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

Certificate of a Pharmaceutical Product[1]

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

No. of Certificate : **DD/794/39C/2022-1-211-2** **Valid up to: 04/03/2025**
Exporting (Certifying) Country : **INDIA**
Importing (Requesting) Country : **As per Annexure-II**
1. Name and dosage form of product : **Doxorubicin Hydrochloride for Injection USP 10 mg / vial**

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

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

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] **Yes**

1.3 Is this product actually on the market in the exporting country? **Yes**

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

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

2 A

A.1 Number of product license[7] : **DD/794**
And date of issue : **16/07/2019**

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

A.3 Status of product license holder [8] : a

Manufacturing of Dosage forms

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

A.4 Is summary basis of Approval appended?[10]

No

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

Not provided

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

2 B Not applicable.

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

(Name and address)

B.2 Status of applicant (**Not applicable.**)

B.2.1 For categories b and c the name and address of the Manufacturer producing the dosage form are[9] : **Not applicable**

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

Required Requested Consideration

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

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

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

Yes If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years): **Yearly**

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

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

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

Yes If no, explain

Address of certifying authority :

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

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

Signature:

Stamp and date:

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

2 3 MAY 2022

Digitally signed by Dicusar Vladimir
Date: 2022.12.14 20:03:58 EET
Reason: MoldSign Signature
Location: Moldova

General instructions

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

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, international Nonproprietary Names (INNs) or National Nonproprietary names.
3. The formula (Complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license holder.
5. When applicable, append details of any restriction, applied to the sale, distribution or administration of the product that is specified in the product license.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the license is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market.
   (a) manufactures the dosage form :
   (b) Packages and/or labels a dosage form manufactured by an independent company; or
   (c) is involved in none of the above.
9. This information can be provided only with the consent of the product-license holder or, in the case of non- registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authori-ties that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).
12. In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission must be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration:
   (a) the product has been developed exclusively for the treatment of conditions particularly tropical diseases. not endemic in the country of export;
   (b) the product has been reformulated with a view to improving its stability under tropical conditions;
   (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
   (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
   (e) any other reason, please specify.
14. Not applicable means that manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practice in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series. No. 822. 1992, Annex 1).
16. This section is to completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

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

ANNEXURE - I

CERTIFICATE NO. DD/794/39C/2022-1-211-2 **VALID UPTO 04/03/2025**

ACTIVE AND INACTIVE COMPOSITION – QUALITATIVE AND QUANTITATIVE

Name of Product : **Doxorubicin Hydrochloride for Injection USP 10mg/vial**

Composition : **Each Lyophilized Vial Contains:**

Doxorubicin hydrochloride USP 10mg
Lactose Monohydrate NF..... 50mg

Sr. No.	Ingredients	Specifications	Quantity Input (mg / ml)
1.	Doxorubicin Hydrochloride	USP	8.334
2.	Lactose Monohydrate	NF	41.667
3.	Methyl Paraben	USP	0.8334
4.	Water for injection	USP	q.s.

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

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

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

Signature
Stamp & Date

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

23 MAY 2022

ANNEXURE-II

No. of Certificate : **DD/794/39C/2022-1-211-2** **Valid up to: 04/03/2025**

Name of the Product : **Doxorubicin Hydrochloride for Injection USP 10mg/vial**

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

1. Afghanistan	44. Cuba	85. Iran	128. Morocco	171. South Korea
2. Albania	45. Cyprus	86. Iraq	129. Mozambique	172. Spain
3. Algeria	46. Czech Republic	87. Ireland	130. Myanmar	173. Sri Lanka
4. Angola	47. Czechoslovakia[1]	88. Israel	131. Namibia	174. Sudan
5. Argentina	48. Democratic Republic of Congo	89. Italy	132. Nepal	175. Suriname
6. Armenia		90. Ivory Coast	133. Netherlands Antilles	176. Swaziland
7. Aruba	49. Denmark	91. Jamaica	134. Netherlands	177. Sweden
8. Australia	50. Djibouti	92. Japan	135. New Zealand	178. Switzerland
9. Austria	51. Dominica	93. Jordan	136. Nicaragua	179. Syria
10. Azerbaijan	52. Dominican Republic	94. Kazakhstan	137. Niger	180. Tadzhikistan
11. Bahamas	53. Ecuador	95. Kenya	138. Nigeria	181. Taiwan
12. Bahrain	54. Egypt	96. Kingdom of Tonga	139. North Korea	182. Tajikistan
13. Baltic	55. El Salvador	97. Kiribati	140. Norway	183. Tanzania
14. Bangladesh	56. Equatorial Guinea	98. Korea	141. Oman	184. Thailand
15. Barbados	57. Eritrea	99. Korea Republic of	142. Pakistan	185. Tobago
16. Belarus	58. Estonia	100. Kosova	143. Palau	186. Togo
17. Belgium	59. Ethiopia	101. Kuwait	144. Panama	187. Tonga
18. Belize	60. European Community	102. Kyrgyzstan	145. Papua New Guinea	188. Trinidad
19. Benin	61. Fiji	103. Laos	146. Paraguay	189. Tunisia
20. Bhutan	62. Finland	104. Latvia	147. Peru	190. Turkey
21. Bolivia	63. France	105. Lebanon	148. Puerto Rico	191. Turkmenistan
22. Bosnia	64. Gabon	106. Lesotho	149. Philippines	192. UAE
23. Botswana	65. Gambia	107. Liberia	150. Poland	193. Uganda
24. Brazil	66. Guatemala	108. Libya	151. Portugal	194. Ukraine
25. Brunei	67. Georgia	109. Libyan Arab Jamahiriya	152. Qatar	195. Union of Soviet Socialist Republics[1]
26. Bulgaria	68. German Democratic Republic[2]		153. Republic of Benin	
27. Burkina Faso		110. Liechtenstein	154. Republic de Guinee	196. United Arab Emirates
28. Burundi	69. Germany Federal Republic of[2]	111. Liochtonstoin	155. Republic of Maldives	197. United Kingdom
29. Byelorussia		112. Lithuania	156. Romania	198. United States
30. Cambodia	70. Germany	113. Luxembourg	157. Russia	199. Uruguay
31. Cameroon	71. Ghana	114. Macau	158. Rwanda	200. USA
32. Canada	72. Greece	115. Madagascar	159. Saudi Arabia	201. Uzbekistan
33. Central African Republic	73. Grenada	116. Malawi	160. Senegal	202. Vanuatu
	74. Guinea	117. Malaysia	161. Serbia and Montenegro	203. Venezuela
34. Chad	75. Guinea Equatorial	118. Maldives		204. Vietnam
35. Chile	76. Guyana	119. Mali	162. Seychelles	205. West Indies
36. China	77. Haiti	120. Malta	163. Sierra Leone	206. World
37. Cook Islands	78. Holland	121. Marshall Islands	164. Singapore	207. Yemen
38. Colombia	79. Honduras	122. Mauritania	165. Slovakia	208. Yugoslavia[1]
39. Columbia	80. Hong Kong	123. Mauritius	166. Slovenia	209. Zaire
40. Congo	81. Hungary	124. Mexico	167. Solomon Islands	210. Zambia
41. Costa Rica	82. Iceland	125. Moldova	168. Somalia	211. Zimbabwe
42. Council of Europe	83. India	126. Monaco	169. Somaliland	
43. Croatia	84. Indonesia	127. Mongolia	170. South Africa	

Address of Certifying Authority:
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Telephone No. : 0091–0260–2230470
Fax No. : 0091–0260–2230570

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

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

Signature
Stamp & Date
23 MAY 2022