GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION

L.Dis.No.7186/E(K)/TS/2015 Dated: 06-06-2015.

From.

M.Amruth Rao, M.Pharm, L.L.M.
Designated officer, Deputy Director,
Licensing & Controlling Authority,
Drugs Control Administration,
Vengalraonagar,
Hyderabad.

To.

M/s.OPTIMUS GENERICS Ltd,
S-8, S-9, S-13/P & S-14/P,
Green Industrial Park
Polepally Village,
Jadcherla Mandal,
Mahaboobnagar District-509301
Telangana State.

Sir,

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: 16.04.2015
2. Joint Inspection report dt:13.05.2015.

-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 and CDSCO, Zonal Office, Hyderabad vide reference 2nd cited.

This Certificate is valid for a period of Two years from the date of issue.

Deputy Director (Enforcement) Drugs Control Administration HYDERABAD Government of Telangana Designated Officer for Telangana

Yours faithfully,

6/6/2015

DESIGNATED OFFICER, DEPUTY DIRECTOR,
LICENSING & CONTROLLING AUTHORITY
DRUGS CONTROL ADMINISTRATION

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

1. CETIRIZINE DIHYDROCHLORIDE 10 mg TABLETS
   Each film coated tablet contains:

Cetirizine Dihydrocloride	Ph.Eur	10 mg
Excipients	q.s	
Color:Opadry White		

2. AMLODIPINE 5 mg TABLETS
   Each uncoated tablet contains:

Amlodipine Besilate	Ph.Eur	
Equivalent to Amlodipine		5 mg
Excipients	q.s	

3. AMLODIPINE 10 mg TABLETS
   Each uncoated tablet contains:

Amlodipine Besilate	Ph.Eur	
Equivalent to Amlodipine		10 mg
Excipients	q.s	

4. TELMISARTAN TABLETS 20 mg
   Each uncoated tablet contains:

Telmisartan	Ph.Eur	20 mg
Excipients	q.s	

5. TELMISARTAN TABLETS 40 mg
   Each uncoated tablet contains:

Telmisartan	Ph.Eur	40 mg
Excipients	q.s	

6. TELMISARTAN TABLETS 80 mg
   Each uncoated tablet contains:

Telmisartan	Ph.Eur	80 mg
Excipients	q.s	

Manufacturer : M/s. OPTIMUS GENERICS Ltd,
S-8, S-9, S-13/P & S-14/P, Green Industrial park, Polepally Village, Jadcherla Mandal, Mahaboobnagar District-509301, Telangana State.

Deputy Director (Enforcement) * Drugs Control Administration * HYDERABAD * Government of Telangana * Designated Officer for Telangana

6/6/2015

L.Dis.No.7186/E(K)/TS/2015 Issue of WHO GMP Certificate of M/s OPTIMUS GENERICS Ltd, S-8, S-9, S-13/P & S-14/P, Green Industrial park, Polepally Village, Jadcherla Mandal, Mahaboobnagar District-509301, Telangana State.

When applicable : Placing the product on the market as detailed above.

It is certified that the above products had been authorized to be placed on the market for use in the Country.

Drug Licence No. : 19/MN/AP/2014/F/G dated:03.05.2014 under Form – 25 valid upto 02.05.2019

It is also certified that (a) the manufacturing plant in which the product is produced is subject to inspection at suitable intervals.

The Unit M/s. OPTIMUS GENERICS Ltd, S-8, S-9, S-13/P & S-14/P, Green Industrial park, Polepally Village, Jadcherla Mandal, Mahaboobnagar District-509301, Telangana State was inspected jointly by Mr.Santosh, DI, Kothur, Hyderabad and Mr.Chandrasekhar, DI, CDSCO, Hyderabad on 13.05.2015.

(b) The manufacturer conforms to requirements for Good Manufacturing Practices in the manufacturer and Quality Control (As recommended by the World Health Organisation) in respect of 06 (Six) products to be sold or distributed with in the Country or origin (or to be exported).

This Certificate is valid for Two years from the date of issue.

Deputy Director (Enforcement) * Drugs Control Administration * HYDERABAD * Government of Telangana * Designated Officer for Telangana

6/6/2015

DESIGNATED OFFICER, DEPUTY DIRECTOR,
LICENSING & CONTROLLING AUTHORITY