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DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

Dated: 23.05.2019

L.Dis.No.0903/E1/2019

To
M/s Hetero Drugs Limited, Unit-I,
Sy.No. 213, 214 & 255,
Bonthapally Village, Gummadidala Mandal
Sangareddy District, Telangana, India.

Sirs,

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

Ref: 1. Your application dated:25.02.2019.
2. Joint Inspection Report dated:20.05.2019 & 21.05.2019.

I forward herewith **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE CERTIFICATE** for the products recommended by the Joint Inspection Team consisting of officers of Drugs Control Administration, Telangana State, 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

DRUGS CONTROL ADMINISTRATION HYDERABAD JD(FAC) GOVERNMENT OF TELANGANA

23/05

Dr.B.VENKATESWARLU
Joint Director & Licensing Authority

DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L.Dis.No.0903/E1/2019 – Issue of WHO GMP Certificate to M/s.Hetero Drugs Limited, Unit-I, Sy.No.213, 214 & 255, Bonthapally Village, Gummadidala Mandal, Sangareddy District, Telangana State, India bearing licence No.9/MD/AP/96/B/R, dt:09.05.1993 & 04.02.1998.

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

1. Amlodipine Besylate	USP
2. Amlodipine Besilate	Ph.Eur / JP
3. Aprepitant	IH / USP / Ph.Eur
4. Citalopram Hydrobromide	Ph.Eur / USP
5. Cyclobenzaprine Hydrochloride	USP
6. Clopidogrel Bisulfate	IH / USP / Ph.Eur
7. Donepezil Hydrochloride Monohydrate	IH / USP
8. Donepezil Hydrochloride Anhydrous	IH / USP / JP
9. Dorzolamide Hydrochloride	Ph.Eur / USP
10. Duloxetine Hydrochloride	USP / Ph.Eur
11. Doxazosin Mesilate	Ph.Eur
12. Eprosartan Mesylate	IH / USP
13. Fosinopril Sodium	USP / Ph.Eur
14. Famciclovir	IH / USP
15. Glimepiride	Ph.Eur / USP
16. Itraconazole	USP / Ph.Eur
17. Lansoprazole	USP / Ph.Eur
18. Lercanidipine Hydrochloride	IH
19. Nebivolol Hydrochloride	IH
20. Omeprazole Magnesium	USP / Ph.Eur
21. Pantoprazole Sodium Sesquihydrate	Ph.Eur / USP
22. Perindopril Tert-Butylamine	Ph.Eur
23. Rabeprazole Sodium	IH / Ph.Eur
24. Riluzole	IH / USP
25. Sertraline Hydrochloride	Ph.Eur / USP
26. Sildenafil Citrate	USP / Ph.Eur / IH

HYDERABAD

DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L.Dis.No.0903/E1/2019 – Issue of WHO GMP Certificate to M/s.Hetero Drugs Limited, Unit-I, Sy.No.213, 214 & 255, Bonthapally Village, Gummadidala Mandal, Sangareddy District, Telangana State, India bearing licence No.9/MD/AP/96/B/R, dt:09.05.1993 & 04.02.1998.

27. Tolterodine Tartrate	IH / USP / Ph.Eur
28. Solifenacin Succinate	IH / Ph.Eur
29. Topiramate	IH / USP
30. Tetrabenazine	IH
31. Valacyclovir Hydrochloride Anhydrous	Ph.Eur
32. Pramipexole Di hydrochloride Monohydrate	USP / Ph.Eur
33. Roflumilast	IH
34. Fosaprepitant Dimeglumine	IH
35. Atovaquone	USP / IH
36. Apremilast	IH
37. Bupropion Hydrochloride	USP
38. Ivabradine Hydrochloride	IH
39. Metoprolol Succinate	USP
40. Vigabatrin	USP
41. Tolvaptan	IH
42. Felbamate	USP

Manufacturer : M/s. Hetero Drugs Limited, Unit-I, Sy.No. 213, 214 & 255, Bonthapally Village, Gummadidala Mandal, Sangareddy District, Telangana, India.

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

It is certified that these products has been authorized to be placed on the market for use in the country and exporting countries.

Drug Licence No. : 9/MD/AP/96/B/R dt: 09-05-1993 & 04.02.1998 in Form- 25 & 28.

