



DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No. 753/E1/2019

Dated: 20.06.2019

To
M/s Hetero Labs Limited, Unit-I
Sy.No.10, I.D.A., Gaddapotharam Village,
Jinnaram 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: 15.02.2019.
2. Joint Inspection Report dated: 02.05.2018 & 03.05.2018.

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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 CDSCO 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,

B. Venkateswarlu
20/06/19

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





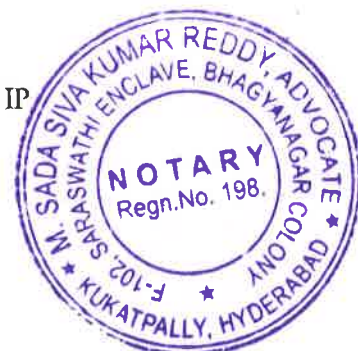
DRUGS CONTROL ADMINISTRATION Government of Telangana



L.Dis.No. 753/E1/2019 - Grant of WHO GMP Certificate to M/s.Hetero Labs Limited, Unit-I, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District, Telangana State, India in Form-25 bearing No.25/MD/AP/97/B/R, dt:31.01.1997.

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

1. ATOMOXETINE HYDROCHLORIDE	USP / Ph.Eur / IH
2. NEVIRAPINE ANHYDROUS	USP
3. CANDESARTAN CILEXETIL	USP / Ph.Eur / IH
4. LOPINAVIR	USP / IH / IP / Ph.Eur
5. LETROZOLE	USP / Ph.Eur
6. PEMETREXED DISODIUM	IH
7. CISPLATIN	USP / Ph.Eur
8. ABIRATERONE ACETATE	IH / USP / IP
9. ARIPIPRAZOLE	IH / USP / Ph.Eur
10. ABACAVIR SULFATE	USP / Ph.Eur
11. ANASTROZOLE	IH / USP / Ph.Eur / IP
12. ATAZANAVIR SULFATE	IH
13. BICALUTAMIDE	IH / USP / Ph.Eur / IP
14. CAPECITABINE	IH / USP / Ph.Eur / IP
15. CILAZAPRIL	BP
16. DIDANOSINE	USP / Ph.Eur
17. EFAVIRENZ	IH / USP / IP
18. EMTRICITABINE	USP / IH / IP
19. ESCITALOPRAM OXALATE	IH / USP / Ph.Eur
20. FINASTERIDE	USP / Ph.Eur / IH / IP
21. GEMCITABINE HYDROCHLORIDE	USP / Ph.Eur
22. HYDRALAZINE HYDROCHLORIDE	Ph.Eur
23. IMATINIB MESYLATE	IP / Ph.Eur / IH
24. IRBESARTAN	USP / Ph.Eur
25. LAMIVUDINE	USP / Ph.Eur / IP
26. LEVETIRACETAM	USP / Ph.Eur
27. LOSARTAN POTASSIUM	USP / Ph.Eur / JP



B. [Signature] 2016



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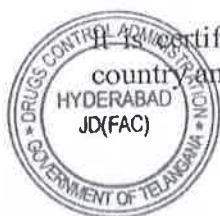
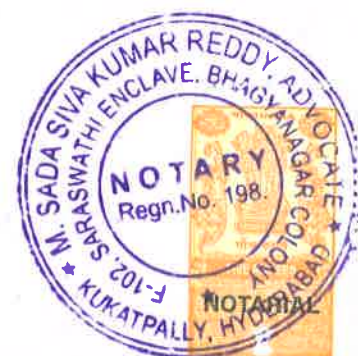
28. PIOGLITAZONE HYDROCHLORIDE	IH / USP / Ph.Eur / JP
29. OSELTAMIVIR PHOSPHATE	USP / Ph.Eur / IH
30. QUETIAPINE FUMARATE	USP / Ph.Eur / IH / IP
31. RAMIPRIL	USP / Ph.Eur / IP
32. SAQUINAVIR MESYLATE	USP / Ph.Eur
33. SIMVASTATIN	USP / Ph.Eur
34. STAVUDINE	USP
35. TENOFOVIR DISOPROXIL FUMARATE	IH
36. TERBINAFINE HYDROCHLORIDE	USP / Ph.Eur
37. TORSEMIDE ANHYDROUS	Ph.Eur
38. ZIDOVUDINE	USP / Ph.Eur / IP
39. ZONISAMIDE	IP / USP
40. BORTEZOMIB	IH
41. ERLOTINIB HYDROCHLORIDE	IH / IP
42. ETORICOXIB	IH
43. MARAVIROC	IH
44. SOFOSBUVIR	IH
45. TENOFOVIR DISOPROXIL	IH
46. LENALIDOMIDE	IH
47. POMALIDOMIDE	IH
48. AXITINIB	IH
49. REGORAFENIB	IH

Manufacturer

M/s. Hetero Labs Limited, Unit-I
Sy.No. 10, I.D.A., Gaddapotharam Village,
Jinnaram 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.

