DCA
DRUGS CONTROL ADMINISTRATION
TELANGANA

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No.8989/A2/2018. Dated 22 -03-2019.

To

M/s. Vasudha Pharma Chem Limited,
Unit-I, Plot. No. 37/A, 38, 39 A & B,
Phase – I, IDA., Jeedimetla,
Hyderabad – 500 055,
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 29.12.2018.
2. Joint Inspection Report dated 07.02.2019 & 08.02.2019.
3. Compliance Report dated 13.02.2019.
4. Compliance Verification Report dated 14.03.2019 of Drugs Inspector., Balangar (Mfg.) Zone.

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I forward herewith **WORLD HEALTH ORGANIZATION GOOD MANUFACTURING PRACTICE CERTIFICATE** for the products recommended by the Joint Inspection Team consisting of officers of Central Drugs Standard Control Organization and officer from Drugs Control Administration, Telangana for **Export** Purpose.

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

DRUGS CONTROL ADMINISTRATION HYDERABAD JD(FAC) GOVERNMENT OF TELANGANA

Yours faithfully,

22/03/19

Dr. B. VENKATESHWARLU
JOINT DIRECTOR(FAC)
LICENSING & CONTROLLING AUTHORITY

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No.8989/A2/2018

Dated 22-03-2019.

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

1.	DOMPERIDONE	BP/Ph.Eur./JP
2.	DOMPERIDONE MALEATE	BP/Ph.Eur.
3.	LORATADINE	USP/Ph.Eur.
4.	DESLORATADINE	Ph.Eur./IH/USP.
5.	AMITRIPTYLINE HYDROCHLORIDE	BP/USP/Ph.Eur./JP
6.	CYCLOBENZAPRINE HYDROCHLORIDE	USP
7.	PIMOZIDE	USP/BP/Ph.Eur.
8.	EBASTINE	BP/Ph.Eur./JP
9.	LOPERAMIDE HYDROCHLORIDE	USP/Ph.Eur./BP
10.	OXATOMIDE	IHS
11.	KETOROLAC TROMETHAMINE	USP
	KETOROLAC TROMETAMOL	Ph.Eur.
12.	DONEPEZIL HYDROCHLORIDE	USP/JP
13.	DONEPEZIL HYDROCHLORIDE MONOHYDRATE	USP
14.	CYPROHEPTADINE HYDROCHLORIDE	USP/Ph.Eur./BP
15.	OLMESARTAN MEDOXOMIL	USP/BP/Ph.Eur.
16.	CISAPRIDE MONOHYDRATE	USP
17.	NEBIVOLOL HYDROCHLORIDE	IHS
18.	PIRIBEDIL	IHS

Manufacturer : **M/s. Vasudha Pharma Chem Limited,**
Unit – I. Plot. No. 37/A, 38, 39 A & B, Phase – I,
IDA., Jeedimetla, Hyderabad – 500 055, Telangana, INDIA.

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

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

Drug Licence No. : **105/RR/AP/97/B/R** dated 25.09.1997, in Form – 25

The Unit of **M/s. Vasudha Pharma Chem Limited**, Unit – I. Plot. No. 37/A, 38, 39 A & B, Phase – I, IDA., Jeedimetla, Hyderabad – 500 055, Telangana, INDIA, was inspected by Smt. Sunita Joshi, Drugs Inspector, O/o the Deputy Drugs Controller(India), CDSCO, Zonal Office, Hyderabad and Mr. Chandrasekhar, Drugs Inspector, Balanagar (Mfg.) Zone, Drugs Control Administration, Telangana on 07.02.2019 and 08.02.2019 and Compliance Verification inspected by Mr. Chandrasekhar, Drugs Inspector, Balanagar (Mfg.) Zone, Drugs Control Administration, Telangana on 14.03.2019

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 (**EIGHTEEN** in number) for Export in the international market.

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

B. Venkateshwarlu 22/03/19

Dr. B. VENKATESHWARLU
JOINT DIRECTOR(FAC)
LICENSING & CONTROLLING AUTHORITY

To
M/s. Vasudha Pharma Chem Limited, Unit – I. Plot. No. 37/A, 38, 39 A & B,
Phase – I, IDA., Jeedimetla, Hyderabad – 500 055, Telangana, INDIA.

DRUGS CONTROL ADMINISTRATION HYDERABAD JD(FAC) GOVERNMENT OF TELANGANA