

# DRUGS CONTROL ADMINISTRATION Government of Telangana



L.Dis.No:91759/TS/2022

Dated:29/06/2022 Valid until:27/06/2025

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of World Health Organisation G.M.P. Certificate – Regarding

Ref: 1. Your letter dated: 17/06/2022.

2. Joint Inspection report -

-x-x-x-x-

With reference to your application cited, I forward herewith **World Health Organisation GOOD MANUFACTURING PRACTICE**Certificate for the products mentioned in the Joint Inspection Report of the Officers of Drugs Control Administration, Telangana State & Drugs Inspector, CDSCO, Hyderabad vide reference 2nd cited.



Digitally Signed By

**RAMDHAN GUGULOTH** 

**Deputy Director and Certifying Authority** 

DRUGS CONTROL ADMINISTRATION TELANGANA STATE

Date:29-06-2022 17:37:43 PM

L.Dis.No:91759/TS/2022

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## LIST OF PRODUCTS APPROVED UNDER WHO-GMP CERTIFICATION SCHEME FOR EXPORT PURPOSE

| S.No | Generic Name                           | Brand Name   | Composition                                                 | PackSize | Market |
|------|----------------------------------------|--------------|-------------------------------------------------------------|----------|--------|
| 1    | Abiraterone Acetate tablets USP 250 mg | ABERISTA 250 | Each Uncoated tablet contains Abiraterone acetate USP 250mg | NA       | Export |
| 2    | Abiraterone Acetate tablets 250 mg     | ABERISTA 250 | Each Uncoated tablet contains Abiraterone acetate 250mg     | NA       | Export |
| 3    | Abiraterone Acetate tablets 250 mg     | BIRATO 250   | Each Uncoated tablet contains Abiraterone acetate 250mg     | NA       | Export |
| 4    | Abiraterone Acetate tablets USP 250 mg | ABIRAND 250  | Each Uncoated tablet contains Abiraterone acetate USP 250mg | NA       | Export |
| 5    | Abiraterone Acetate tablets USP 250 mg | ABITREE 250  | Each Uncoated tablet contains Abiraterone acetate USP 250mg | NA       | Export |
| 6    | Abiraterone Aretate A                  | W HOSPING OA | Each Uncoated tablet contains Abiraterone acetate USP 250mg | NA       | Export |

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ATTESTED

Attested https://www.ods.telanganagov.in

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M. SADA SIVA KUMAR PRODY, 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,

Shalini Bansal Assistant Director

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### **DRUGS CONTROL ADMINISTRATION** Government of Telangana



