FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

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

No. of certificate : **COPP/CERT/KD/113699/2022/11/40819/198616** **Valid Upto :27 Apr 2025**

Exporting Country : INDIA

Importing Country : **MOLDOVA**

1. Name and dosage form of product : **Doxorubicin Hydrochloride for Injection BP 10mg. (Lyophilised)**

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

Doxorubicin Hydrochloride BP 10 mg	Methylparaben BP 1 mg	Lactose BP q.s.

For complete qualitative composition including excipients :[4]

1.2 Is this product licensed to be placed on the market for use in the exporting country ?[5] Yes ☒ No ☐

1.3 Is this product actually on the market in the exporting country ? Yes ☒ No ☐ Unknown ☐

2A.1 Number of product license:[7] **KD/141 In Form 28**
and date of issue: **20 Apr 2007**

2A.2 Product License holder (Name and address) :
NAPROD LIFE SCIENCES PVT. LTD. PLOT NO. G-17/1, MIDC, TARAPUR, BOISAR, DIST. PALGHAR 401506 MAHARASHTRA STATE, INDIA

2A.3 Status of product-license Holder :[8]
A ☒ B ☐ C ☐

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is:[9]

2A.4 Is summary basis of Approval appended ?[10]
Yes ☐ No ☒

2A.5 Is the attached, officially approved product information complete and consonant with the license ?[11]
Yes ☐ No ☐ Not Provided ☒

2A.6 Applicant for certificate if different from License holder :[12]
Not Applicable

2B.1 Applicant for certificate (name and address) :

2B.2 Status of applicant :
A ☐ B ☐ C ☐

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form is[9]

2B.3. Why is marketing authorization lacking ?
☐ Not required ☐ Not requested ☐ Under Consideration ☐ Refused

2B.4 Remarks :[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced ? if no or not applicable proceed to question **4.** **Yes** ☒ **No** ☐ **Not Applicable**[14] ☐

3.1 Periodicity of routine inspections(years) : **Once a year**

3.2 Has the manufacture of this type of dosage form been inspected ? Yes ☒ No ☐

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation ?[15]
Yes ☒ No ☐ Not Applicable [14] ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?[16]
Yes ☒ No ☐

If no, explain :

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64/65
Fax: +91-22-26591959
5TSM10811369920220610101

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**10 Jun 2022**

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Digitally signed by Chirtoacă Iurie
Date: 2022.12.14 17:41:52 EET
Reason: MoldSign Signature
Location: Moldova

INDO LATIN AMERICAN CHAMBER OF COMMERCE
25 JUN 2022
NEW DELHI, INDIA

Attested
RAVI
Executive Secretary
017255

Apostik

GENERAL INSTRUCTION :

Please refer to the guidelines for full instruction 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 hand written.Additional sheets 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-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. Sections 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 dosages 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 … Licence holder or, in the case of non-registered products, the applicant . Non-co… agreed to inclusion of this information.It sh… part of the product Licence. If the producti… valid.
10. This refers to the document, prepared by … the product has been licensed.
11. This refers to product information approv… of product characteristics (SPC).
12. In this circumstance, permission for issu… permission must be provided to the auth…
13. Please indicate the reason that the applic…
    (a) the product has been developed … diseases -- not endemic in the countr…
    (b) the product has been reformulated …
    (c) the product has been reformulated … in the country of import:
    (d) the product has been reformulated…
    (e) any other reason, please specify.
14. Not applicable means that the manu… certificate and inspection is conducted…
15. The requirements for good practices … are those included in the thirty- sec… Preparations (WHO Technical Report Series, … applicable to biological products have been formulated by the WHO … Standardization (WHO Technical Report Series , No . 822, 1992, Annex 1).
16. The Section is to be completed when the product - licence 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 this Model Certificate is available on diskette in Word Perfect from the Division of Drug Management and Policies. World Health Organization, 1211 Geneva 27, Switzerland.