

AMSTILE
(5)

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,

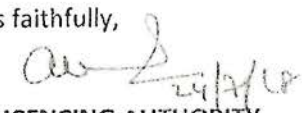
Sub:- Drugs and Cosmetics Act, 1940 and rules made there under - **Issue of World Health Organization G.M.P. Certificate** - Reg.

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

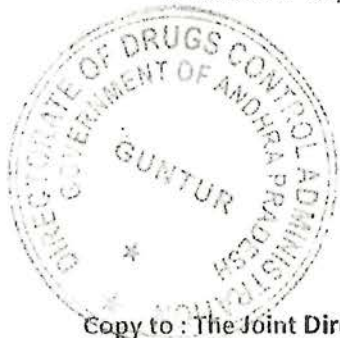
I, forward herewith **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Joint Inspection Report of the Officers of Drugs Control Administration, Andhra Pradesh and CDSCO, Hyderabad.

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.

Yours faithfully,


**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
1.	BOSENTAN MONOHYDRATE	IH
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
9.	LAMOTRIGINE	Ph.Eur/USP/IP
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
19.	RALTEGRAVIR POTASSIUM	IH
20.	SIMVASTATIN	IP/USP/ Ph.Eur /JP
21.	SITAGLIPTIN PHOSPHATE	IH/IP
22.	SUMATRIPTAN	IP/JP
23.	SUMATRIPTAN SUCCINATE	BP/USP/IP/ Ph.Eur
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



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





L.Dis.No.816/DCA/AP/2016

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.

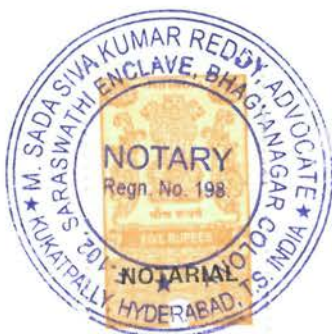


To
M/s. Divi's Laboratories Limited
Unit-2, Chippada (V), Annavaram (Post)
Bheemunipatnam (M),
Visakhapatnam District - 531162,
Andhra Pradesh, India.

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

ATTESTED

G. Dayanand
G. DAYANAND
Asst. Secretary
Andhra Chamber of Commerce
Secunderabad-500 003 India



ATTESTED

M. Sada Siva Kumar Reddy
M. SADA SIVA KUMAR REDDY, B.Com., B.L.
ADVOCATE & NOTARY
Appointed by Govt., India
G.O. Ms. No. 198, Rev (Regn-II), dt. 11.04.2000
102, Saraswathi Enclave, Bhagyanagar Colony,
Kukatpally, Hyderabad, T.S., India. (Ph: 98486 44395)



भारत सरकार / GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)

The contents of this document are hereby accepted for use in the Republic of India.

Country

REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT

has been signed by N/A

acting in his capacity of N/A

bears the seal/stamp of ASST. SECY, ANDHRA CHAMBER OF
COMMERCE, SECUNDERABAD

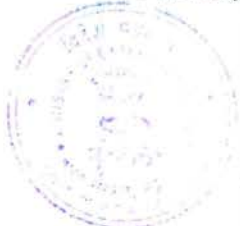
Certified

at NEW DELHI, INDIA the 14-Aug-2019
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. APHY0009936119

Seal / Stamp

is issued to DIVIS LABORATORIES LTD

Signature



(PHIL CHANAP)
Joint Secretary (OI)
Ministry of External Affairs (OI)
New Delhi

Gobierno de Andhra Pradesh
Administración de Control de Drogas

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

Fecha: 24-07-2018

Desde:

M.B.R. Prasad M. Pharm, M. Phil, AIC

Director & Licensing Authority

O/o the Director General

Drugs Control Administration

Chuttugunta

Guntur – 522 004

Para:

M/s. Divi's Laboratories Limited,

Unit-2, Chippada (V), Annavaram (Post)

Bheemunipatnam (M)

Visakhapatnam District -531162

Andhra Pradesh, India.

Señores,

Sub: - Acta de Drogas y cosméticos, 1940 y reglas establecidas bajo – Emitida por la Organización de la Salud Certificado BPM – Reg

Ref: 1) Su aplicación dt. 27-06-2018

2) L. Dis. No. 1484/DCA/AP/2017 Dt: 26-06-2018 del Director, DCA, Guntur.

3) Inspección: Fecha: 03-05-2018 a 04-05-2018 y 31-05-2018

Yo, Organización Mundial de la Salud Buenas Prácticas de Manufactura certifico los productos mencionados en el reporte de inspección de los oficiales de la Administración de Control de Drogas, Andhra Pradesh y CDSCO, Hyderabad.

Este certificado es válido por un período de 3 años desde la fecha de la emisión y éste certificado es para exportación de productos solamente.

Atentamente,

Director y Autoridad Licenciante

Administración de Control de Drogas.

Gobierno de Andhra Pradesh
Administración de Control de Drogas

Fabricante

M/s Divi's Laboratories Limited

Unit-2. Chippada (V) Annavaram (Post)

Bheemunipatnam (M)

Visakhapatnam District – 531 162

Andhra Pradesh, India.

Licencia No.

02/VP/AP/2003/B/R,

Dt. 18-01-2003, Valido hasta 17-01-2023

En el formulario 25,

Esto certifica que:

- a) El sitio de manufactura de la planta donde los productos son fabricados está sujeto a inspección en intervalos.

La unidad M/s. Divi's Laboratories Limited, Unit-2, Chippada (V), Annavaram (Post),

Bheemunipatnam (M), Visakhapatnam District- 531162, Andhra Pradesh, India. Fue conjuntamente inspeccionada por Smt. D. Suneetha, Inspector, Visakhapatnam (MFg) y Sri. R. Srinivasan, Assistant Drugs Controller (I), CDSCO, Visakhapatnam desde 03-05-2018 al 04-05-2018 y 31-05-2018.

- b) El Sitio de manufactura conforme a requerimiento de las Buenas Prácticas de Manufactura en la fabricación y control de Calidad (Como recomendado por la Organización Mundial de la Salud) respecto a los productos mencionados (27) para exportación en el mercado internacional.

Este certificado es válido por un período de 3 años desde la fecha de emisión y este certificado es para exportación solamente.

A

M/s. Divi's Laboratories Limited

Unit-2, Chippada (V), Annavaram (Pos)

Bheemunipatnam (M)

Visakhapatnam District – 531162

Andhra Pradesh, India.

Sin nada más que agradecer su buena acogida,

Se despide atentamente,

NOVARTIS CHILE S.A

A handwritten signature in blue ink, appearing to read 'pp Qllp', written over a horizontal line.

Q.F. Bernardita Garín H.

Director Técnico

