DRUGS CONTROL ADMINISTRATION
Government of Telangana

CERTIFICATE OF A PHARMACEUTICAL PRODUCT^1

No of Certificate : 4276091/TS/2024

Valid UpTo: **14/05/2026**

1.Name and Dosage form of Product:

Bedaquiline Tablets 100 mg Each Uncoated Tablet Contains Bedaquiline Fumarate Equivalent to Bedaquiline ----- 100 mg

Exporting(Certifying)Country: **INDIA**

Importing(Requesting) country **Cambodia**

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

Active ingredients and amount per unit dose: Bedaquiline Fumarate IH 120.890 mgFor complete composition including excipients, see attached: Lactose monohydrate (Sheffield SD Fastflo 316) Ph. Eur 143.000 mg, Maize Starch (Maize Starch B) Ph. Eur 65.000 mg, Hydroxypropyl MethylCellulose (Methocel E 5 Premium LV) Ph. Eur 9.000 mg, Polysorbate (Tween 80) Ph. Eur 1.000 mg, Purified Water Ph. Eur Q..S, Microcrystalline Cellulose (Avicel PH 102) Ph. Eur 84.110 mg, Croscarmellose Sodium (Ac-Di-Sol) Ph. Eur 20.000 mg, Colloidal Silicon Dioxide (HDK N 20) Ph. Eur 2.500 mg , Magnesium Stearate (Ligamed -MF-2V) Ph. Eur 4.500 mg.

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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: **" L.Dis.No.1746935/TS/2021 S No: 1 Dated: 30/09/2021"**

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 , Nandigama Mandal , Ranga Reddy District Pincode 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 na

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) na

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, Hyderabad500038, India
Telephone No : 91-040-23814119 Fax No :91-040-23814360

Name of the authorized person:
Digitally Signed By
B SOWBHAGYA LAXMI
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:11-03-2024 17:30:02 PM

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