

L.Dis.No:0617/E1/2020

Dated: 20-02-2020

To

M/s. MSN Pharmachem Private Limited

Plot. No.212/A,B,C,D,Phase-II,
IDA Pashamylaram,
Pashamylaram (Village),
Patancheru (Mandal),
Sangareddy District,
Pin Code-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.20.01.2020
2.CDSCO Recommendation Letter Ref No.5-6(099 A3)2019/7493
dt:13.02.2020 of Deputy Drugs , Controller(India) Zonal
Office,CDSCO BHAVAN,Hyderabad.

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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 Three years from the date of issue This certificate is meant for Export of drugs only.

Yours faithfully



Dr.B. Venkateswarlu
Joint Director(FAC) & Licensing Authority



L.Dis.No: 0617/E1/2020 – for issue of WHO GMP Certificate.

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

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



Blue
20/10/20

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

26	Vilazodone Hydrochloride	- In House
27	Carbinoxamine Maleate	- USP
28	Saxagliptin Monohydrate	- In House
29	Lurasidone Hydrochloride	- In House
30	Levomilnacipran Hydrochloride	- In House
31	Sitagliptin Hydrochloride	- In House
32	Rilpivirine Hydrochloride	- In House
33	Vortioxetine Hydrobromide	- In House
34	Clopidogrel Bisulfate	-USP
35	Clopidogrel Hydrogen Sulfate	-Ph.Eur.
36	Sumatriptan	-USP
37	Sitagliptin Phosphate Anhydrous	-In House
38	Darunavir Ethanolate	-In House
39	Fesoterodine Fumarate	- In House
40	Fesoterodine Hydrochloride	-In House
41	Aripiprazole Lauroxil	-In House

Manufacturer : **M/s. MSN Pharmachem Private Limited**
Plot. No.212/A,B,C,D, Phase-II,
IDA Pashamylaram,
Pashamylaram (Village),
Patancheru (Mandal),
Sangareddy District,
Pin Code-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



B. V. 20/02/20

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

The Unit M/s. MSN Pharmachem Private Limited, Plot. No.212/A,B,C,D, Phase-II,IDA Pashamylaram,Pashamylaram (Village),Patancheru (Mandal),Sangareddy District,Pin Code-502 307,Telangana. India was inspected by Mrs.L.Suganthi- Drugs Inspector, CDSCO Zonal Office, Hyderabad on 01.07.2019 & 02.07.2019, and Mr.Ch.Karthik Siva Chaitanya, Drugs Inspector, Drugs Control Administration, Hyderabad, Telangana on 02.08.2019.

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 (Forty One Numbers) for Export in the International market.

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Yours faithfully

B. Venkateswarlu
20/07/20

Dr.B. Venkateswarlu
Joint Director(FAC) & Licensing Authority