



GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION

Office of the Director General,
Drugs and Copyright,
Drugs Control Administration,
Vengalraonagar, Hyderabad-
Dated: 29.05.2019

L.Dis.No. 664/A3/2019

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

1. List enclosed.

Manufacturer : M/s.Divi's Laboratories Limited
: Unit-1, Lingo jigudem Village, Choutuppal Mandal,
Yadadri Bhuvanagiri - District,
Telangana -508252, India
When applicable : Placing the product on the market as
: detailed below

It is certified that the above product had been authorized to be placed on the
market for use in the Country.

Drug License No. : 86/NG/AP/95/B/R dated: 28-04-1995.
: Under Form-25 and 28 valid 31.12.2022.

It is also certified that (a) the manufacturing plant in which the product is produced
is subject to inspection at suitable intervals.

The Unit M/s. Divi's Laboratories Limited, Unit-1, Lingo jigudem Village,
Choutuppal Mandal, Yadadri Bhuvanagiri District, Telangana-508252, India was
inspected jointly by Dr.Jay Jyoti Roy, Drug Inspector, O/o. CDSCO, Hyderabad and
Mr.G.Anil Reddy , Drug Inspector(Mfg) Zone, DI of this Department.

(b) The manufacturer conforms to requirements for Good Manufacturing Practices
in the manufacturer and quality control (As recommended by the World Health
Organisation) in respect of Eighteen (18) for Export in the international market.

This Certificate is valid for 3 years from the date of issue:

Dr.B.VENKATESWARLU
Joint Director(FAC)& Licensing Authority



M/s. Divi's Laboratories Limited
Unit-1, Lingo jigudem Village, Choutuppal Mandal,
Yadadri Bhuvanagiri District, Telangana -508252, India

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Notary Public, Delhi



ATTESTED

Sanjay Singh
Assistant Secretary
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

18 FEB 2021



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

Country

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This public document
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has been signed by

DR B VENKATESWARLU

acting in the capacity of

JT DIRECTOR

bears the seal/stamp of

ASST SECERATRY, PHD CHAMBER

COMMERCE AND INDUSTRY, NEW DELHI

Certified

at NEW DELHI, INDIA the 18-Feb-2021

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. DLND0004960821

Seal / Stamp

is issued to DIVI'S LABORATORIES LIMITED

Signature

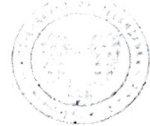
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(सुनील चनाप)
(SUNIL CHANAP)
अनुमान अधिकारी (ओ आई)
Section Officer (OI)
श्री. पी. वी. ब्रमरा / C.P.V. Director
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi



GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION



L.Dis.No. 664/A3/2019

Dated: 29.05.2019.

To,
M/s: Divi's Laboratories Limited,
Unit-I, Lingojigudem Village,
Choutuppal Mandal,
Yadadri Buvaigiri District-508252,
Telangana State, India

Sirs,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Approval
Issue of World Health Organisation G.M.P. Certificate Regarding.
Ref: 1. Your application dated: 04.02.2019
2. Joint Inspection report dated: 01.05.2019 & 02.05.2019.

I forward herewith WORLD HEALTH ORGANIZATION GOOD
MANUFACTURING CERTIFICATE for the product recommended by the joint
inspection team consisting of officers of Central Drugs Standard Control Organisation and
officer from Drugs Control Administration Telangana for Export purpose.

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

Yours faithfully,

B. Venkateswarlu
29/05/19

Dr.B.VENKATESWARLU
Joint Director(FAC) & Licensing Authority



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Sanjay Singh
Assistant Secretary
PHD Chamber of Commerce and Industry
New Delhi (INDIA)



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(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

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GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION

Office of the Director General,
Drugs and Copyright,
Drugs Control Administration,
Vengalraonagar, Hyderabad-
Dated: 29.05.2019

L.Dis.No. 664/A3/2019

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

S.No.	PRODUCTS
1.	[REDACTED]
2.	Desloratadine (Ph.Eur)
3.	Dextromethorphan (USP)
4.	Dextromethorphan Hydrobromide (IP/USP/BP/Ph.Eur/JP/CP)
5.	Diltiazem HCl (IP/USP/BP/Ph.Eur/JP/CP)
6.	Fosphenytoin Sodium (USP)
7.	Iopamidol (USP/BP/Ph.Eur/JP)
8.	Levetiracetam (USP/BP/Ph.Eur)
9.	Nabumetone (USP/BP/Ph.Eur/JP)
10.	Naproxen (IP/USP/BP/Ph.Eur/JP)
11.	Naproxen Sodium (USP/Ph.Eur)
12.	Niacin (IP/USP/BP/Ph.Eur/JP)
13.	Proguanil Hydrochloride (IP/USP/BP/Ph.Eur)
14.	Quetiapine fumarate (IP/Ph.Eur /USP/IHS)
15.	Tamsulosin Hydrochloride (IP/USP/BP/Ph.Eur/JP)
16.	Telmisartan (IP/USP/BP/Ph.Eur)
17.	Valacyclovir Hydrochloride (USP/BP/Ph.Eur/JP)
18.	Zolpidem tartrate (IP/USP/BP/Ph.Eur/JP)



