Serial No. 756/20
11 JAN 2020

FOOD & DRUGS ADMINISTRATION MADHYA PRADESH,
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: *11* **Valid Upto: 27.08.2022**

Exporting (certifying country) : Indla

Importing (requesting country) : **UZBEKISTAN**

1. Name and dosage form of the product : Tetracycline Hydrochloride Ophthal USP 1%
1.1 Active ingredient(s)[2] and amount(s) per unit dose[3] **TETRACYCLINE 1% - EYE**
(Trade Name given by Manufacturer)
Each gm contains:
Tetracycline Hydrochloride USP 10 mg

For complete composition including excipients, see attached[4] : NA

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]:

2 A

A.1 Number of product licence[7] and date of issue: **28/2/99**
17.10.2014

A.2 Product licence holder: (name and address) **M/s Alpa Laboratories Ltd.**
33/2, A.B. Road,
Pigdamber - 453 446,
Indore (MP) India

A.3 Status of product licence holder[8]:
a ☒ b ☐ c ☐

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

A.4 Is a summary basis for approval appended?[10]
Yes ☐ No ☒

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

A.6 Applicant for certificate, if different from licence holder (name and address)[12]: Not applicable

2 B

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

B.2 Status of applicant:
a ☐ b ☐ c ☐

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

B.3 Why is marketing authorization lacking?
not required ☐ not requested ☐ under consideration ☐ refused ☐

B.4 Remarks[13]:

3.0 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): **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 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:

Address of certifying authority:

The Licensing Authority
Office of the Controller
Food & Drugs Administration, Idagah Hills
Bhopal (Madhya Pradesh)
Telephone No. 0755-2666058
Fax No. 0755-2665385

Name of authorized person: Shobhit Koshta

Signature:

Stamp and date:
The Licensing Authority,
Office of the Controller
Food & Drugs Administration, Idagah Hills
Bhopal (Madhya Pradesh)

Shobhit
Dy.Drugs Controller &
Licensing Authority
Food & Drugs Administration
Madhya Pradesh

Digitally signed by Sîli Oleg
Date: 2022.01.05 09:35:35 EET
Reason: MoldSign Signature
Location: Moldova

ATTESTED
MOHAN PAL
NOTARY, DISTT. INDORE
M.P. GOVT.

12 DEC 2019

GENERAL INSTRUCTION:

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 in 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 specified in the product License.

6. Section 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) Manufacturing the dosage forms.
   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 non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion if 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 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 of Product Characteristics (SPC).

12. In this circumstance, permission for issuing the certificate is required from the product License holder. This permission 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 condition 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 ingredient.

14. Not applicable means that the manufacture is taking place in 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 certification 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 product have been formulated by the WHO expert Committee of Biological Standardization (WHO Technical Report Series No. 822, 1992, Annex – 11).

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 particular importance when foreign contractors are involved in the manufacture of the product in case circumstance the applicant should supply the certifying authority with information to identity 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.

17. The layout for this Model Certificate is available on diskette in World Perfect form the Division of Drug Management and Policies. WHO Health Organization 1211 Geneva 27, Switzerland.