

**L.Dis.No:17503/E(R)/TS/2015**

**Dated: 12-01-2016**

**To**  
**M/s. MSN Pharmachem Private Limited**  
Plot. No.212/A,B,C,D,Phase-II,  
IDA Pashamylaram,  
Pashamylaram (Village),  
Patancheru (Mandal),  
Medak District-502 307,Telangana. India.

Sirs,

Sub:- Drugs and Cosmetics Act, 1940 and Rules made thereunder –  
Issue of World Health Organisation Good Manufacturing Practice  
Certificate-Regarding.

Ref:- 1. Your application Dt.06.11.2015  
2. Joint Inspection report Dt.**04.01.2016 & 05.01.2016.**

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I forward herewith **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE CERTIFICATE** for the products recommended by the Joint Inspection Team consisting of officers of Central Drugs Standard Control Organization and Officers from Drugs Control Administration, Telangana, India for Export purpose.

This Certificate is valid for a period of Two years from the date of issue This certificate is meant for Export of drugs only.

Yours faithfully



**M.AMRUTH RAO**

**Licensing & Controlling Authority**



**L.Dis.No: 17503/E(R)/TS/2015**

**Dated: 12-01-2016**

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

- |    |                                   |                       |
|----|-----------------------------------|-----------------------|
| 1  | Aprepitant                        | - In-house            |
| 2  | Aripiprazole                      | - In-house/USP/Ph.Eur |
| 3  | Atorvastatin Calcium              | - In-house / USP      |
| 4  | Atorvastatin Calcium Trihydrate   | - Ph.Eur.             |
| 5  | Clopidogrel Bisulfate             | - USP                 |
| 6  | Clopidogrel Hydrogen Sulfate      | - Ph.Eur.             |
| 7  | Darifenacin Hydrobromide          | -In-house             |
| 8  | Memantine Hydrochloride           | - In-house / USP      |
| 9  | Montelukast Sodium                | - USP/Ph.Eur          |
| 10 | Moxifloxacin Hydrochloride        | - Ph-Eur./BP/ USP     |
| 11 | Nebivolol Hydrochloride           | - In-house            |
| 12 | Oseltamivir Phosphate             | - Ph.Eur. / USP       |
| 13 | Pregabalin                        | - In-house            |
| 14 | Ranolazine                        | - In-house            |
| 15 | Sumatriptan                       | - USP                 |
| 16 | Sumatriptan Succinate             | - USP/Ph.Eur.         |
| 17 | Telmisartan                       | - USP/Ph.Eur.         |
| 18 | Tolterodine Tartrate              | - In-house            |
| 19 | Lacosamide                        | - In House            |
| 20 | Sitagliptin Phosphate Monohydrate | - In House            |
| 21 | Sitagliptin Phosphate Anhydrous   | - In House            |
| 22 | Vildagliptin                      | - In House            |
| 23 | Milnacipran Hydrochloride         | - In House            |
| 24 | Moxifloxacin                      | - In House            |
| 25 | Darunavir Ethanolate              | - In House            |



*[Handwritten signature]*  
12/1/2016

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26	Darunavir	- In House
27	Agomelatine	- In House
28	Saxagliptin Hydrochloride	- In House
29	Linagliptin	- In House
30	Fesoterodine Fumarate	- In House
31	Atazanavir Sulfate	- In House
32	Vilazodone Hydrochloride	- In House
33	Carbinoxamine Maleate	- USP
34	Fesoterodine Hydrochloride	- In House
35	Saxagliptin Monohydrate	- In House
36	Lurasidone Hydrochloride	- In House
37	Levomilnacipran Hydrochloride	- In House

**Manufacturer :** **M/s. MSN Pharmachem Private Limited**  
Plot. No.212/A,B,C,D, Phase-II,  
IDA Pashamylaram,  
Pashamylaram (Village),  
Patancheru (Mandal),  
Medak District-502 307,Telangana. India.

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

**Drug Licence No. :** **07/MD/AP/2006/B/R, dt.23.01.2006**  
**In Form-25**

It is also certified that the manufacturing plant in which the products are produced is subject to inspection at suitable intervals.



*[Handwritten Signature]*  
12/1/2016



L.Dis.No: 17503/E(R)/TS/2015 , Issue of WHO GMP Certificate

The Unit M/s. MSN Pharmachem Private Limited, Plot. No.212/A,B,C,D, Phase-II, IDA Pashamylaram, Pashamylaram (Village), Patancheru (Mandal), Medak District-502 307, Telangana. India. was jointly inspected by Mr. Chandrashekhar Anaji Pawar- Drugs Inspector, CDSCO Zonal Office, Hyderabad, and Sri.Ch.Karthic Siva Chaitanya, Drugs Inspector, Drugs Control Administration, Hyderabad, Telangana on 04.01.2016 & 05.01.2016.

The manufacturer conforms to requirement for Good Manufacturing Practices in the manufacture and quality control (As recommended by the World Health Organization) in respect of products mentioned above (Thirty Seven numbers) for Export in the International market.

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Yours faithfully

**M.AMRUTH RAO**

**Licensing & Controlling Authority**

**To**  
**M/s. MSN Pharmachem Private Limited**  
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