



DRUGS CONTROL ADMINISTRATION
Government of Telangana



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

B. Venkateswarlu
20/02/20

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.



Blm
20/02/20





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

**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. V. V.
20/02/20





DRUGS CONTROL ADMINISTRATION
Government of Telangana



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

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.

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

B. Venkateswarlu
20/02/20

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



भारत सरकार
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)

GOVERNMENT OF INDIA
APOSTILLE
(Convention de La Haye du 5 octobre 1961)

Country
REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT
has been signed by **DR. B VENKATESWARLU**
acting in the capacity of **JT. DIRECTOR**
bears the seal/stamp of **SECRETARY, RAIGAD CHAMBER OF COMMERCE & INDUSTRY**

Certified
at **NEW DELHI, INDIA** the **11-Mar-2020**
by **SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS**
No. **MHMC0007204420**

Seal / Stamp
is issued to **MSN PHARMACHEM PVT. LTD.**

Signature



(सुनील चनाप)
(SUNIL CHANAP)
अनुमति अधिकारी (ओ.आई.)
Section Officer (OI)
सी. प्रो. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs New



For Raigad Chamber of Commerce & Industry

Sharad Mhatre
Sharad Mhatre
Secretary

09 MAR 2020



ADMINISTRACIÓN DE CONTROL DE MEDICAMENTOS
Gobierno de Telangana



Apostille

L.Dis.No:0617/E1/2020

Fecha: 20-02-2020

Para

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

Señor,

Asunto: Acta de Medicamentos y Cosméticos 1940 y Reglamentos subsecuentes – Con respecto a -
Emisión de Certificado de Buenas Prácticas de Manufactura de la Organización Mundial de la Salud.

Ref: 1. Su solicitud con fecha 20.01.2020.
2. CDSCO Carta de Recomendación No. Ref. 5-6(099 A3)2019/7493
fecha: 13.02.2020 del Delegado de Medicamentos, Controlador (India) Oficina de Zona,
CDSCO BHAVAN, Hyderabad.

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En el presente reenvío el **CERTIFICADO DE BUENAS PRÁCTICAS DE MANUFACTURA DE LA ORGANIZACIÓN MUNDIAL DE LA SALUD** para los productos recomendados por el Equipo de Inspección Conjunta consistiendo de oficiales de la Organización de Control Estándar Central de Medicamentos y los Oficiales de la Administración de Control de Medicamentos, Telangana, India con el propósito de Exportación.

Este certificado es válido por un período de Tres años desde la fecha de emisión. Este certificado tiene solo como propósito la Exportación de medicamentos.

Atentamente



B. Venkateswarlu
20/02/20

Dr. B. Venkateswarlu

Director Conjunto (FAC) & Autoridad Licenciadora





L.Dis.No: 0617/E12020 – para emisión de Certificado OMS BPM

LISTA DE PRODUCTOS APROBADOS BAJO EL ESQUEMA DE
CERTIFICACIÓN OMS BPM CON EL PROPÓSITO DE EXPORTACIÓN

1	Aprepitant	- Interno/USP & Ph.Eur
2	Aripiprazol	- Interno/USP/Ph.Eur
3	Atorvastatina Cálrica	- Interno/USP
4	Atorvastatina Cálrica Trihidrato	- Ph.Eur.
5	Hidrobromuro de Darifenacina	- Interno
6	Clorhidrato de Memantina	- Interno/USP
7	Montelukast Sódico	- USP/Ph.Eur
8	Clorhidrato de Moxifloxacina	- Ph-Eur./BP/USP
9	Clorhidrato de Nebivolol	- Interno
10	Fosfato de Oseltamivir	- Ph.Eur./USP
11	Pregabalina	- Interno/Ph.Eur/USP
12	Ranolazina	- Interno
13	Succinato de Sumatriptán	- USP/Ph.Eur.
14	Telmisartan	- USP/Ph.Eur.
15	Tartrato de Tolterodina	- Interno
16	Lacosamida	- Interno/Ph.Eur.
17	Sitagliptina Fosfato Monohidrato	- Interno/USP/Ph.Eur.
18	Vildagliptina	- Interno
19	Clorhidrato de Milnacipran	- Interno
20	Moxifloxacino	- Interno
21	Darunavir	- Interno
22	Agomelatina	- Interno
23	Clorhidrato de Saxagliptina (Dihidrato)	- Interno
24	Linagliptina	- Interno
25	Sulfato de Atazanavir	- Interno/Ph. Eur.



