DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

DRUGS CONTROL ADMINISTRATION
Government of Telangana

CERTIFICATE OF A PHARMACEUTICAL PRODUCT^1

No of Certificate : 4276244/TS/2024

Valid UpTo: **27/06/2025**

1.Name and Dosage form of Product:
Deferasirox Tablets 180 mg Each Film Coated Tablet Contains Deferasirox 180 mg

Exporting(Certifying)Country: **INDIA**

1.1 Active Ingredients(s)^2 and amount(s) per unit dose^3:
Active ingredients (s): Deferasirox IH 180.00 mg
For complete composition including excipients, see attached :
Cellulose Microcrystalline (Avicel PH 102) Ph. Eur 54.290 mg
Croscarmellose sodium (Ac-Di-Sol) Ph.Eur 7.500 mg
Low substituted Hydroxypropyl cellulose (L-HPC LH 21) Ph.Eur 4.00 mg
Poloxamer 188 (Kolliphor P 188) Ph.Eur 0.660 mg
Povidone K 30 (Plasdone K29/32) Ph. Eur 8.250 mg
Purified water Ph.Eur Q.S
Lactose Monohydrate (Supertab 30 GR) Ph.Eur 54.050 mg
Croscarmellose Sodium (Ac- Di-Sol) Ph.Eur 7.500 mg
Low -substituted Hydroxypropyl cellulose (L-HPC LH 21) Ph.Eur 4.00 mg
Silica Colloidal anhydrous (HDK N20) Ph.Eur 1.500 mg
Sodium stearyl fumarate (Alubra PG 100) Ph. Eur 2.350 mg
Hydrogenated Castor oil (Kolliwax HCO) Ph.Eur 5.900 mg
Opadry Yellow 03H520019 IH 10.00 mg
Purified water Ph.Eur Q.S

For complete qualitative composition including excipients see above^4

Importing(Requesting) country **Moldova**

Digitally signed by Şarco Alexandru
Date: 2024.07.18 15:38:10 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: **Lic.No. 5/MN/TS/2014/F/G Dated : 26/08/2019 S.No: 189**

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 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 :

Attested
Shalini Bansal
Assistant Director

INDO LATIN AMERICAN CHAMBER OF COMMERCE
22 MAR 2024
NEW DELHI, INDIA
035740

ATTESTED
M. SADA SIVA KUMAR REDDY, B.Com., B.L.,
ADVOCATE & NOTARY
Appointed by Govt., India
G.O.Ms.No.198, Rev (Regn-II), dt. 11.04.2000
102, Saraswathi Enclave, Bhagyanagar Colony,
Kukatpally, Hyderabad, TS India (Ph:98480 44395

M. SIVA KUMAR REDDY ADVOCATE
SARASWATHI ENCLAVE, BHAGYANAGAR
NOTARY
Regn. No. 198
NOTARIAL

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TELANGANA

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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

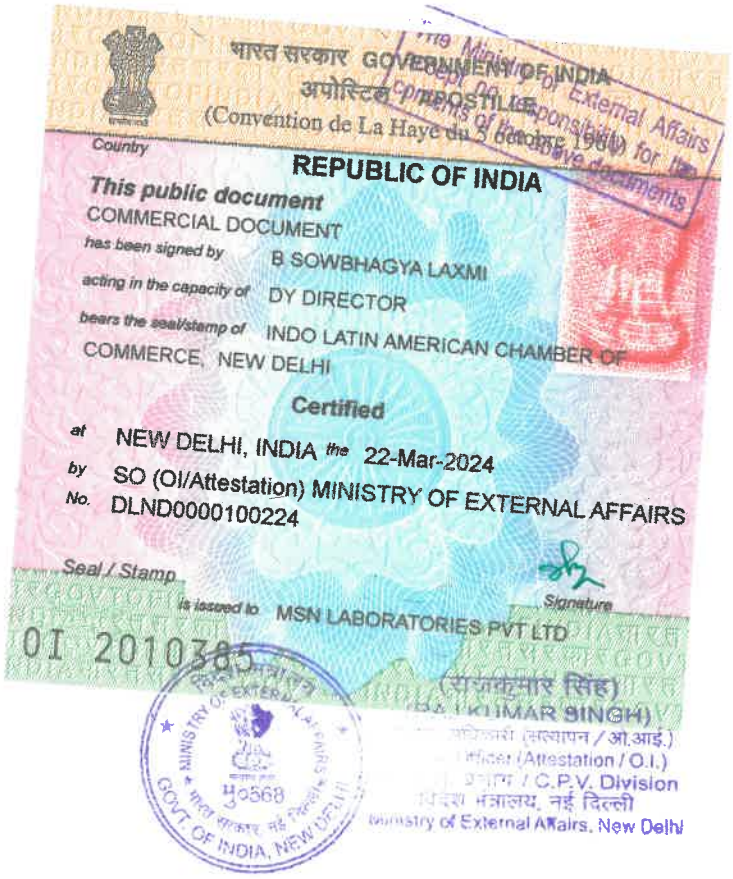
Address of Certifying Authority.
Drugs Control Administration, Vengalraonagar, Hyderabad500038, India
Telephone No : 91-040-23814119 Fax No :91-040-23814360

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 17:30:51 PM

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

INDO LATIN AMERICAN CHAMBER OF COMMERCE
22 MAR 2024
NEW DELHI, INDIA

NOTARY
Regn No 198


भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल APOSTILLE
(Convention de La Haye du 5 octobre 1961)
Country
REPUBLIC OF INDIA
This public document
COMMERCIAL DOCUMENT
has been signed by B SOWBHAGYA LAXMI
acting in the capacity of DY DIRECTOR
bears the seal/stamp of INDO LATIN AMERICAN CHAMBER OF COMMERCE, NEW DELHI
Certified
at NEW DELHI, INDIA the 22-Mar-2024
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. DLND0000100224
Seal / Stamp
Signature
is issued to MSN LABORATORIES PVT LTD
OI 2010385
(राजकुमार सिंह)
KUMAR SINGH)
Officer (Attestation / O.I.)
C.P.V. Division
Ministry of External Affairs, New Delhi
MINISTRY OF EXTERNAL AFFAIRS
GOVT. OF INDIA, NEW DELHI
Ministry of External Affairs
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