| 41   | Dapagliflozin and<br>Metformin<br>Hydrochloride<br>Extended Release<br>Tablets 5mg/1000mg | NA              | Each Film Coated Contains Dapagliflozin 5 mg<br>Metformin Hydrochloride USP/Ph.Eur.1000 mg (<br>As extended release) | NA                              | Export       |
|------|-------------------------------------------------------------------------------------------|-----------------|----------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------|
| 42   | Dapagliflozin and<br>Metformin<br>Hydrochloride<br>Extended Release<br>Tablets 5mg/500mg  | NA"             | Each Film Coated Tablet Contains Dapagliflozin 5 mg Metformin Hydrochloride USP/Ph.Eur.500 mg (As extended release)  | NA                              | Export       |
| 43   | Dapagliflozin Tablets 10 mg                                                               | NA              | Each Film Coated Contains Dapagliflozin 10 mg                                                                        | NA                              | Export       |
| 44   | Dapagliflozin Tablets 5                                                                   | NA              | Each Film Coated Contains Dapagliflozin 5 mg                                                                         | NA                              | Export       |
| 45   | Dasatinib tablets 100                                                                     | NA              | Each film coated tablet contains Dasatinib 100 mg                                                                    | NA                              | Export       |
| 46   | Dasatinib tablets 20 mg                                                                   | NA              | Each film coated tablet contains Dasatinib 20 mg                                                                     | NA                              | Export       |
| 47   | Dasatinib tablets 50 mg                                                                   | NA              | Each film coated tablet contains Dasatinib 50 mg                                                                     | NA                              | Export       |
| 48   | Dasatinib tablets 70 mg                                                                   | NA              | Each film coated tablet contains Dasatinib 70 mg                                                                     | NA                              | Export       |
| 19   | Decitabine for injection 50 mg/vial                                                       | NA              | Each vial contains Decitabine 50 mg                                                                                  | NA                              | Export       |
| 50   | Deferasirox dispersible<br>Tablets 125 mg                                                 | NA              | Each Dispersible Tablet contains Deferasirox . 125 mg                                                                | NA                              | Export       |
| 51   |                                                                                           | NA              | Each Dispersible Tablet contains Deferasirox . 250 mg                                                                | NA                              | Export       |
| 52   | Deferasirox dispersible<br>Tablets 500 mg                                                 | NA              | Each Dispersible Tablet contains Deferasirox . 500 mg                                                                | NA                              | Export       |
| 53   | Deferasirox Tablets 180                                                                   | FERASIRO 180    | Each Film Coated Tablet Contains Deferasirox 180 mg                                                                  | NA                              | Export       |
| 54   | Deferasirox Tablets 180                                                                   | NA              | Each Film Coated Tablet Contains Deferasirox 180 mg                                                                  | NA                              | Export       |
| 55   | Deferasirox Tablets 180<br>mg                                                             | NA              | Each Film Coated Tablet Contains Deferasirox 180 mg Colours: Titanium Dioxide-USP Ferric Oxide Yellow-USP-NF         | NA                              | Export       |
| 56   | Deferasirox Tablets 360                                                                   | FERASIRO 360    | Each Film Coated Tablet Contains Deferasirox 360 mg                                                                  | NA                              | Export       |
| 57   | Deferasirox Tablets 360 mg                                                                | NA              | Each Film Coated Tablet Contains Deferasirox 360 mg                                                                  | NA                              | Export       |
| 58   | Deferasirox Tablets 360<br>mg                                                             | NÄ              | Each Film Coated Tablet Contains Deferasirox 360 mg Colours: Titanium Dioxide-USP Ferric Oxide Yellow-USP-NF         | NA                              | Export       |
| 59   | Deferasirox Tablets 90 mg                                                                 | FERASIRO 90     | Each Film Coated Tablet Contains Deferasirox 90 mg                                                                   | WAAR REDU<br>WALAVE. BA         | Export       |
| 30   | Deferasirox Tablets 90<br>mg                                                              | RICAN CHAMBER O | Each Film Coated Tablet Contains Deferasirox 90 mg                                                                   | NA                              | Export       |
| 06-2 | 022                                                                                       | 3 D MAY 2026    | = 4                                                                                                                  | https://www.odis<br>Regn No 198 | s.te myana y |
|      | 100                                                                                       | O U MAI 2024    | W. C.                                                                            | ALLY HYDERABA                   | 13 N         |

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#### DRUGS CONTROL ADMINISTRATION **Government of Telangana**



| 112 | Vortioxetine Tablets 5 mg | NA               | Each Film Coated Tablets Contains Vortioxetine<br>Hydrobromide Equivalent to Vortioxetine 5 mg                                                                                                    | NA | Export |  |
|-----|---------------------------|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|--------|--|
|     |                           | Manufacturer:    | M/S 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 |    |        |  |
|     |                           | Drug License No: | b. 5/MN/TS/2014/F/G, Dated:25/08/2014 Under Form 25&28 ,valid upto 24/08/2024  Placing the product on the market as detailed below.                                                               |    |        |  |
|     |                           | When applicable  |                                                                                                                                                                                                   |    |        |  |

The Unit M/S 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 Telangana State,India was inspected jointly by

#### It is certified that:

- i. The above products had been authorized to be placed on the market for use in the country and exported countries
- ii. The manufacturing plant in which the product is produced is subject to inspection at suitable intervals.
- iii. The manufacturer conforms to requirements for Good Manufacturing Practices in the manufacture and Quality Control (As recommended by the World Health Organisation) in respect of #Error products to be sold or distributed with in the Country of origin (or to be exported).

Digitally Signed By **RAMDHAN GUGULOTH Deputy Director and Certifying Authority** DRUGS CONTROL ADMINISTRATION **TELANGANA STATE** 

Date: 29-06-2022 17:37:43 PM

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Shalini Bansh Assistant Dimo