DCA
DRUGS CONTROL ADMINISTRATION
TELANGANA

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No:85815/TS/2022

Dated:22/04/2022
Valid until:20/04/2025

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of World Health Organisation G.M.P. Certificate– Regarding

Ref: 1. Your letter dated:**31/03/2022.**
2. Joint Inspection report .

-x-x-x-x-

With reference to your application cited, I forward herewith **World Health Organisation GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Joint Inspection Report of the Officers of Drugs Control Administration,Telangana State & Drugs Inspector, CDSCO, Hyderabad vide reference 2nd cited.

Digitally Signed By
RAMDHAN GUGULOTH
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:22-04-2022 11:59:58 AM

L.Dis.No:85815/TS/2022

Dated:22/04/2022
Valid until:20/04/2025

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

S.No	Generic Name	Brand Name	Composition	PackSize	Market
1	ALFUZOSIN HYDROCHLORIDE USP				Export
2	AMLODIPINE BESILATE Ph.Eur./JP				Export
3	AMLODIPINE BESYLATE USP				Export
4	APREMILAST IH (Specific Quantity export)				Export
5	APREPITANT USP/Ph.Eur.				Export
6	ATORVASTATIN CALCIUM TRIHYDRATE USP/Ph.Eur.				Export

Federation of Indian Micro and Small & Medium Enterprises Chamber of Commerce & Industry FISME No. 11/(RE-2012)/2008-11 Hyderabad

M. SADA SIVA KUMAR REDDY, ADVOCATE SAMATHI ENCLAVE, BHAGYANAGAR COLONY KUKATPALLY, HYDERABAD NOTARY Regn.No. 198 NOTARIAL F-102, SAMATHI

ATTESTED
Ramadevi.C

ATTESTED
M. SADA SIVA KUMAR REDDY, B.Com., B.L
ADVOCATE & NOTARY

7	CITALOPRAM HYDROBROMIDE Ph.Eur./USP	Export
8	CLOPIDOGREL BISULFATE USP/Ph.Eur	Export
9	CYCLOBENZAPRINE HYDROCHLORIDE USP	Export
10	DEUTETRABENAZINE IH (Specific quantity export)	Export
11	DEXLANSOPRAZOLE IH	Export
12	DONEPEZIL HYDROCHLORIDE USP	Export
13	DONEPEZIL HYDROCHLORIDE ANHYDROUS USP/JP	Export
14	DORZOLAMIDE HYDROCHLORIDE USP/Ph.Eur.	Export
15	DULOXETINE HYDROCHLORIDE USP/Ph.Eur.	Export
16	ELTROMBOPAG OLAMINE IH	Export
17	ENTECAVIR MONOHYDRATE USP	Export
18	ESOMEPRAZOLE MAGNESIUM DIHYDRATE USP/Ph.Eur.	Export
19	FAMCICLOVIR USP	Export
20	FOSAPREPITANT DIMEGLUMINE IH	Export
21	FOSINOPRIL SODIUM Ph.Eur.	Export
22	GLIMEPIRIDE USP/Ph.Eut.	Export
23	ITRACONAZOLE USP	Export
24	IVABRADINE HYDROCHLORIDE IH	Export
25	LANSOPRAZOLE USP/Ph.Eur.	Export
26	LERCANIDIPINE HYDROCHLORIDE IH	Export
27	LEVOFLOXACIN HEMIHYDRATE USP/IP/IH	Export

Federation of Indian Micro and Small & Medium Enterprises
Chamber of Commerce & Industry
FISME
No. 11/(TE-2012)/2009-11
Hyderabad