23/05/19

DRUGS CONTROL ADMINISTRATION GOVERNMENT OF TELANGANA HYDERABAD JD(FAD)

DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L.Dis.No.0903/E1/2019 – Issue of WHO GMP Certificate to M/s.Hetero Drugs Limited, Unit-I, Sy.No.213, 214 & 255, Bonthapally Village, Gummadidala Mandal, Sangareddy District, Telangana State, India bearing licence No.9/MD/AP/96/B/R, dt:09.05.1993 & 04.02.1998.

The firm **M/s. Hetero Drugs Limited, Unit-I,** Sy.No.213, 214 & 255, Bonthapally Village, Gummadidala Mandal, Sangareddy District, Telangana State, India was jointly inspected by Mr. A.N. Kranthi Kumar Drugs Inspector & Mr. Ch. Karthik Siva Chaitanya, Drugs Inspector, Drugs Control Administration, Telangana State on 20.05.2019 & 21.05.2019.

The manufacturer conforms to requirement for **Good Manufacturing Practices** in the manufacturing and quality control (As recommended by the **World Health Organization**) in respect of the products mentioned above **(Forty Two)** for Export in the international market.

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

DRUGS CONTROL ADMINISTRATION * GOVERNMENT OF TELANGANA *
HYDERABAD
JD(FAC)

23/05/19

Dr.B.VENKATESWARLU
Joint Director & Licensing Authority

To
M/s. HETERO DRUGS LIMITED, Unit-I
Sy.No.213, 214 & 255, Bonthapally Village,
Gummadidala Mandal, Sangareddy District,
Telangana State, India.

UNCONTROLLED
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DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

Dated: 28.02.2019

L.Dis.No.245/E1/2019

To
M/s Hetero Drugs Limited, Unit-I
Sy.No.213, 214 & 255, Bonthapally Village,
Gummadidala Mandal, Sangareddy District,
Telangana State, India.

Sirs,

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

Ref: 1. Your application dated: 16.01.2019.
2. Joint Inspection Report dated: 12.10.2018 & 13.10.2018.

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, Zonal Office, Hyderabad and Drugs Control Administration, Telangana State, 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,

28/02/19

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

DRUGS CONTROL ADMINISTRATION
HYDERABAD
JD(FAC)
GOVERNMENT OF TELANGANA

DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L.Dis.No. 245/E1/2019 - Grant of WHO GMP Certificate to M/s.Hetero Drugs Limited, Unit-I, Sy.No.213, 214 & 255, Bonthapally Village, Gummadidala Mandal, Sangareddy District, Telangana State, India in Form-25 bearing No.9/MD/AP/96/B/R, dt:09.05.1993 & 04.02.1998.

Drug Licence No. : **9/MD/AP/96/B/R, dt: 09.05.1993 & 04.02.1998 in Form–25.**

The firm **M/s. Hetero Drugs Limited, Unit-I**, Sy.No.213, 214 & 255, Bonthapally Village, Gummadidala Mandal, Sangareddy District, Telangana State, India was jointly inspected by Mr.R.Dharmaraj Rajaram, ADC(I), CDSCO, Zonal Office, Hyderabad and Mr.A.N.Kranthi Kumar, Drugs Inspector, Drugs Control Administration, Telangana State on 12.10.2018 & 13.10.2018.

The manufacturer conforms to requirement for **Good Manufacturing Practices** in the manufacturing and quality control (As recommended by the **World Health Organization**) in respect of the products mentioned above **(Thirteen)** for Export in the international market.

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

DRUGS CONTROL ADMINISTRATION * HYDERABAD JD(FAC) * GOVERNMENT OF TELANGANA

28/02/19

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

To
M/s. HETERO DRUGS LIMITED, Unit-I
Sy.No.213, 214 & 255, Bonthapally Village,
Gummadidala Mandal, Sangareddy District,
Telangana State, India.

DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L.Dis.No. 245/E1/2019 - Grant of WHO GMP Certificate to M/s.Hetero Drugs Limited, Unit-I, Sy.No.213, 214 & 255, Bonthapally Village, Gummadidala Mandal, Sangareddy District, Telangana State, India in Form-25 bearing No.9/MD/AP/96/B/R, dt:09.05.1993 & 04.02.1998.

