No of Certificate: L.Dis. No. 13345 / D1 / 8 / 2021 Date: 23.9.2021

GOVERNMENT OF TAMIL NADU - CHENNAI
CERTIFICATE OF PHARMACEUTICAL PRODUCT[1]
This Certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes overleaf)

1. Name and dosage form of the product: **RABIES VACCINE B.P. 'RAB' - Abhayrab**
Exporting (certifying Country): **INDIA**
Importing (requesting Country): **MOLDOVA**
Dosage/Pharmaceutical Form: Lyophilized powder for Solution for Injection
Rabies Vaccine for Human use prepared in Cell Cultures (Purified Vero Cell Rabies Vaccine)
Purified lyophilized Rabies antigen derived from Rabies Virus (L.Pasteur 2061/Vero Strain propagated in Vero cells) Inactivated
Potency: ≥2.5 I.U. Per vial
Stabilizer: Maltose and Human Albumin…q.s. Preservative: Thiomersal 0.01% w/v
Pack Size: 0.5ml on reconstitution with accompanying 1 ampoule of 0.5ml diluent for reconstitution: 0.9% w/v Sodium Chloride Inj. B.P.
Dosage: 0.5 ml single immunizing dose for Intramuscular Injection or 0.1 mL dose per site for Intradermal Injection.

1.2. Is this product licensed to be placed on the market for use in the exporting country?[5] (✓Yes/ No) (key in as appropriate)
If the Answer to 1.2 is yes, continue with section 2A and Omit section; If the answer to 1.2 is no, omit section 2A and continue with section 2B[6]:
1.3. Is the product actually on the market in the exporting country? (✓Yes/ No)

2A
2A.1. Number of product licence[7] and date of issue: Form 28-D bearing License no: 15; Date issue: 11.01.2000.
2A.2. Product-license holder: Human Biologicals Institute (A Division of Indian Immunologicals Limited), Kozhipannai, Pudumund (Post), Dr. Basavaiah Nagar, Udhagamandalam – 643 007, Tamil Nadu, India
2.A.3. Status of product license holder: [8] (key in appropriate category) a ☑ b c
2.A.3.1. For Categories b and c the name and address of the manufacturer producing the dosage form is:[9] NA
2.A.4. Is a summary basis for approval appended?[10] (Yes/No✓) (Key is appropriate)
2. A.5. Is the attached, officially approved product information complete and consonant with the licence?[11] (✓Yes/No/Not provided) (Key is appropriate)
2. A.6. Applicant for certificate, if different from license holder (Name and Address)[12]: NA

2B
2. B.1. Applicant for certificate (name and address): NA
2. B.2. Status of applicant: (Key in appropriate category): NA
a b c
2. B.2.1. For categories (b) and (c) the Name and Address of the manufacturer producing the dosage form is:[9] NA
2. B.3. Why is marketing authorization lacking? NA
(Not required/Not requested/Under consideration/Refused)
(Key in as appropriate)
2. B.4. Remarks[13]: NA
☐

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (✓Yes/No/Not Applicable)[14]
If not or not applicable, proceed to question 4.
3.1. Periodicity of routine inspections (years): Twice in a year
3.2. Has the manufacture of this type of dosage form been inspected? (✓Yes/ No) (Key in as appropriate)
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?[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: NA
This Certificate is Valid for one year from date of issue
Address of certifying authority: Director of Drugs Control
Anna Salai 259-261, Tamil Nadu, Chennai – 600 006
Telephone: +91-44-24335068
Fax: +91-44-24321830

Name of authorized person : K. SIVABALAN B.Pharm
Signature:
Stamp and date: 23/9/2021

Digitally signed by Chirtoacă Iurie
Date: 2021.11.12 20:06:36 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 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-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 only be provided with the consent of the product-license holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
12. In this circumstance, permission for issuing the certificate is required from the product-license 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 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 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 requirements for good practices 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 be 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