DRUGS CONTROL ADMINISTRATION
Government of Telangana

CERTIFICATE OF A PHARMACEUTICAL PRODUCT^1

No of Certificate : 1933068/TS/2021 Valid UpTo: **04/06/2024**

1. Name and Dosage form of Product:

Bicalutamide Tablets USP 50 mg

Exporting(Certifying)Country: **INDIA**

Importing(Requesting) country **BRAZIL**

1.1 Active Ingredients(s)^2 and amount(s) per unit dose^3:

Each film coated tablet contains Bicalutamide USP 50mg
Complete qualitative composition including excipients: Lactose monohydrate (Pharmatose 200M) 61.000mg USP-NF, Crospovidone (Kollidon CL-F) 8.667mg USP-NF, Povidone (Kollidon 25) 3.333mg USP, Magnesium stearate 2.000mg USP-NF, Opadry white Y-1-7000 2.500mg In-House, Purified water 39.727mg USP/Ph. Eur.

For complete qualitative composition including excipients see above^4

1.2 Is this Product licensed to be placed on the market for use in Exporting country?^5 **Yes**

1.3 Is this product actually on the marketing in the Exporting Country? **Yes**

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 continue with section 2B^6

2A.1 Number of Product Licence^7: **50/MN/AP/2009/F/R, Dated 19.12.2009**

2A.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.

2A.3 Status of License Holders^8 : a

2A.3.1 For Category b and c the name and address of the manufacturer producing the dosage form is ^9 not applicable

2A.4 Is Summary basis of approval appended ? ^10 Yes

2A.5 Is the Attached, officially approved production information complete and consonant with the license?^11: Not Provided

2A.6 Applicant for Certificate, if different from licence holder (name and address) not applicable

2B.1 Applicant for Certificate(Name and Address)

2B.2 Status of Applicant^8

2B2.1 For Categories (b) and (c) the name and address of the manufacturer producing the dosage form is^9

2B.3 Why is marketing authorisation lacking?

2B.4 Remarks^13 :

4 Does the certifying authority arrange for periodic spection of the manufacturing plant in which the dosage form is produced?^14 Yes

4.1 Periodicity of routine inspection(years) Once in a Year

4.2 Has the Manufacture of this type of dosage from been inspected? Yes

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

4.0 Does the information Submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?^16 Yes

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Date: 2021.12.15 11:09:45 EET
Reason: MoldSign Signature
Location: Moldova

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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 approvedinformation 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 quantitative composition are preferred, but their provision is subject to the agreement of the product licence 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) manufactures the dosage form;
   (b) packages and/or labels a dosage form manufactured by an independent company; or
   (c) is involved in non 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 productionsite 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 theproduct has been licensed.
11. This refers to the product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SmPC).
12. In this circumstance, permission for issuing the certificate is required from the product license holder. This permission must be provided tothe 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 countryof export;
   (b) the product has been reformulated with a view to improving its stability underP tropical conditions;
   (c) the product has been reformulated to exclude excipients not approved for used 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 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 isconducted 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 thethirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series No. 823, 1992Annex 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 theapplicant 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.