

L.Dis.No:108120/TS/2023

Dated:25/03/2023
Valid until:23/03/2026

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:03/01/2023.
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:25-03-2023 16:00:54 PM

L.Dis.No:108120/TS/2023

Dated:25/03/2023

Valid until:23/03/2026

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

| S.No | Generic Name | Brand Name | Composition | PackSize | Market |
|------|--|----------------------|--|----------|--------|
| 1 | ABACAVIR SULFATE AND LAMIVUDINE TABLETS 600 / 300 mg, (As per CDSCO Recommendation Letters vide Ref. Nos. 1) 5-6 (201 A9/2022/5725, dated. 16.03.2023 for 172 products, 2) 5-6 (201 A11/2022/5749, dated. 17.03.2023 for 171 Products and Joint inspection dates: 05.01.2023 & 06.01.2023 of Deputy Drugs Controller (India), Hyderabad. | | Each film coated tablet contains: Abacavir sulfate USP Equivalent to Abacavir 600 mg, Lamivudine USP 300 mg, Colour: Titanium dioxide, FD & C yellow # 6 (Sunset yellow aluminum lake) | | Export |
| 2 | ABACAVIR SULFATE AND LAMIVUDINE TABLETS 600/300 mg | ABACAVEX - L 600/300 | Each film coated tablet contains: Abacavir sulfate USP Equivalent to Abacavir 600 mg, Lamivudine USP 300 mg, Colour: Titanium dioxide, FD & C yellow # 6 (Sunset yellow aluminum lake) | | Export |
| 3 | ALENDRONIC ACID TABLETS 70 mg | ALDRONA 70 | Each uncoated tablet contains: Sodium alendronate Ph.Eur 91.363 mg, Equivalent to Alendronic acid 70 mg | | Export |
| 4 | ALFUZOSIN HYDROCHLORIDE SUSTAINED RELEASE TABLETS 10 mg | | Each film coated sustained release tablet contains: Alfuzosin Hydrochloride Ph.Eur 10 mg, Colour: Titanium dioxide | | Export |
| 5 | ALFUZOSIN HYDROCHLORIDE SUSTAINED RELEASE TABLETS 10 mg | HI-ALFA SR 10 mg | Each film coated sustained release tablet contains: Alfuzosin Hydrochloride Ph.Eur 10 mg, Colour: Titanium dioxide | | Export |
| 6 | ALFUZOSIN HYDROCHLORIDE TABLETS 2.5 mg | | Each film coated tablet contains: Alfuzosin Hydrochloride Ph. Eur 2.5 mg, Colour: Titanium Dioxide | | Export |
| 7 | AMLODIPINE BESILATE TABLETS 10 mg | | Each un-coated tablet contains: Amlodipine Besilate Ph. Eur, Equivalent to Amlodipine 10 mg | | Export |
| 8 | AMLODIPINE BESILATE TABLETS 10 mg | KARDAM 10 | Each un-coated tablet contains: Amlodipine Besilate Ph.Eur, Equivalent to Amlodipine 10 mg | | Export |
| 9 | AMLODIPINE BESILATE TABLETS 5 mg | | Each un-coated tablet contains: Amlodipine Besilate Ph.Eur, Equivalent to Amlodipine 5 mg | | Export |



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|----|--|-------------------|---|--------|
| 50 | CARVEDILOL TABLETS 3.125 mg | | Each film coated tablet contains: Carvedilol Ph.Eur 3.125 mg, Colour: Titanium Dioxide. | Export |
| 51 | CARVEDILOL TABLETS 6.25 mg | CARVIANZA 6.25 mg | Each film coated tablet contains: Carvedilol Ph.Eur 6.25 mg, Colour: Titanium Dioxide | Export |
| 52 | CARVEDILOL TABLETS 6.25 mg | VACODIL 6.25 | Each film coated tablet contains: Carvedilol Ph.Eur 6.25 mg, Colour: Titanium Dioxide | Export |
| 53 | CARVEDILOL TABLETS 6.25 mg | | Each film coated tablet contains: Carvedilol Ph.Eur 6.25 mg, Colour: Titanium dioxide. | Export |
| 54 | CETIRIZINE HYDROCHLORIDE TABLETS 10 mg | CETRIDAY 10 | Each film coated tablet contains: Cetirizine Dihydrochloride Ph.Eur 10 mg, Colour: Titanium Dioxide | Export |
| 55 | CETIRIZINE HYDROCHLORIDE TABLETS 10 mg | | Each film coated tablet contains: Cetirizine Hydrochloride Ph.Eur 10 mg, Colour: Titanium Dioxide | Export |
| 56 | CETIRIZINE HYDROCHLORIDE TABLETS 5 mg | | Each film coated tablet contains: Cetirizine Dihydrochloride Ph.Eur 5 mg, Colour: Titanium Dioxide | Export |
| 57 | CETIRIZINE HYDROCHLORIDE TABLETS 5 mg | CETRIDAY 5 | Each film coated tablet contains: Cetirizine Dihydrochloride Ph.Eur 5 mg, Colour: Titanium Dioxide | Export |
| 58 | CIPROFLOXACIN TABLETS BP 250 mg | | Each film coated tablet contains: Ciprofloxacin Hydrochloride Ph. Eur, Equivalent to Ciprofloxacin 250 mg, Colour: Titanium dioxide | Export |
| 59 | CIPROFLOXACIN TABLETS BP 250 mg | RECIPRO 250 | Each Film-coated tablet Contains: Ciprofloxacin Hydrochloride Ph.Eur, Equivalent to Ciprofloxacin 250 mg, Colour: Titanium dioxide | Export |
| 60 | CIPROFLOXACIN TABLETS BP 500 mg | RECIPRO 500 | Each film coated tablet contains: Ciprofloxacin Hydrochloride Ph. Eur Equivalent to Ciprofloxacin 500 mg, Colour: Titanium dioxide | Export |
| 61 | CIPROFLOXACIN TABLETS BP 500 mg | | Each film coated tablet contains: Ciprofloxacin Hydrochloride Ph.Eur, Equivalent to Ciprofloxacin 500 mg, Colour: Titanium dioxide | Export |
| 62 | CITALOPRAM HYDROBROMIDE TABLETS 10 mg | AUOPRAM 10 | Each film coated tablet contains: Citalopram Hydrobromide Ph. Eur Equivalent to Citalopram base 10 mg, Colour: Titanium Dioxide | Export |
| 63 | CITALOPRAM HYDROBROMIDE TABLETS 20 mg | | Each film coated tablet contains: Citalopram Hydrobromide Ph.Eur, Equivalent to Citalopram base 20 mg, Colour: Titanium Dioxide | Export |
| 64 | CITALOPRAM HYDROBROMIDE TABLETS 40 mg | AUOPRAM 40 | Each film coated tablet contains: Citalopram Hydrobromide Ph. Eur Equivalent to Citalopram base 40 mg, Colour: Titanium Dioxide | Export |
| 65 | CITALOPRAM HYDROBROMIDE TABLETS 40 mg | | Each film coated tablet contains: Citalopram Hydrobromide Ph.Eur, Equivalent to Citalopram base 40 mg, Colour: Titanium Dioxide | Export |
| 66 | CLARITHROMYCIN TABLETS BP 250 mg | | Each film coated tablet contains: Clarithromycin Ph.Eur 250 mg, Colour: Titanium dioxide and Iron oxide yellow | Export |

