GOVERNMENT OF HIMACHAL PRADESH
HEALTH AND FAMILY WELFARE DEPARTMENT
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 : **WHO-GMP-CERT/HFW-H(Drugs)665/12/19-094 Valid Upto : 06.02.2022**

Exporting Country : **INDIA**

Importing (requesting) country : **KENYA**

1. Name and dosage form of product : **Isoniazid and Rifapentine coated Tablets (300 mg + 300 mg)**

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3]

Each film coated tablet contains:

Isoniazid	**BP**	**300 mg**
Rifapentine		**300 mg**

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

2A

A.1 Number of product license[7] and date of issue:
MB/11/848 Dated 11.03.2019

A.2 Product License holder: (Name and address)

Oxalis Labs.
Factory: Village Theda, P O Lodhimajra, Tehsil Baddi, Distt. Solan (H.P.) 174101

Regd. Office: 201 , Mahavir Industrial Estate, Near Paper Box, Off Mahakali Caves Road, Andheri (E), Mumbai – 400 093 , 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 provided ☒

A.6 Applicant for certificate if different from license holder [12] : **Macleods Pharmaceuticals Limited**
Atlanta Arcade, Marol Church Road , Andheri (E), Mumbai 400 059 , India

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 are[9]

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 question 4.

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

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 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:
State Drugs Controller,
Controlling cum Licensing Authority,
2nd Floor, Himuda Complex, Phase-1,
Baddi Distt. Solan [H.P.]-173 205, INDIA
01795-244288, sdc4hp@gmail.com

Licensing Authority cum Drug Controller Himachal Pradesh

Name of the authorized person: **Navneet Marwaha**

Signature:

Digitally signed by Chirtoacă Iurie
Date: 2021.09.02 12:24:00 MSK
Reason: MoldSign Signature
Location: Moldova

Stamp and date

3-4-18
(NAVNEET MARWAHA)
State Drugs Controller
Controlling cum Licensing Authority
Baddi,Distt.Solan (H.P.)-173205
01795-244288,sdc4hp@gmail.com

EXPLANATORY NOTES

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceuticals 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 strength 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. 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) Manufacturers 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 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 change 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 licensed.

11. This refers to 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 of import:
   (d) the product has been reformulated to meet a different maximum dosages 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 Pharmaceuticals Preparations (WHO) Technical Report Series, No.823, 1992, Annex 1). Recommendations specifically applicable to biological product has been formulated by the WHO Expert Committee on Biological Standarazation (WHO) Technical Report Series No. 822, 1992, Annex 1).

16. The 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 Word Perfect from the Division of Drug Management and Policies. World Health Organization, 1211 Geneva 27, Switzerland