OFFICE OF THE DIRECTOR OF DRUGS CONTROL
359, ANNASALAI, CHENNAI – 600 006,
TAMIL NADU, INDIA

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 the Certificate: 1.Dis.No. 1082/D1/3/2024 dt. 22.2.2024

Exporting (certifying) Country : **INDIA**		ISSUED DATE :
Importing (requesting) Country : **MYANMAR**		EXPIRY DATE :
1.0	Name and dosage form of products :	**ISONIAZID TABLETS BP 300 mg**
1.1	Active ingredient(s) [2] and amounts(s) per unit dose [3]	Each un coated tablet contains: Isoniazid BP 300 mg
For complete qualitative composition including excipients see attached [4]		-- Not Applicable --
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? 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 with section 2B [6].	Yes ☑ No ☐ Unknown ☐

2A. APPLICABLE

A.1.0 Number of product licence [7] and date of issue :
Form 25 bearing No. TN00003934
Dated: 19.10.2015 Valid up to 18.10.2025

A.2.0 Product – license holder : (Name and Address):
M/s Micro Labs Limited, Unit – 03,
92, Sipcot Industrial Complex, Hosur – 635 126, India

A.3.0 Status of the product – 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.4.0 Is Summary Basis of Approval appended? [10] : ☐ Yes ☑ No

A.5.0 Is the attached, officially approved product information complete and consonant with the license? [11] :
☐ Yes ☐ No ☑ Not Provided

A.6.0 Applicant for the certificate, if different from License Holder [12]
NOT APPLICABLE

2.B NOT APPLICABLE

B.1.0 Applicant for certificate (Name and Address) :

B.2.0 Status of applicant [8] :
☐ a ☐ b ☐ c ☐ d

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

B.3.0 Why is marketing authorization lacking?
Not Required ☐ Under Consideration ☐
Not Required ☐ Refused ☐

B.4.0 Remarks [13] :

3.0 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced ? [14]
If not applicable, proceed to question 4. ☑ Yes ☐ No ☐ No applicable

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

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

3.3 Does the facilities and operations conform to GMP as recommended by the WHO ? [15] ☑ Yes ☐ No ☐ No applicable

4.0 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the is product? [16]
If no, explain. ☑ Yes ☐ No

THIS CERTIFICATE EXPIRES ONE YEAR FROM THE DATE ISSUED

Address of the certifying authority: **Director of Drugs Control**
Office of the Director of Drugs Control
359, Annasalai, Chennai – 600 006,
Tamil Nadu, India
Tele Fax: 00–91–44–24321830

Signature:

K. SIVABALAN B.Pharm
Director of Drugs Control
359, Anna Salai, Chennai - 600 006.

Stamp and Date:

22/2/2024

Digitally signed by Chirtoacă Iurie
Date: 2021.11.30 15:27:35 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 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 Non-proprietary Names (INNs) or National Non-proprietary Names.
3) The formula (complete composition) of dosage form should be given on the certificate or be appended.
4) Details of qualitative 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 - 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 must be updated or it will cease to be valid.
10) This refers to the document, prepared by some national regulatory authorities, that summaries 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 a Summary of Product Characteristics (SmPC)
12) In this circumstance, permission of 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; the product has been reformulated with a view to improving its stability under tropical conditions;
   b) the product has been reformulated to exclude excipients not approved for used in pharmaceutical products in the country of import;
   c) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
   d) any other reason, please specify.
14) Not applicable means that the manufacture is taking 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 drug 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 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.