ATTESTED

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26 APR 2023

<https://www.gdls.telangana.gov.in>

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, T.S., India. (Ph: 98480 44395)



M. SRINIVASA RAO
Deputy Secretary

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 **RAMDHAN GUGULOTH**
 acting in the capacity of **DY. DIRECTOR**
 bears the seal/stamp of **FEDERATION OF INDIAN MICRO AND SMALL & MEDIUM ENTERPRISES**

Certified

at **NEW DELHI, INDIA** the **01-May-2023**
 by **SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS**
 No. **APHY0003625223**

Seal / Stamp is issued to **AUROBINDO PHARMA LTD** Signature

01 1038508



(संदीप कुमार)
(Sandeep Kumar)
 असुरक्षित अधिकारी (सत्यापन / ओ.आई.)
 Senior Officer (Attestation/O.I.)
 सी.ई.डी. विभाग / C.E.D. Division
 विदेश मंत्रालय, नई दिल्ली
 Ministry of External Affairs, New Delhi

ATTESTED

M. SRINIVASA RAO
 Deputy Secretary



ATTESTED
 SADA BY: KUMAR REDDY, B.Com., B.L.
 DATE & NOTARY
 Notary Public for Govt., India
 102, Sakinaka, Sakinaka Colony
 Hyderabad - 500004 (P.O. 08480 41305)



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|-----|---|--------------------------------|---|--------|
| 340 | ZIDOVUDINE ORAL SOLUTION USP 50mg / 5ml | | Each 5 ml contains: Zidovudine USP 50 mg, Sodium Benzoate 0.2% added preservative | Export |
| 341 | ZIDOVUDINE TABLETS USP 300 mg | | Each film coated tablet contains: Zidovudine USP 300 mg, Colour: Titanium Dioxide | Export |
| 342 | ZIDOVUDINE TABLETS USP 300 mg | AURO-ZIDOVUDINE TABLETS 300 mg | Each film coated tablet contains: Zidovudine USP 300 mg, Colour: Titanium Dioxide | Export |
| 343 | ZOLPIDEM TARTRATE TABLETS USP 10 mg | | Each film coated tablet contains: Zolpidem Tartrate USP 10 mg, Colour: Titanium dioxide | Export |

Manufacturer: M/S M/s M/S AUROBINDO PHARMA LIMITED. UNIT-III, SY.NO.313 AND 314, BACHUPALLY VILLAGE, BACHUPALLY MANDAL, MEDCHAL - MALKAJGIRI DISTRICT,PINCODE 500090,TELANGANA STATE,INDIA

Drug License No: 19/HD/AP/95/F/R,

Dated:01/01/2022 Under Form 25&28 ,valid upto 31/12/2026

When applicable Placing the product on the market as detailed below.

The Unit M/S M/s M/S AUROBINDO PHARMA LIMITED. UNIT-III, SY.NO.313 AND 314, BACHUPALLY VILLAGE, BACHUPALLY MANDAL, MEDCHAL - MALKAJGIRI DISTRICT,PINCODE 500090,TELANGANA STATE,INDIA was inspected jointly by

It is certified that:

- The above products had been authorized to be placed on the market for use in the country and exported countries
- The manufacturing plant in which the product is produced is subject to inspection at suitable intervals.
- 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 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:25-03-2023 16:00:54 PM

This Document is Digitally Signed. Signature is not required

