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.
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- 14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
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- 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.

|                       |   | F 2-1                 |  | 101.6  |
|-----------------------|---|-----------------------|--|--|
| L Afghanistan         | 44. Cuba  | 85. Iran              | 28 Morocco   | 171 South Korea                                  |
| 2 Albania             | 45 Cyprus   | 86 Iraq               | 129 Mozambique   | 172 Spain  |
| 3 Algeria             | 46 Czech Republic                                   | 87 Ireland            | 130 Myanmar  | 173 Sri Lanka                                    |
| 4 Angola              | 47. Czechoslovakia¹                                 | 88. Israel            | #31 Namibia  | 174. Sudan                                       |
| 5 Argentina           | 48 Democratic Republic                              | 89. Italy             | #32 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              | #35 New Zealand  | 178. Switzerland                                 |
| 9 Austria             | 51 Dominica   | 93. Jordan            | 136 Nicaragua  | 179 Syria  |
| 10. Azerbaijan        | 52 Dominican Republic                               | 94 Kazakhstan         | 137. Niger   | \$80. Tadzhikistan                               |
| 11 Bahamas            | 53 Ecuador  | 95 Kenya              | 138, Nigeria   | 181 Taiwan                                       |
| 12 Bahram             | 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 Ornan  | 184 Thailand                                     |
| 15 Barbados           | 57. Eritren   | 99. Korca Republic of | 142. Pakistan  | 185 Tobago                                       |
| 16. Belarus           | 58. Estonia   | 100 Kosova            | 143 Palau  | 186 l'ogo  |
| 17 Belgium            | 59 Ethiopia   | 101 Kuwait            | 144, Panama  | 187 Tonga  |
| 18 Belize             | 60 European Community                               | 102 Kyrgyzstan        | 145. Papua New James   | L D. Tripidad                                    |
| 19 Benin              | 6l Fiji   | 103 Laos              | 145 Papua New Amica<br>146 Paragu<br>147 Peru  | 1977 (m. sin<br>1977 (p):<br>1791   Tindhichedan |
| 20 Bhutan             | 62 Finland  | 104 Latvia            | 147 Peru   | 19000000   |
| 21 Bolivia            | 63 France   | 105 Lebanon           | 148. Purito livro  | 7 (9) Turkbehatan                                |
| 22 Bosnia             | 64 Gabon  | 106. Lesotho          | 149. Bail andres.  |  |
| 23 Botswana           | 65 Gambia   | 107 Liberia           | 149. Frill times (in:  |  |
| 24 Brazil             | 66 Guatemala  | 108 Libya             | 51 Portugal  |  |
| 25 Brunei             | 67 Georgia  | 109 Libyan Arab       | 52 Dillur  | 195 Union of Societ                              |
| 26 Bulgaria           | 68 German Democratic                                | Janiahiriya           | 153. Republic of Benin-  | Socialist Republics                              |
| 27 Burkina Faso       | Republic <sup>2</sup>                               | 110 Liechtenstein     | 154 Tepublicate Guines, c.   |  |
| 28 Burundi            | 69 Germany Federal                                  | 111. Liochtonstoin    | P. S. S. Communication College Start Branches  | 107 Paris J 17 Feel and                          |
| 29. Byelorussia       | Republic of <sup>2</sup>                            | 112 Lithuania         | 156 Riberta  | 198. United States                               |
| 30 Cambodia           | 70 Germany  | 113. Luxembourg       | 157. Russia : //c  | 199 Urunday                                      |
| 31. Cameroon          | 71 Ghana  | 114 Macau             | 158 Rwanda LAN   | 199 Urlioday<br>(200) P.S.A<br>(II. Uzbekistan   |
| 32. Canada            | 72 Greece   | 115 Madagascar        | 159 Saudi Arabia   | Zul. Uzbekistan                                  |
| 33 Central African    | 73 Grenada  | 116 Malawi            | 160 Senegal  | 202 Vanuatu                                      |
| Republic              | 74 Guinca   | 117 Malaysia          | 161 Serbia and   | 203 Venezuela                                    |
| 34. Chad              | 2. 20 <b>.</b> 2. 2 . 2 . 2 . 2 . 2 . 2 . 2 . 2 . 2 |                       | Montenegro   | 204 Vietnam                                      |
| 34. Chad<br>35. Chile | 75 Guinea Equatorial                                | 118 Maldives          | 162 Seychelies   | 205 West Indies                                  |
|                       | 76 Guvana   | 119 Mali              |  | 206 World  |
| 36 China              | 77 Haiti  | 120 Malta             | 163 Sierra Lcone   |  |
| 37 Cook Islands       | 78 Holland  | 121 Marshall Islands  | 164 Singapore<br>165 Slovakia  | 207 Yemen<br>208 Yugoslavia                      |
| 38 Colombia           | 79 Honduras   | 122 Mauritania        | 166 Slovenia   | 208 Yugosiavia<br>209 Zaire                      |
| 39 Columbia           | 80 Hong Kong  | 123 Mauritius         | #67 Selomon Islands  | 210 Zambia                                       |
| 40. Congo             | 81. Hungary   | 124 Mexico            | The state of the s | 211 Zimbabwe                                     |
| 41 Costa Rica         | 82 Iceland  | 125 Moldova           | 168 Somalia  | Z11.Z.Imbabwe                                    |
| 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 permitter Kensiks AUTHORITY

