DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L. Dis. No.6157/E(S)/TS/2016 Dated: -08-2016

To

M/s.Fleming Laboratories Ltd
Survey No.270, Navabpet Village
Shivampet Mandal, Medak District
Telangana State, India.

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: 21.05.2016
2. Joint Inspection report dt:29.07.2016.

-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.

Joint Director (Enf) Drugs Control Administration HYDERABAD Government of Telangana Licensing & Controlling Authority

Yours faithfully,

24/8/2016

M AMRUTH RAO
Joint Director & Licensing Authority

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

1. Buclizine HCL	BP
2. Carisoprodol	USP/Ph.Eur
3. Cyproheptadine HCL	Ph.Eur/BP
4. Flunarizine Di HCL	Ph.Eur
5. Meclizine HCL	USP
6. Meclozine HCL	BP/Ph.Eur
7. Pentoxifylline	USP

Manufacturer : M/s.Fleming Laboratories Ltd
Survey No.270, Navabpet Village
Shivampet Mandal, Medak District
Telangana State, India.

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. : 153/MD/AP/96/B/R dated:25.11.1994 under Form – 25 valid upto 31.12.2016

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. M/s.Fleming Laboratories Ltd, Survey No.270, Navabpet Village, Shivampet Mandal, Medak District, Telangana State, India was inspected jointly by Sri.M.Vara Prasad, Drugs Inspector, Sangareddy Zone (Mfg), DCA, Hyderabad and Sri.A.N.Kranthi Kumar, Drugs Inspector, Drugs Control Administration, Hyderabad on 29.07.2016.

(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 07 (Seven) 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.

Joint Director (Enf) Drugs Control Administration HYDERABAD Government of Telangana Licensing & Controlling Authority

M AMRUTH RAO
Joint Director & Licensing Authority