DRUGS CONTROL ADMINISTRATION
Government of Telangana

CERTIFICATE OF A PHARMACEUTICAL PRODUCT^1

No of Certificate : 3288145/TS/2022 Valid UpTo: **25/06/2025**

1.Name and Dosage form of Product: Exporting(Certifying)Country: **INDIA**

Macitentan Tablets 10 mg Each Film coated tablet contains Macitentan 10 mg

1.1 Active Ingredients(s)^2 and amount(s) per unit dose^3: Importing(Requesting) country **Peru**

Active ingredients: Macitentan IH 10.000 mg For Complete composition including excipients , see attached Lactose monohydrate USP-NF 32.860 mgMicrocrystalline cellulose USP-NF 20.000 mg Sodium starch glycolate USP-NF 2.800 mg Sodium Lauryl sulfate USP-NF 0.140 mg Povidone 30 USP-NF 3.500 mg Purified water USP Q.S Magnesium Stearate USP-NF 0.700 mg Opadry AMB white OY-B-28920 IH 2.000 mg

For complete qualitative composition including excipients see above^4

Digitally signed by Şarco Alexandru
Date: 2024.07.22 12:11:36 EEST
Reason: MoldSign Signature
Location: Moldova

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: **L.Dis.No.5/MN/TS/2014/F/G, Dated 26/08/2019 S.No – 371**

2A.2 Product License Holder(Name and address): M/s MSN LABORATORIES PRIVATE LIMITED, Formulation Division, Unit-II, Sy. No.1277 1319 to 1324, Nandigama (Village Mandal), Rangareddy District - 509228, 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 No

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 :

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

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

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

3.3 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

DRUGS CONTROL ADMINISTRATION
Government of Telangana

Address of Certifying Authority.
Drugs Control Administration, Vengalraonagar, Hyderabad 500038, India
Telephone No : 91-040-23814119 Fax No : 91-040-23814360

Name of the authorized person:
Digitally Signed By
RAMDHAN GUGULOTH
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:23-08-2022 17:26:53 PM

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