Blv
20/02/20





L.Dis.No: 0617/E12020 – para emisión de Certificado OMS BPM

LISTA DE PRODUCTOS APROBADOS BAJO EL ESQUEMA DE
CERTIFICACIÓN OMS BPM CON EL PROPÓSITO DE EXPORTACIÓN

26	Clorhidrato de Vilazodone	- Interno
27	Maleato de Carbinoxamina	- USP
28	Saxagliptina Monohidrato	- Interno
29	Clorhidrato de Lurasidona	- Interno
30	Clorhidrato de Levomilnacipran	- Interno
31	Clorhidrato de Sitagliptina	- Interno
32	Clorhidrato de Rilpivirina	- Interno
33	Hidrobromuro de Vortioxetina	- Interno
34	Clopidogrel Bisulfato	- USP
35	Clopidogrel Hidrógeno Sulfato	- Ph. Eur.
36	Sumatriptán	- USP
37	Sitagliptina Fosfato Anhidro	- Interno
38	Darunavir Etanolato	- Interno
39	Fesoterodina Fumarato	- Interno
40	Fesoterodina Clorhidrato	- Interno
41	Aripiprazol Lauroxil	- Interno

Fabricante

: 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



Donde aplique

: Coloque el producto en el mercado como se detalla en la continuación.

No. de Licencia de Medicamento

: 07/MD/AP/2006/B/R, fecha 23.01.2006

En Forma-25



B. V. ...
20/02/20



L.Dis.No: 0617/E12020 – para emisión de Certificado OMS BPM

Se certifica además que la planta de manufactura en la cual los productos son producidos está sujeta a inspección a intervalos adecuados.

La Unidad 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 fue inspeccionada por Sra. L. Suganthi – Inspector de Medicamentos, CDSCO Oficina de Zona, Hyderabad el 01.07.2019 & 02.07.2019, y Sr. Ch. Karthic Siva Chaitanya, Inspector de Medicamentos, Administración de Control de Medicamentos, Hyderabad, Telangana 02.08.2019.

El fabricante está conforme a los requerimientos para las Buenas Prácticas de Manufactura en la Fabricación y Control de Calidad (como lo recomienda la Organización Mundial de la Salud) con respecto a los productos mencionados anteriormente (Cuarenta y uno en número) para la Exportación en el mercado Internacional.

Este certificado es válido por un período de Tres años desde la fecha de emisión. Este certificado tiene solo como propósito la Exportación de medicamentos.

Atentamente

B. Venkateswarlu
20/02/20

Dr. B. Venkateswarlu

Director Conjunto (FAC) & Autoridad Licenciadora



 भारत सरकार
GOVERNMENT OF INDIA
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Country
REPUBLIC OF INDIA

This public document
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DR. B VENKATESWARLU
acting in the capacity of
JT. DIRECTOR
bears the seal/stamp of
SECRETARY, RAIGAD CHAMBER OF
COMMERCE & INDUSTRY

Certified
at NEW DELHI, INDIA the 11-Mar-2020
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. MHMC0007204420

Seal / Stamp
is issued to MSN PHARMACHEM PVT. LTD.

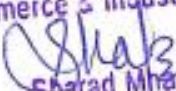
Signature



(सुनील चनाप)
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अतिरिक्त अधिकारी (ओ.आई.)
Section Officer (OI)
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विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New



For Raigad Chamber of Commerce & Industry


Sharad Mhatre
Secretary

0.9 MAR 2020

Apostille



DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No:0617/E1/2020

Dated: 20-02-2020

To
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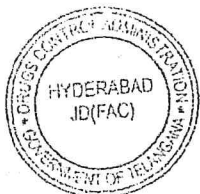
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Joint Director(FAC) & Licensing Authority





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**LIST OF PRODUCTS APPROVED UNDER WHO GMP
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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.



Blm
20/02/20





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

**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
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Manufacturer

: **M/s. MSN Pharmachem Private Limited**
Plot. No.212/A,B,C,D, Phase-II,
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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. V. V.
20/02/20







DRUGS CONTROL ADMINISTRATION
Government of Telangana



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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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20/02/20

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



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GOVERNMENT OF INDIA
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Country
REPUBLIC OF INDIA

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acting in the capacity of **JT. DIRECTOR**
bears the seal/stamp of **SECRETARY, RAIGAD CHAMBER OF COMMERCE & INDUSTRY**

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by **SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS**
No. **MHMC0007204420**

Seal / Stamp
is issued to **MSN PHARMACHEM PVT. LTD.**

Signature



(सुनील चनाप)
(SUNIL CHANAP)
अनुमति अधिकारी (ओ.आई.)
Section Officer (OI)
सी. प्रो. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs New



For Raigad Chamber of Commerce & Industry

Sharad Mhatre
Sharad Mhatre
Secretary

09 MAR 2020