



DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No.0903/E1/2019

Dated: 23.05.2019

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



B. Venkateswarlu
23/05/19
Dr.B.VENKATESWARLU

Joint Director & Licensing Authority



ATTESTED

M. Srinivasa Rao
M. SRINIVASA RAO
Deputy Secretary



ATTESTED

M. Sada Siva Kumar Reddy
M. SADA SIVA KUMAR REDDY, B.Com., B.L.,
ADVOCATE & NOTARY
Appointed by Govt. of A.P., India
G.O Ms.No.198, Rev (Regn-II), dt. 11.04.2000
102, Saraswathi Enclave, Bhagyanagar Colony,
Kukatpally, Hyderabad, A.P., India (Ph. 98480 44395)



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

Country

REPUBLIC OF INDIA

This public document

COMMERCIAL DOCUMENT

has been signed by B VENKATESWARLU

acting in the capacity of JT DIRECTOR

bears the seal/stamp of FEDERATION OF INDIAN MICRO AND
SMALL & MEDIUM ENTERPRISES

Certified

at NEW DELHI, INDIA the 15-Sep-2021

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. APHY0001956121

Seal / Stamp

is issued to HETERO DRUGS LTD.

Signature



अनुमति अधिकारी (अपोस्टिल/ओ.आई.)
Section Officer (Attestation/O.I.)
सी.पी.वी. विभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi





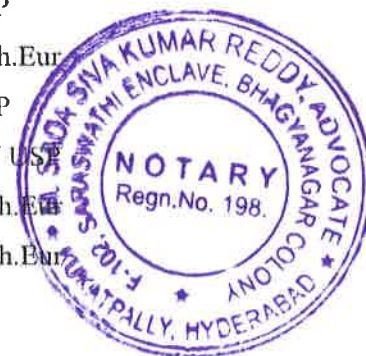
DRUGS CONTROL ADMINISTRATION
Government of Telangana



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



R. V. [Signature]



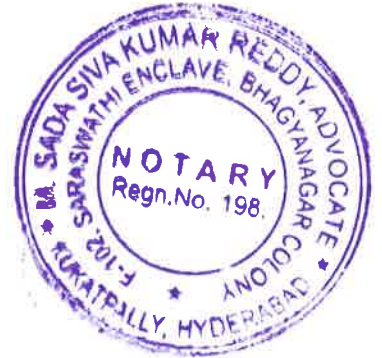


DRUGS CONTROL ADMINISTRATION
Government of Telangana



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.



B. V. S. R. S. R.
23/05/19





DRUGS CONTROL ADMINISTRATION
Government of 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.



B. Venkateswarlu
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.



ATTESTED

M. Srinivasa Rao
M. SRINIVASA RAO
Deputy Secretary



ATTESTED

M. Sada Siva Kumar Reddy
M. SADA SIVA KUMAR REDDY, B.Com., B.L.
ADVOCATE & NOTARY
Appointed by Govt. of A.P., India
G.O.Ms.No.198, Rev (Regn-II), dt. 11.04.2000
102, Saraswathi Enclave, Bhagyanagar Colony,
Kukatpally, Hyderabad, A.P., India (Ph: 98480 44395)

Handwritten text in Hindi, likely a signature or note, is visible in the upper left area of the page.

 **भारत सरकार GOVERNMENT OF INDIA**
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)

Country **REPUBLIC OF INDIA**

This public document
COMMERCIAL DOCUMENT
has been signed by **B VENKATESWARLU**
acting in the capacity of **JT. DIRECTOR**
bears the seal/stamp of **FEDERATION OF INDIAN MICRO AND
SMALL & MEDIUM ENTERPRISES**

Certified
at **NEW DELHI, INDIA** the **15-Sep-2021**
by **SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS**
No. **APHY0001956221**

Seal / Stamp is issued to **HETERO DRUGS LTD.**

Signature 



(सुनील चनप)
(SUNIL CHANAP)
अनुभाग अधिकारी (सत्यापन / ओ.आई.)
Section Officer (Attestation/O.I.)
सी.पी.वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi