

**L.Dis.No:91074/TS/2022**

**Dated:27/06/2022**  
**Valid until:25/06/2025**

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: **09/06/2022**.  
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:27-06-2022 15:23:43 PM

**L.Dis.No:91074/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	BROMOCRIPTINE MESYLATE TABLETS 0.8 mg		Each tablet contains: Bromocriptine Mesylate 0.945mg Equivalent to Bromocriptine Anhydrous 0.8 mg		Export
2	DOLUTEGRAVIR, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS 50 mg/300 mg/300 mg		Each film coated tablet contains: Dolutegravir 50mg Equivalent to Dolutegravir Sodium 52.60mg Lamivudine USP 300mg Tenofovir Disoproxil Fumarate 300mg Equivalent to Tenofovir Disoproxil 245mg		Export
3	EMTRICITABINE AND TENOFOVIR ALAFENAMIDE TABLETS 200 mg / 25 mg (Specific Quantity Export)		Each film coated tablet contains: Emtricitabine 200mg Tenofovir Alafenamide 25mg Equivalent to Tenofovir Alafenamide Hemifumarate 28.043mg		Export

4	FAMOTIDINE TABLETS USP 20 mg		Each tablet contains, Famotidine USP 20 mg	Export
5	FAMOTIDINE TABLETS USP 40 mg		Each tablet contains, Famotidine USP 40 mg	Export
6	FAMOTIDINE TABLETS USP10 mg		Each tablet contains, Famotidine USP 10 mg	Export
7	IVABRADINE TABLETS 5 mg		Each tablet contains: Ivabradine Hydrochloride 5.39 mg Equivalent to Ivabradine 5 mg	Export
8	IVABRADINE TABLETS 7.5 mg		Each tablet contains: Ivabradine Hydrochloride 8.085 mg Equivalent to Ivabradine 7.5mg	Export
9	LAMIVUDINE TABLETS USP 100mg		Each tablet contains: Lamivudine USP 100mg	Export
10	LEVETIRACETAM ORAL SOLUTION USP 100mg/ml		Each milliliter (1ml) of oral solution contains: Levetiracetam USP 100mg	Export
11	MESALAMINE DEALYED RELAESE TABLETS USP 1.2 mg (Specific Quantity Export)	COLIMEND	Each Delayed Release tablet contains: Mesalamine USP 1.2 mg	Export
12	Mesalamine Rectal Suppositories 1000 mg		Each Rectal Suppository Contains: Mesalamine USP 1000 mg	Export
13	OXCARBAZEPINE TABLETS USP 150 mg		Each film coated tablet contains: Oxcarbazepine USP 150mg	Export
14	OXCARBAZEPINE TABLETS USP 300 mg		Each film coated tablet contains: Oxcarbazepine USP 300 mg	Export
15	OXCARBAZEPINE TABLETS USP 600 mg		Each film coated tablet contains: Oxcarbazepine USP 600 mg	Export
16	PANTOPRAZOLE SODIUM FOR DEALYED RELEASE SUSPENSION 40 mg (Specific Quantity Export)		Each pack contains: Pantoprazole Sodium Sesquihydrate 45.1 mg Equivalent to Pantoprazole 40 mg	Export
17	SOLIFENACIN SUCCINATE TABLETS 10 mg	GOAB 10	Each film coated tablet contains: Solifenacin Succinate 10mg	Select
18	SOLIFENACIN SUCCINATE TABLETS 5 mg	GOAB 5	Each film coated tablet contains: Solifenacin Succinate 5 mg	Export
19	VENLAFAXINE EXTENDED RELAESE CAPSULES USP 150mg		Each capsule contains: Venlafaxine Hydrochloride USP 169.714mg Equivalent to Venlafaxine 150 mg	Export
20	VENLAFAXINE EXTENDED RELAESE CAPSULES USP 37.5 mg		Each capsule contains: Venlafaxine Hydrochloride USP 42.428 mg Equivalent to Venlafaxine 37.50 mg	Export
21	VENLAFAXINE EXTENDED RELAESE CAPSULES USP 75 mg		Each capsule contains: Venlafaxine Hydrochloride USP 84.857 mg Equivalent to Venlafaxine 75 mg	Export



22	ZAFIRLUKAST TABLETS 10 mg		Each film coated tablet contains: Zafirlukast 10 mg		Export
23	ZAFIRLUKAST TABLETS 20 mg		Each film coated tablet contains: Zafirlukast 20 mg		Export

Manufacturer: M/S M/s M/S. ANNORA PHARMA PRIVATE LIMITED,  
SY.NO.261, ANNARAM VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY  
DISTRICT,PINCODE 502313,TELANGANA STATE,INDIA

Drug License No: 24/MD/TS/2016/F/G,  
Dated:20/10/2021 Under Form 25 ,valid upto 19/10/2026

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

The Unit M/S M/s M/S. ANNORA PHARMA PRIVATE LIMITED, SY.NO.261, ANNARAM VILLAGE, GUMMADIDALA MANDAL,  
SANGAREDDY DISTRICT,PINCODE 502313,TELANGANA STATE,INDIA 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 #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:27-06-2022 15:23:43 PM

This Document is Digitally Signed. Signature is not required