GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

L.Dis.No.5881/P&B/2019 **Dated: 12/12/2019**

From
M B R Prasad, M.Pharm, MPhil, A.I.C
Director,
O/o the Director General
Drugs and Copyrights,
Drugs control Administration
Chuttugunta,Guntur -522004

To
M/s Hetero Drugs Limited (Unit –IX),
Plot No.1, Hetero Infrastructure SEZ Ltd,
N.Narasapuram (V), Nakkapalli Mandal,
Andhra Pradesh, India .531081.

Sir,

Sub: Drugs and cosmetics Act, 1940 and rules made there under – Issue of World Health Organization Good Manufacturing Practice Certificate –Regarding.

Ref: 1. Your application dated:08/08/2019
2. Recommendation letter from CDSCO, Hyderabad, Ref: 5-6(067 A7)2019/5536 Dated: 31/10/2019
3. Inspection dated: 07/11/2019.

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With reference to your application 1st cited ,you are here by informed that the following products are included in the **WORLD HEALTH ORGANIZATION GOOD MANUFACTURING PRACTICE CERTIFICATE** issued vide this office letter 2nd cited basing on the recommended be the Joint Inspection team consisting of officers of Drugs Control Administration, Andhra Pradesh, India for Export purpose.

This Certificate is valid for a period of Three years from the date of issue and this certificate is meant for Export of Drugs only.

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH GUNTUR

DIRECTOR 13/12/19
DRUGS CONTROL ADMINISTRATION

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

Office of the Director General
Drugs and Copyrights
Drugs Control Administration
Guntur.

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

S.No.	Product name	Specifications
1	Acyclovir	USP/Ph.Eur/ BP
2	Bupropion Hydrochloride	USP
3	Celecoxib	USP/Ph.Eur
4	Cinacalcet Hydrochloride	IHS.
5	Citalopram Hydrobromide	USP/Ph.Eur
6	Dabigatran Etexilate Mesylate	IHS.
7	Darifenacin Hydro Bromide	IHS.
8	Diclofenac Diethylamine	.IHS
9	Diclofenac potassium	USP/Ph.Eur
10	Diclofenac sodium	USP/Ph.Eur
11	Divalproex sodium	.IHS/USP
12	Eletriptan Hydrobromide	.IHS
13	Esomeprazole Magnesium Dihydrate	Ph.Eur/USP
14	Esomeprazole Magnesium Trihydrate	USP/Ph.Eur
15	Fenofibrate	USP/Ph.Eur
16	Fesoterodine Fumarate	.IHS
17	Fexofenadine Hydrochloride	USP/Ph.Eur
18	Gabapentin	USP/Ph.Eur
19	Ganciclovir	USP & Ph.Eur
20	Lacosamide	.IHS/Ph.Eur
21	Lopinavir	IHS./USP/Ph.Eur
22	Lurasidone Hydrochloride	IHS.
23	Memantine Hydrochloride	IHS./USP
24	Metaxalone	IHS./USP
25	Mirabegron	.IHS
26	Nabumetone	USP/Ph.Eur
27	Pitavastatin Calcium	IHS.
28	Pregabalin	IHS./USP/Ph.Eur
29	Raloxifene Hydrochloride	USP/Ph.Eur
30	Risedronate Sodium	USP

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31	Risedronate Sodium Hemipentahydrate	Ph.Eur
32	Ritonavir	USP/Ph.Eur
33	Rivastigmine	Ph.Eur
34	Rizatriptan Benzoate	IHS./USP/Ph.Eur
35	Rosuvastatin Calcium	IHS./Ph.Eur
36	Sertraline Hydrochloride	USP/Ph.Eur
37	Sevelamer Carbonate	IHS.
38	Silodosin	.IHS
39	Valganciclovir Hydrochloride	USP/IHS.
40	Ritonavir Premix (Amorphous)	.IHS
41	Prasugrel Hydrochloride	.IHS
42	Rilpivirine Hydrochloride	.IHS
43	Zafirlukast	.IHS

Manufacturer : M/s. Hetero Drugs Limited (Unit IX),
Plot No .1, Hetero Infrastructure SEZ Ltd,
N.Narasapuram(V), Nakkapalli Mandal
Visakhapatnam District, Andhra Pradesh, India.

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

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. "48/VP/AP/2010/B/R; Dt: 20/10/2010" valid upto 19/10/2020

It is also certified that (a) the manufacturing plant in which the products are produced is subjected to inspection suitable intervals.

The unit **M/s Hetero Drugs Limited** (Unit IX), Plot No.1, Hetero Infrastructure SEZ Ltd, N.Narasapuram (Village), Nakkapalli Mandal, Visakhapatnam district, Andhra Pradesh was inspected by Mr.Yugander, Drugs Inspector, Narsipatnam (Mfg.), Drugs Control Administration on 07/11/2019.

The manufacturer conforms to requirements for **Good Manufacturing Practices** in the manufacturing and quality control (As recommended by the **World Health Organization**) in respect of the products mentioned above (43) for Export in the international market.

This Certificate is valid for three years and this certificate is meant for export purpose only.

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH GUNTUR

DIRECTOR
DRUGS CONTROL ADMINISTRATION