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

1.	ALFUZOSIN HYDROCHLORIDE	USP / Ph.Eur / IP / BP
2.	ELTROMBOPAG OLAMINE	IH
3.	ENTECAVIR MONOHYDRATE	IH / USP
4.	ESOMEPRAZOLE SODIUM	IH
5.	LEVOFLOXACIN HEMIHYDRATE	USP / IH / IP
6.	LISINOPRIL DIHYDRATE	USP / Ph.Eur / JP / BP / IH
7.	MONTELUKAST SODIUM	USP / Ph.Eur / IH
8.	MOXIFLOXACIN HYDROCHLORIDE	USP / IH / Ph.Eur
9.	OLANZAPINE	USP / Ph.Eur / IP / JP
10.	OMEPRAZOLE	USP / Ph.Eur / IP
11.	PROGUANIL HYDROCHLORIDE	Ph.Eur / USP
12.	RALTEGRAVIR POTASSIUM	IH
13.	PANTOPRAZOLE HEMI-MAGNESIUM	IH

Manufacturer : M/s. Hetero Drugs Limited, Unit-I
Sy.No.213, 214 & 255, Bonthapally Village,
Gummadidala Mandal, Sangareddy District,
Telangana State, India.

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

It is certified that these products has been authorized to be placed on the market for use in the country and exporting countries.

28/02/19

DRUGS CONTROL ADMINISTRATION
HYDERABAD
JD(FAC)
GOVERNMENT OF TELANGANA

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DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L.Dis.No.2644/E1/2019

Dated: 04.10.2019

To
M/s Hetero Drugs Limited, Unit-I
Sy.No.213, 214 & 255, Bonthapally Village,
Gummadidala Mandal, Sangareddy District,
Telangana State, India.

Sirs,

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

Ref: 1. Your application dated: 17.07.2019.
2. Joint Inspection Report dated: 20.05.2019 & 21.05.2019.

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, Zonal Office, Hyderabad and Drugs Control Administration, Telangana State, 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.

DRUGS CONTROL ADMINISTRATION * GOVERNMENT OF TELANGANA * HYDERABAD JD(FAC)

Yours faithfully,

04/10/19

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

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& CONFIDENTIAL

DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L.Dis.No. 2644/E1/2019 - Grant of WHO GMP Certificate to M/s.Hetero Drugs Limited, Unit-I, Sy.No.213, 214 & 255, Bonthapally Village, Gummadidala Mandal, Sangareddy District, Telangana State, India in Form-25 bearing No.9/MD/AP/96/B/R, dt:09.05.1993 & 04.02.1998.

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

1.	VALACYCLOVIR HYDROCHLORIDE MONOHYDRATE	Ph.Eur / IH
2.	DEXLANSOPRAZOLE	IH
3.	ESOMEPRAZOLE MAGNESIUM DIHYDRATE	USP / Ph.Eur

Manufacturer : M/s. Hetero Drugs Limited, Unit-I
Sy.No.213, 214 & 255, Bonthapally Village,
Gummadidala Mandal, Sangareddy District,
Telangana State, India.

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

It is certified that these products has been authorized to be placed on the market for use in the country and exporting countries.

Drug Licence No. : **9/MD/AP/96/B/R, dt: 09.05.1993 & 04.02.1998 in Form–25.**

The firm **M/s. Hetero Drugs Limited, Unit-I,** Sy.No.213, 214 & 255, Bonthapally Village, Gummadidala Mandal, Sangareddy District, Telangana State, India was jointly inspected by Mr.R.Dharmaraj Rajaram, ADC(I), CDSCO, Zonal Office, Hyderabad and Mr.A.N.Kranthi Kumar, Drugs Inspector, Drugs Control Administration, Telangana State on 20.05.2019 & 21.05.2019.

The manufacturer conforms to requirement for **Good Manufacturing Practices** in the manufacturing and quality control (As recommended by the **World Health Organization**) in respect of the products mentioned above **(Three)** for Export in the international market.

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

DRUGS CONTROL ADMINISTRATION * GOVERNMENT OF TELANGANA *
HYDERABAD
JD(FAC)

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

To
M/s. HETERO DRUGS LIMITED, Unit-I
Sy.No.213, 214 & 255, Bonthapally Village,
Gummadidala Mandal, Sangareddy District,
Telangana State, India.