APOSTILE

(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,

24/7/18

DIRECTOR & LICENCING AUTHORITY
DRUGS CONTROL ADMINISTRATION

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH GUNTUR

Copy to : The Joint Director, Visakhapatnam

ANDHRA CHAMBER OF COMMERCE SEC'BAD. (INDIA)

M. SADA SIVA KUMAR REDDY, ADVOCATE NOTARY Regn. No. 198 F-102, SARASWATHI ENCLAVE, BHAGYANAGAR COLONY KUKATPALLY, HYDERABAD, T.S. INDIA

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

DIRECTORATE OF DRUGS CONTROL ADMINISTRATION GOVERNMENT OF ANDHRA PRADESH GUNTUR

29/7/18

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

ANDHRA CHAMBER OF COMMERCE SEC'BAD. (INDIA)

M. SADA SIVA KUMAR REDDY, ADVOCATE, SARASWATHI ENCLAVE, BHAGYANAGAR COLONY, KUKATPALLY, HYDERABAD, T.S. INDIA. NOTARY Regn No 198

L.Dis.No.836/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.

DIRECTOR 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.

ATTESTED

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

ANDHRA CHAMBER OF COMMERCE SECBAD. (INDIA)

M. SADA SIVA KUMAR REDDY, ADVOCATE ★ SARASWATHI ENCLAVE, BHAGYANAGAR COLONY ★ KUKATPALLY, HYDERABAD ★ INDIA
NOTARY Regn. No. 198
NOTARIAL

ATTESTED

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: 98480 44395)

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

Country REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT
has been signed by N/A
acting in the capacity of N/A
bears the seal/stamp of ASST. SECY, ANDHRA CHMABER 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

CHANAP
Officer (OI)
C.P.V. Division
External Affairs, 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, Hyberabad.

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, Assstant 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

Q.F. Bernardita Garín H.

Director Técnico