

**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.



Copy to: The Joint Director, Visakhapatnam

Yours faithfully,

**DIRECTOR & LICENCING AUTHORITY
DRUGS CONTROL ADMINISTRATION**

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



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24/7/18
DIRECTOR
Drugs Control Administration
Government of Andhra Pradesh
Chuttugunta, Guntur-522 004

L.Dis.No.816/DCA/AP/2018

Dated: 07-07-2018

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

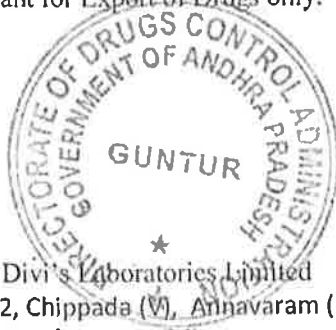
It is also certified that

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.



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

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24/7/18
DIRECTOR & LICENCING AUTHORITY
DRUGS CONTROL ADMINISTRATION