औषधी लाईसेंत प्रश्निकारी DRUGS CONTROL DEPARTMENT

Signature: औषधी निष्ठण विभाग

UT OF DAMAN & DIU, DAMAN

सच प्रदेश रूपण एवं रोख, रूपण

1 5 JUN 2020

Stamp and date:

|          |  |               |                       | <b>Q</b>                                  |
|----------|--|---------------|-----------------------|---|
|          | f Certificate; DD/794/20C/2020-1-211-I   | 1             | /alid Up to: 04/01/20 | 022                                       |
|          | rting (Certifying) Country   | :             | India                 |   |
|          | rling (Requesting) Country   | :             | As per Annexure-      | 2   |
| 1        | Name and dosage form of Product  | ;             | Eprubicin Hydroc      | chloride for Injection 10mg/vial          |
| l · 1    | Active ingredient(s) <sup>2</sup> and amount(s) per unit dose <sup>3</sup>   | :             | Composition:          |   |
|          |  |               | Each vial contains    | -   |
|          |  |               | Lactose monohyda      | thloride                                  |
|          | For complete qualitative composition including excipients  | 500           | attached* Annexu      | ······································    |
| 1,2      | Is this product licensed to be placed on the market for use  |               |                       |   |
| 1.3      | Is this product actually on the market in the exporting cou  |               |                       | : Yes                                     |
|          | If the answer to 1 2 is yes, continue with section 2 A and o   |               |                       | . 163                                     |
|          | If the answer to 1.2 is no, omit section 2 A and continue se   |               |                       |   |
|          |  |               |                       |   |
| 2.A.1    | Number of product licence <sup>7</sup> and date of issue   |               |                       | DD/794 Dated 11/12/2019                   |
| ~ ? A Z  | Product Licence holder (Name & Address)  |               |                       | 2 Bruck Pharma Pvi. 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   |               |                       | ž a                                       |
| 2.A.J.1  | dosage form is <sup>9</sup>  | cture         | r producing the       | : Not applicable                          |
| 2 A.4    | Is a summary basis for approval appended?10  |               |                       | i NO                                      |
| 2 A 5    | Is the attached, officially approved product information cowith the licence? $^{\rm H}$  |               |                       | Not DAVISANG AUTHOR                       |
| 2 A.6    | Applicant for certificate, if different from licence holder (n   | ame           | and address)12        | or seplicable                             |
| 2.B.1    | Applicant for certificate (Name & Address)   |               |                       | WE TO A                                   |
| 2.B.2    | Status of applicant  |               |                       | * NA                                      |
| 2.B 2.1  | For categories (b) and (c) the name and address of the mand dosage form is: 9  | ıfactı        | arer producing the    | a approvate &                             |
| 2.B3     | Why is marketing authorization lacking?  |               |                       | 1   |
| 2 B.4    | Remark <sup>13</sup>   |               |                       | · NA PROPERTY SALES                       |
| 'n       | Developed to the state of the s |               |                       | UAMAN                                     |
| <b>3</b> | Does the certifying authority arrange for periodic inspection form is produced? (yes/no/not applicable) 12   | oft           | ne manufacturing pla  | nt in which the dosage : Yes              |
|          | If Not or Not applicable proceed to question 4   |               |                       |   |
| 31       | Periodicity of routine inspection (years)  |               |                       | : Yearly                                  |
| 3 2      | Has the manufacture of this type of dosage form been inspe-  |               |                       | : Yes                                     |
| 3.3      | Do the facilities and operation confirm to GMP as recomme Organization ? <sup>15</sup>   | n <b>de</b> d | by World Health       | ; Yes                                     |
| 4        | Does the information submitted by the applicant satisfy the all aspects of the manufacture of the product? <sup>16</sup>   | certif        | ying authority on     | : 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. 2001, 2022, |               |                       |   |
|          | Telephone No.: 0091 = 0260 = 2230470<br>Fax No.: 0091 = 0260 = 2230570   |               |                       | 2//                                       |
|          | · • · •  |               | Name of Authoriz      | ed Person: Dr VK DAS                      |

Signature Stamp and Date

1 5 JUN 2020

Name of Authorized Person: Dr. V.K. DAS
DRUGS LICENSING AUTHORITY औषधी लाईसेंस प्राधिकारी DRUGS CONTROL DEPARTMENT

