GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

L.Dis.No. 816/DCA/AP/2018 Dated: 24-07-2018

From:
M.B.R. Prasad, M.Pharm, M.Phil, AIC
Director & Licensing Authority
O/o the Director General
Drugs Control Administration
Chuttugunta
Guntur – 522 004

To
M/s. Divi's Laboratories Limited,
Unit-2, Chippada (V), Annavaram (Post)
Bheemunipatnam (M)
Visakhapatnam District - 531162
Andhra Pradesh, India.

Sirs,

Sub:- Drugs and Cosmetics Act, 1940 and rules made there under – **Issue of World Health Organization G.M.P. Certificate** – Reg.

Ref: 1.Your application dt.27-06-2018
2. L.Dis.No. 1484/DCA/AP/2017 Dt:26-06-2018 of the Director, DCA, Guntur
3. Joint Inspection Dated: 03-05-2018 to 04-05-2018 & 31-05-2018

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, Andhra Pradesh and CDSCO, Hyderabad.

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

Yours faithfully,

24/7/18

DIRECTOR & LICENCING AUTHORITY
DRUGS CONTROL ADMINISTRATION

Copy to : The Joint Director, Visakhapatnam

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

Office of the Director,
Licensing & Approving Authority,
Drugs Control Administration,
Chuttugunta,
Guntur – 522 004

L.Dis.No.816/DCA/AP/2018 Dated: 24-07-2018

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

S.No	Name of the product	Grades
2.	BUPROPION HYDROCHLORIDE	USP
3.	CAPECITABINE	USP/IP/Ph.Eur
4.	CARBIDOPA	IP/BP/USP/Ph.Eur/JP
5.	DEXTROMETHORPHAN HYDROBROMIDE	USP/BP/JP/Ph.Eur/IP
6.	ENTACAPONE	Ph.Eur
7.	GABAPENTIN	USP/Ph.Eur
8.	IRBESARTAN	USP/Ph.Eur
10.	LEVODOPA	BP/JP/Ph.Eur/USP/IP
11.	LOSARTAN POTASSIUM	USP/Ph.Eur/IP/JP
12.	MESALAMINE	IP/USP/BP/Ph.Eur
13.	NAPROXEN	IP/BP/USP/ Ph.Eur /JP
14.	NAPROXEN SODIUM	USP/ Ph.Eur /BP
15.	OLMESARTAN MEDOXOMIL	Ph.Eur /USP
16.	ORLISTAT	USP/IH
17.	PHENYLEPHRINE HCl	BP/ Ph.Eur /USP/JP/IP
18.	PREGABALIN	IP/USP/ Ph.Eur /IH/BP
24.	TRIPROLIDINE HYDROCHLORIDE	BP/USP/IP
25.	VALSARTAN	USP/ Ph.Eur /IP
26.	VENLAFAXINE HYDROCHLORIDE	Ph.Eur /USP/BP
27.	VIGABATRIN	USP/BP/ Ph.Eur

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH GUNTUR

24/7/18

DIRECTOR
Drugs Control Administration
Government of Andhra Pradesh
Chuttugunta, Guntur-522 004

L.Dis.No.816/DCA/AP/2018 Dated: 24-07-2018

Manufacturer	:	M/s. Divi's Laboratories Limited Unit-2, Chippada (V), Annavaram (Post) Bheemunipatnam (M) Visakhapatnam District – 531 162 Andhra Pradesh, India.
Drug Licence No.	:	02/VP/AP/2003/B/R, ***Dt.18-01-2003, Valid up to 17-01-2023*** In Form-25

It is also certified that

a) The manufacturing plant in which the products are produced is subject to inspection at suitable intervals.

The unit **M/s. Divi's Laboratories Limited**, Unit-2, Chippada (V), Annavaram (Post), Bheemunipatnam (M), Visakhapatnam District - 531162, Andhra Pradesh, India. **was jointly inspected by Smt. D. Suneetha, Drugs Inspector, Visakhapatnam (Mfg) and Sri. R. Srinivasan, Assistant Drugs Controller(I), CDSCO, Visakhapatnam from 03-05-2018 to 04-05-2018 & 31-05-2018.**

b) The Manufacturer conforms to requirement for Good Manufacturing Practices in the manufacture and quality control (As recommended by the World Health Organization) in respect of products mentioned above (**Twenty Seven Numbers**) for Export in the International Market.

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

24/7/18

DIRECTOR & LICENCING AUTHORITY
DRUGS CONTROL ADMINISTRATION

To
M/s. Divi's Laboratories Limited
Unit-2, Chippada (V), Annavaram (Post)
Bheemunipatnam (M),
Visakhapatnam District - 531162,
Andhra Pradesh, India.