M. SADA SIVA KUMAR REDDY, ADVOCATE
SARASWATHI ENCLAVE, BHAGYANAGAR COLONY
NOTARY
Regn.No. 198.
HYDERABAD

28	LISINOPRIL DIHYDRATE BP/USP/Ph.Eur./JP				Export
29	METOPROLOL SUCCINATE USP				Export
30	MIRTAZAPINE USP/BP/Ph.Eur.				Export
31	MONTELUKAST SODIUM USP/Ph.Eur.				Export
32	MOXOFLOXACIN HYDROCHLORIDE USP/Ph.Eur.				Export
33	NEBIVOLOL HYDROCHLORIDE IH				Export
34	OLANZAPINEUSP/Ph.Eur./JP/IP				Export
35	OMEPRAZOLE USP/Ph.Eur./IP				Export
36	OMEPRAZOLE MAGNESIUM USP/Ph.Eur.				Export
37	PANTOPRAZOLE HEMI-MAGNESIUM IH (Specific Quantity export)				Export
38	PANTOPRAZOLE SODIUM SESQUIHYDRATE USP/Ph.Eur.				Export
39	PERINDOPRIL TERT-BUTYLAMINE Ph.Eur.				Export
40	PRAMIPEXOLE DIHYDROCHLORIDE USP				Export
41	PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE Ph.Eur.				Export
42	PROGUANIL HYDROCHLORIDE USP/Ph.Eur.				Export
43	RABEPRAZOLE SODIUM Ph.Eur.				Export
44	RABEPRAZOLE SODIUM USP				Export
45	RALTEGRAVIR POTASSIUM USP/Ph.Eur.				Export
46	RILUZOLE USP				Export

M. SADA SIVA KUMAR REDDY, ADVOCATE
F-102, SARASWATHI ENCLAVE, BHAGYANAGAR COLONY
KUKATPALLY, HYDERABAD
NOTARY
Regn.No. 198.

47	ROFLUMILAST IH				
48	SERTRALINE HYDROCHLORIDE USP/Ph.Eur.				Export Export
49	SILDENAFIL CITRATE USP/Ph.Eur./IH				Export
50	SOLIFENACIN SUCCINATE Ph.Eur./IH				Export
51	TETRABENAZINE IH				Export
52	TOLTERODINE TARTRATE USP/Ph.Eur./IH				Export Export
53	TOLVAPTAN IH				Export
54	TOPIRAMATE USP/IH				Export
55	VALACICLOVIR HYDROCHLORIDE Ph.Eur.				Export Export
56	VENLAFAXINE HYDROCHLORIDE USP/Ph.Eur.				Export
57	VIGABATRIN Ph.Eur. (Specific Quantity export)				Export
58	VIGABATRIN USP (Specific Quantity export)				Export

Manufacturer: M/S **M/s M/S. HETERO DRUGS LIMITED, UNIT-I, SY.NO.213, 214& 255, BONTHAPALLY VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT,PINCODE 502313,TELANGANA STATE,INDIA**

Drug License No: **9/MD/AP/96/B/R,**
Dated:01/01/2022 **Under Form 25** ,valid upto **31/12/2026**

When applicable Placing the product on the market as detailed below.

The Unit M/S **M/s M/S. HETERO DRUGS LIMITED, UNIT-I, SY.NO.213, 214& 255, BONTHAPALLY VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT,PINCODE 502313,TELANGANA STATE,INDIATelangana State,India** was inspected jointly by

It is certified that:

i. The above products had been authorized to be placed on the market for use in the country and exported countries
ii. The manufacturing plant in which the product is produced is subject to inspection at suitable intervals.
iii. The manufacturer conforms to requirements for Good Manufacturing Practices in the manufacture and Quality Control (As recommended by the World Health Organisation) in respect of products to be sold or distributed with in the Country of origin (or to be exported).

