DRUGS CONTROL ADMINISTRATION
Government of Telangana

Certificate of a Pharmaceutical Product

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

No. of certificate: **3363/E1/2020-2** Validity: 30.07.2022

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **MOLDOVA**

1. Name and dosage form of product: **LINEZOLID TABLETS 600mg**

1.1 Active ingredient(s) and amount(s) per unit dose[3]: **Each film coated tablet contains**
Linezolid 600mg

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 ☐

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]

2A

A.1 Number of product license[7]
And date of issue: **50/MN/AP/2009/F/R, Dated 19.12.2009**

A.2 Product License Holder: (Name and Address)
M/s. Hetero Labs Limited
Unit V, TSIIC Formulation SEZ,
Sy. No 439,440,441 & 458
Polepally Village, Jadcherla Mandal,
Mahaboob Nagar Dist.Telangana State.
India.

A.3 Status of product-license Holder[8]: a ☒ b ☐ c ☐

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] Yes ☐ No ☒

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

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

2B

B.1 Applicant for certificate (name and address)

B.2 Status of applicant:
a☐ b ☐ c☐ d☐

B.2.1 For categories b and c the name and address of the Manufacturer producing the dosage form are9

B.3 Why is marketing authorization lacking?

Not required ☐ Not requested ☐

Under consideration ☐ Refused ☐

B.4 Remark[13]:

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 no or not applicable proceed to question4.

3.1 Periodicity of routine inspections (years): **Once in 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 the Organization?[15]
Yes ☒ No. ☐ Not applicable ☐

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: Drugs Control Administration
Vengalrao Nagar, Hyderabad – 500038. INDIA.

Telephone number: 0091-40-23814360

Name of authorized person: **Dr. Y. NAVEEN KUMAR**

Joint Director (FAC) & Licensing Authority

Signature:

Stamp and date:

DRUGS CONTROL ADMINISTRATION * HYDERABAD JD(FAC) * GOVERNMENT OF TELANGANA

29/9/2020

Dr. Y. NAVEEN KUMAR
M.Pharm.,Ph.D
Joint Director (Enforcement)
Licensing & Controlling Authority (FAC)
Drugs Control Administration
Government of Telangana
Hyderabad-500 038, T.S.

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Date: 2021.09.02 10:23:17 MSK
Reason: MoldSign Signature
Location: Moldova

DRUGS CONTROL ADMINISTRATION
Government of Telangana

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 presented in type rather then 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 Non-proprietary Names (INNs) or national non-proprietary 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) Manufacturers 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-completions 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 must be updated or it will cease to be valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licenses.
11. This refers to the product information approved by the competent national regulator 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 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 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 Annex1)
16. This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 7 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 World Perfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.