DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No:80398/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: **24/01/2022.**
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 17:36:20 PM

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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	Azithromycin 250 mg Capsules		Each empty hard gelatine capsule contains: Azithromycin dihydrate Ph.Eur equivalent to Azithromycin 250 mg Excipient Q.S		Export
2	Dimethyl Fumarate Delayed Release Capsules 120 mg		Each Gastro Resistant hard gelatin capsule contains: Dimethyl Fumarate IH 120 mg, Acid Stage in 0.1 N HCL 0.2 Buffer Stage (in pH 6.8 sodium Phosphate Buffer) 97.4 Excipients Q.S.		Export
3	Dimethyl Fumarate Delayed Release Capsules 240 mg		Each Gastro Resistant hard gelatin capsule contains: Dimethyl Fumarate IH 240 mg, Acid Stage in 0.1 N HCL 0.3 Buffer Stage (in pH 6.8 sodium Phosphate Buffer) 97.8 Excipients Q.S.		Export
4	Gliclazide 60 mg Modified Release Tablets		Each Modified Release Tablet contains: Gliclazide Ph.Eur 60 mg Excipient Q.S		Export

5	Gliclazide Tablets 30 mg		Each Modified Release Tablet contains: Gliclazide Ph.Eur 30 mg Excipient Q.S		Export
6	Hydroxychloroquine Tablets 200 mg		Each Film coated tablet contains: Hydroxychloroquine sulphate B.P 200 mg Excipient Q.S		Export
7	Indoramine Tablets 20 mg		Each Film coated tablet contains: Indoramine Hydrochloride 22 mg equivalent to Indoramine 20 mg Excipient Q.S	Specific Qty Export	Export
8	Methyldopa Tablets 250 mg		Each film coated tablet contains: Methyldopa Ph.Eur 250 mg Excipients QS		Export
9	Methyldopa Tablets 500 mg		Each film coated tablet contains: Methyldopa Ph.Eur 500 mg Excipients QS		Export
10	Paracetamol 500 mg + Cetirizine Hydrochloride 10 mg + Phenylephrine Hydrochloride 10 mg	Combigrip Hot Sip Raspberry	Each 5 gm Sachet contains: Paracetamol B.P 500 mg Cetirizine Hydrochloride Ph.Eur / B.P 10 mg Phenylephrine Hydrochloride Ph.Eur / B.P 10 mg Excipients QS	Specific Qty Export	Export
11	Pyridostigmine Tablets 60 mg		Each Tablet contains: Pyridostigmine Bromide USP 60 mg Excipient Q.S	Specific Qty Export	Export
12	Spironolactone Tablets 100 mg		Each film coated tablet contains: Spironolactone Ph.Eur 100 mg Excipients Q.S		Export
13	Spironolactone Tablets 25 mg		Each film coated tablet contains: Spironolactone Ph.Eur 25 mg Excipients QS		Export
14	Valganciclovir Hydrochloride Powder for Oral solution 50 mg/ml		Each ml of constituted oral solution contains: Valganciclovir Hydrochloride USP equivalent to Valganciclovir 50 mg Excipient Q.S		Export
15	Voriconazole 40 mg/ml powder for oral Suspension		Each ml suspension: Voriconazole USP 40 mg Excipient Q.S		Export

Manufacturer: M/S **EVERTOGEN LIFE SCIENCES LIMITED, PLOT NO S-8,S-9,S-13/P & S-14/P, TSIIC, PHARMA SEZ, GREEN INDUSTRIAL PARK, POLEPALLY(V), JADCHERLA(M), MAHABUBNAGAR, TELANGANA, IN-509301, INDIA.**

Drug License No: **19/MN/AP/2014/F/G & 7/MN/TS/2014/F/G**
Dated:03/05/2014 Under Form 25 valid upto 01/05/2024 and Dated: 04/09/2019 Under Form 28 valid up to 03/09/2024

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

The Unit **M/s EVERTOGEN LIFE SCIENCES LIMITED, PLOT NO S-8,S-9,S-13/P & S-14/P, TSIIC, PHARMA SEZ, GREEN INDUSTRIAL PARK, POLEPALLE(V), JADCHERLA(M), MAHABUBNAGAR,TELANGANA, IN-509301, 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).

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This Document is Digitally Signed. Signature is not required