M. SADA SIVA KUMAR REDDY, ADVOCATE
SARASWATHI ENCLAVE, BHAGYANAGAR COLONY
NOTARY
Regn.No. 198
F-102, KUKATPALLY

DCA
DRUGS CONTROL ADMINISTRATION
TELANGANA

DRUGS CONTROL ADMINISTRATION
Government of Telangana

Digitally Signed By
RAMDHAN GUGULOTH
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:22-04-2022 11:59:58 AM

This Document is Digitally Signed. Signature is not required

M. SADA SIVA KUMAR REDDY, ADVOCATE
F-102, SARASWATHI ENCLAVE, BHAGYANAGAR COLONY
KUKATPALLY, HYDERABAD
NOTARY
Regn.No. 198

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 RAMDHAN GUGULOTH
acting in the capacity of DEPUTY DIRECTOR
bears the seal/stamp of FEDERATION OF INDIAN MICRO AND SMALL & MEDIUM ENTERPRISES

Certified
at NEW DELHI, INDIA the 19-Dec-2022
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. MHAH0000424322

Seal / Stamp
Signature
is issued to HETERO DRUGS LIMITED
OI 686912

MINISTRY OF EXTERNAL AFFAIRS
GOVT. OF INDIA NEW DELHI
पु0563

(संदीप कुमार)
(Sandeep Kumar)
अनुभाग अधिकारी (प्रलेखन / ओ.आई.)
Section Officer (Attestation/O.I.)
C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

ADMINISTRACIÓN DE CONTROL DE FÁRMACOS
GOBIERNO DE TELANGANA

L. Dis. N° 85815/TS/2022 **Fecha: 22/04/2022**
Válido hasta: 20/04/2025

Asunto: Ley de Fármacos y Cosméticos, 1940 y las Normas correspondientes - en relación con Certificado de Buenas Prácticas de Manufactura de la Organización Mundial de la Salud – Respecto a.

Ref: 1. Su solicitud de fecha: 31/03/2022
2. Informe de Inspección,

En relación con su solicitud citada primero, le informamos que los siguientes productos se incluyen en el CERTIFICADO DE BUENAS PRÁCTICAS DE MANUFACTURA DE LA ORGANIZACIÓN MUNDIAL DE LA SALUD emitido en referencia a esta segunda carta citada, en base a lo recomendado por el Equipo de Inspección Conjunta conformado por funcionarios de la Administración de Control de Fármacos, Telangana, CDSCO, Hyderabad,, según lo mencionado en la referencia citada.

Firmado Digitalmente por

RAMDHAN GUGULOTH
Director y Autoridad de Certificaciones (reemplazo)
Administración de control de medicamentos
Estado Telangana
Fecha: 22-04-2022

ADMINISTRACIÓN DE CONTROL DE FÁRMACOS
GOBIERNO DE TELANGANA

Fabricante M/s Hetero Drugs Limited (Unit I),
SY.NO.213, 214&215, BONTHAPALLY VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, 505313, ESTADO TELANGANA, INDIA

Licencia de fármaco: N° 9/MD/AP/96/B/R,
Fecha: 01/01/2022, válido hasta 31/12/2026.

Cuando aplique colocar el producto en el mercado, según lo listado.

La unidad **M/s Hetero Drugs Limited (Unit I)**, SY.NO.213, 214&215, BONTHAPALLY VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, 505313, ESTADO TELANGANA, INDIA, fue inspeccionada por

Se certifica que:

i. Los productos han sido autorizados para la comercialización y uso en el país y exportarlos.
ii. La planta manufacturera en el cual los productos son fabricados está sujeta a inspecciones periódicas
iii. El fabricante cumple con los requerimientos de las buenas prácticas de manufactura y control de calidad (según lo recomendado por la Organización Mundial de la Salud) con respecto a los productos vendidos o distribuidos, tanto en el país como exportados.

Firmado Digitalmente por

RAMDHAN GUGULOTH
Director y Autoridad de Certificaciones (reemplazo)
Administración de control de medicamentos
Estado Telangana
Fecha: 22-04-2022

Certificado que esta traducción es fiel a la original

Garin Hoyng Bernardita

Digitally signed by Garin Hoyng Bernardita
DN: dc=com, dc=novartis, ou=people, ou=GD, serialNumber=871698, cn=Garin Hoyng Bernardita
Date: 2023.03.02 10:50:38 -03'00'

Bernardita Garin
Director Técnico
Novartis Chile S.A