ATTESTED
K. Sujatha
KAMBHAM SUJATHA
Assistant Secretary

ATTESTED
20/06/19
M. SADA SIVA KUMAR REDDY
M. SADA SIVA KUMAR REDDY, B.Com. & A.
ADVOCATE & NOTARY
Appointed by Govt. of A.P., India
G.O.Ms.No.198, Rev (Regn-II), dt. 11.04.2000
102, Sarasathi Enclave, Bhagyanagar Colony,
Kukatpally, Hyderabad, A.P., India (Ph: 98480 4439)

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

REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT
has been signed by N/A
acting in the capacity of DIRECTOR
bears the seal/stamp of ASST. SECY, FEDERATION OF INDIAN
MICRO AND SMALL & MEDIUM ENTERPRISES

Certified
at NEW DELHI, INDIA the 31-Jul-2019
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. APHY0007971419

Seal / Stamp is issued to HETERO LABS LTD.

Signature

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

मिनिस्ट्री ऑफ़ एक्सटर्नल अफ़ेयर्स
GOVT. OF INDIA, NEW DELHI
मु० 568



ATTACHED



DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No. 753/E1/2019 - Grant of WHO GMP Certificate to M/s.Hetero Labs Limited, Unit-I, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District, Telangana State, India in Form-25 bearing No.25/MD/AP/97/B/R, dt:31.01.1997.

Drug Licence No.

25/MD/AP/97/B/R, dt: 31.01.1997
in Form-25.

The firm **M/s. Hetero Labs Limited, Unit-I, Sy.No.10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District, Telangana State, India** was jointly inspected by Mr.Naveen Yadav, Drugs Inspector, Zonal Office, CDSCO Bhavan, Hyderabad and Mr.A.N.Kranthi Kumar, Drugs Inspector, Drugs Control Administration, Telangana State on 02.05.2018 & 03.05.2018.

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 (**Forty Nine**) for Export in the international market.

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



B. Venkateswarlu
20/06/19
Dr.B.VENKATESWARLU
Joint Director (FAC) & Licensing Authority

To
M/s. HETERO LABS LIMITED, Unit-I
Sy.No.10, I.D.A., Gaddapotharam Village,
Jinnaram Mandal, Sangareddy District,
Telangana State, India.

Traducción fiel al original



L. Dis. No. 753/E1/2019

Fecha: 20.06.2019

Para

M/s Hetero Labs Limited, Unit-I
Sy. No. 10, I.D.A., Gaddapotharam Village,
Jinnaram Mandal, Sangareddy District,
Telangana State, India

Señor,

Asunto: Medicamentos y Cosméticos Acta 1940 y Regulaciones en virtud del mismo – Con respecto a
- Emisión de Certificado de Buenas Prácticas de Manufactura de la Organización Mundial de la Salud.

Ref: 1. Su solicitud con fecha 15.02.2019.
2. Reporte de inspección conjunta con fecha: 02.05.2018 & 03.05.2018

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Junto con esto otorgo el **CERTIFICADO DE BUENAS PRÁCTICAS DE MANUFACTURA DE LA ORGANIZACIÓN MUNDIAL DE LA SALUD** para los productos recomendados por el Equipo de Inspección Conjunta de los oficiales de la Oficina de Zona CDSCO, Hyderabad y Administración de Control de Medicamentos, Estado de 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 como propósito la Exportación de medicamentos solamente.

Sinceramente,



B. Venkateswarlu
20/06/19

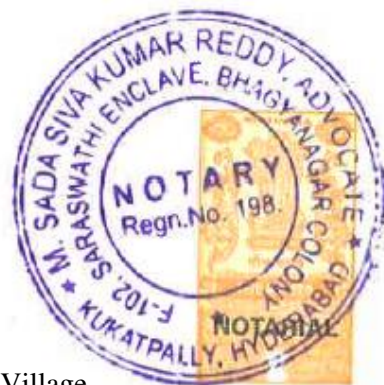
Dr. B. VENKATESWARLU

Director Adjunto (FAC) & Autoridad Licenciadora



L.Dis.No. 753/E1/2019 – Otorga el Certificado OMS BPM a M/s Hetero Labs Limited, Unit-I, Sy. No. 10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Sangareddy District, Telangana State, India en la Forma-25 con No. 25/MD/AP/97/B/R, fecha:31.01.1997.

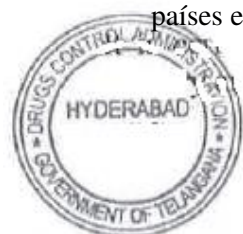
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34. ESTAVUDINA	USP
35. TENOFOVIR DISOPROXIL FUMARATO	IH
36. TERBINAFINA CLORHIDRATO	USP / Ph.Eur
37. TORSEMIDA ANHIDRO	Ph.Eur
38. ZIDOVUDINA	USP / Ph.Eur / IP
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44. SOFOSBUVIR	IH
45. TENOFOVIR DISOPROXIL	IH
46. LENALIDOMIDA	IH
47. POMALIDOMIDA	IH
48. AXITINIB	IH
49. REGORAFENIB	IH



Fabricante : M/s Hetero Labs Limited, Unit-I
Sy. No. 10, I.D.A., Gaddapotharam Village,
Jinnaram Mandal, Sangareddy District,
Telangana State, India.

Cuando aplique : Coloque el producto en el mercado como se detalla
anteriormente.

Se certifica que estos productos han sido autorizados para ser colocados en el mercado para su uso en el país y
países exportadores.



ATTESTED
K. Sujatha
KAMBHAM SUJATHA
Assistant Secretary

ATTESTED
20/06/19
M. SADA SIVA KUMAR REDDY, B.Com. &
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 4439)