औषधी नियंत्रण विभाग UT OF DAMAN & DIU, DAMAN संघ प्रदेश दमन एवं टीव, रोमण

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  - 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/794/20C/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.

| (. Afghanistan        | 44 Cuba                  | 85 Iran              | 128 Morocco  | 171 South Korea   |
|-----------------------|--------------------------|----------------------|--|---|
| 2 Albania             | 45 Cyprus                | 86 Iraq              | 129 Mozambique   | 172 Soain   |
| 3. Algeria            | 46 Czech Republic        | 87 Ireland           | 130 Myanmar  | 173 Sri Lanka   |
| 4 Angola              | 47 Czechoslovakia¹       | 88 Israel            | 131 Namibia  | 174 Sudan   |
| 5 Argentina           | 48 Democratic 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 Diibouti              | 92 Japan             | 135 New Zealand  | 178 Switzerland   |
| 9 Austria             | 51 Dominica              | 93. Jordan           | 136 Nicaragua  | 179 Syria   |
| 10. Azerbaijan        | 52 Dominican Republic    | 94 Kazakhstan        | 137 Niger  | 180 Tadzhikistan  |
| 11 Bahamas            | 53 Ecuador               | 95 Kenya             | 138 Nigeria  | 181 Taiwan  |
| 12 Bahrain            | 54. Egypt                | 96. Kingdom of Tonga | 139 North Korea  | 182 Tajikistan  |
| 13 Baltic             | 55 El Salvador           | 97 Kiribati          | 140 Norway   | 183 Tanzania  |
| 14. Bangladesh        | 56 Equatorial Quinea     | 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   |
| 8 Belize              | 60 European Community    | 102 Kyrgyzstan       | 145. Papua New Guinea                                  | 188 Trinidad  |
| 19. Benin             | 61 Fiji                  | 103. Laos            | 146. Paraguay  | 189 Tunisia   |
| 20 Bhulan             | 62 Finland               | 104. Latvia          | 147. Peru  | 190 Turkey  |
| 21 Bolivia            | 63 France                | 105. Lebanon         | 148. Puerto Ri   | C. Turkmenistan   |
| 22 Bosnia             | 64 Gabon                 | 106. Lesotho         | 149. Philip ses N 1 14                                 | UTA DE  |
| 23 Botswana           | 65 Gambia                | 107. Liberia         | 149. Philip acs 14<br>150. Polling 3<br>151. Surface 3 | 1900 pulls  |
| 24 Brazil             | 66 Guatemala             | 108 Libva            | 51. <b>(a)</b> الأراد                                  | /194, Lineary   |
| 25 Brunei             | 67 Georgia               | 109 Libvan Arab      | 152 Mark 1 1615  | 199 Ummi or avier   |
| 26 Bulgaria           | 68 German Democratic     | Jamahiriya           | 153 Republic of Benin                                  | Significat Republics  |
| 27. Burkina Faso      | Republic <sup>2</sup>    | # 10. Liechtenstein  |  | 196 United Arm Emirates   |
| 28 Burundi            | 69 Germany Federal       | 11 Liochtonstoin     | 155 Republic of Maldivin                               | 197 United Kirtzdom   |
| 29 Byelorussia        | Republic of <sup>2</sup> | 112. Lithuania       |  | 41-498. United States   |
| 30, Cambodia          | 70 Germany               | 113. Luxembourg      | 157 Russia 🐼 🚁 🖂                                       | in 199 Bluenav  |
| 31. Cameroon          | 71 Ghana                 | 14. Macau            | 58. Navanda 🗀  | 200. USA  |
| 32 Canada             | 72 Greece                | 115 Madagascar       | 159. Sa di of pole (1)                                 | 201. Robelasian   |
| 33 Central African    | 73 Grenada               | 1 6 Malawi           | 160 Sene . Dr  | 3/25V millatu   |
| Republic              | 74 Guinea                | 1 7 Malaysia         | 158. Iwanda > 159. Sa di organia > 160. Sene           | 1720 Acresticia   |
| 34, Chad              | 75 Guinea Equatorial     | 18. Maldives         | Montenegro   | 204 Vietnam   |
| 35 Chile              | 76. Guvana               | 1 9 Mali             | 162 Sevehelles   | 205. West Indies  |
| 36 China              | 77 Haiti                 | t20. 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 <sup>1</sup>   |
| 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   | # 100 mm |
| 43. Croatia           | 84 Indonesia             | 127 Mongolia         | 170 South Africa                                       |   |

Address of Certifying Authority:

Drug Licensing Authority,

Administration of Daman & Diu, Drugs Control Dept.,

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

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

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

जीवपी लाईसेंस प्रधिकारी
DRUGS CONTROL DEPARTMENT

Signature Stamp & Date

औषपी निवंत्रण विधाग UT OF DAMAN & DIU, DAMAN संघ प्रदेश रमण एवं दौव, रंदण

1 5 JUN 2020

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