

Certificate of a Pharmaceutical Product¹

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

No. of Certificate : DD/375/12/2022/MMR-I Valid up to: 28/11/2025

Exporting (Certifying) Country : INDIA

Importing (Requesting) Country : MYANMAR

1. Name and dosage form of product : Dolutegravir Sodium Tablet for Oral Suspension
(Dispersible Tablets) 10mg

1.1 Active ingredient(s)² and amount(s) per unit dose³

Each film coated tablet contains:
Dolutegravir Sodium equivalent to
Dolutegravir 10mg

For complete qualitative 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

1.3 Is this product actually on the market in the exporting country? Yes

If the answer to 1.2 is yes, continue with section 2A and omit section 2 B.

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

2 A

2.A.1 Number of product license⁷ and date of issue: DD/375
dated 25.02.2021

2.A.2 Product licence holder : Macleods Pharmaceuticals Ltd.
Office : Atlanta Arcade, 3rd Floor, Marol Church Road,
Near Leela Hotel, Andheri (East), Mumbai – 400 059
Factory : Plot No. 25-27, Survey No. 366, Premier
Industrial Estate, Kachigam, Daman –396210 (U.T.)

2.A.3 Status of product licence holder ⁸ :
Manufacturers the dosage forms

2.A.3.1 For categories b and c the name and address of
the manufacturer producing the dosage form are⁹
: Not applicable

2.A.4 Is summary basis of Approval appended?¹⁰
: No

2.A.5 Is the attached, officially approved product information
complete and consonant with the licence?¹¹
: Not provided

2.A.6 Applicant for certificate if different from licence
holder: ¹² : Not applicable.

2 B Not applicable.

2.B.1 Application for certificate:
(Name and address)

2.B.2 Status of applicant

: Not applicable

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

: Not applicable

2. B.3 Why is marketing authorization lacking?

: Not applicable

2.B.4 Remark : ¹³ --



3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?¹⁴ Yes

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

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization ?¹⁵ Yes

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?¹⁶ Yes

If no, explain.

Address of certifying authority:

UT Administration of Dadra & Nagar Haveli and Daman & Diu,
Assistant Drugs Controller & Licensing Authority,
Drugs Control Department,
Primary Health Centre,
Moti Daman – 396 220

Telephone Number : (0260) 2230470

Fax Number : (0260) 2230570

Name of the authorised person: Dr. Dharmesh Agrawal

ASSISTANT DRUGS CONTROLLER
& LICENSING AUTHORITY (I/c)

Signature:

सहायक औषधि नियंत्रक एवं अनुमति प्रधिकारी

Stamp and date:

DRUGS CONTROL DEPARTMENT

औषधि नियंत्रक विभाग

U.T. OF DADRA & NAGAR HAVELI

AND DAMAN & DIU

संघराज्य ददरा एवं नगर हवेली एवं दमन एवं दीव

- 8 MAY 2023

GENERAL INSTRUCTION

Please refer to the guidelines for full information's 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 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 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 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 Standardization (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.