B. Venkateswarlu
Dr.B.VENKATESWARLU
Joint Director(FAC)& Licensing Authority



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Sanjay Singh
Assistant Secretary
PHD Chamber of Commerce and Industry
New Delhi (INDIA)
18 FEB 2021



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COMMERCE AND INDUSTRY, NEW DELHI

Certified

at NEW DELHI, INDIA the 18-Feb-2021

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. DLND0004961021

Seal / Stamp

Signature

Is Issued to DIVI'S LABORATORIES LIMITED



(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ.आर.)
Section Officer (OI)
सी.पी.वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

DCA

Vania Silva Sepúlveda
Asesor Técnico
Ascend Laboratories SpA

GOBIERNO DE TELANGANA
ADMINISTRACIÓN DE CONTROL DE MEDICAMENTOS

Traducción fiel
al original

Oficina del Director General,
Medicamentos y Derechos de Autor,
Administración de Control de Medicamentos,
Vengalraonagar, Hyderabad-,

Fecha: 29.05.2019.

L.Dis.No. 664/A3/2019

LISTA DE PRODUCTOS APROBADOS BAJO EL ESQUEMA DE
CERTIFICACIÓN OMS-BPM CON EL PROPÓSITO DE EXPORTACIÓN

1. Lista ajunta.

Fabricante : M/s. Divi's Laboratories Limited,
Unit-I, Lingoigudem Village, Choutuppall Mandal,
Yadadri Bhuvanagiri District,
Telangana-508252, India.

Cuándo aplique : Colocar el producto en el mercado según lo siguiente

Se certifica que el producto anterior ha sido autorizado para ser colocado en el mercado para su uso en el País.

Licencia de Medicamento No. : 86/NG/AP/95/B/R, fecha 28-04-1995.
: Bajo Forma -25 y 28 válido hasta 31.12.2022.

También se certifica que (a) la planta de manufactura en la cual el producto es producido está sujeta a inspección a intervalos adecuados.

La Unidad M/s. Divi's Laboratories Limited, Unit-I, Lingoigudem Village, Choutuppall Mandal, Yadadri Bhuvanagiri District, Telangana-508252, India fue inspeccionado en conjunto por el Dr. Jay Jyoti Roy, Inspector de Medicamentos, O/o. CDSCO, Hyderabad y el Sr. G. Anil Reddy, Inspector de Medicamentos (Mfg) de Zona, DI de este departamento.

(b) El fabricante se encuentra conforme a los requerimientos de las Buenas Prácticas de Manufactura en la fabricación y control de calidad (Como lo recomienda la Organización Mundial de la Salud) con respecto a dieciocho (18) para la Exportación al mercado internacional.

Este Certificado es válido por 3 años desde la fecha de emisión.

Dr .B. VENKATESWARLU

Director Adjunto (FAC) & Autoridad Licenciadora

Para
M/s. Divi's Laboratories Limited,
Unit-I, Lingoigudem Village, Choutuppall Mandal,
Yadadri Bhuvanagiri District, Telangana-508252, India.



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Notary Public, Delhi



ATTESTED

Sanjay Singh
Assistant Secretary
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

18 FEB 2021



भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
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bears the seal/stamp of ASST SECERATRY, PHC CHAMBER
COMMERCE AND INDUSTRY, NEW DELHI

Certified

at NEW DELHI, INDIA the 18-Feb-2021
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. DLND0004960821

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is issued to DIVI'S LABORATORIES LIMITED

Signature

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(सुनील चनाप)
(SUNIL CHANAP)
अध्याय अधिकारी (अ. अ. अ.)
Section Officer (OI)
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi



GOBIERNO DE TELANGANA
ADMINISTRACIÓN DE CONTROL DE MEDICAMENTOS



L.Dis.No. 664/A3/2019

Fecha: 29.05.2019.

Para:

M/s. Divi's Laboratories Limited,
Unit-I, Lingoigudem Village,
Choutuppal Mandal,
Yadadri Buvangiri District-508252,
Telangana, India.

Señores,

Asunto: Acta de Medicamentos y Cosméticos de 1940 y Reglas subsecuentes – Con respecto a –
Aprobación de Certificado B.P.M. emitido por la Organización Mundial de la Salud.

Ref: 1. Su aplicación con fecha: 04.02.2019
2. Informe de Inspección Conjunta fecha: 01.05.2019 & 02.05.2019.

Le reenvío el CERTIFICADO DE BUENAS PRÁCTICAS DE MANUFACTURA DE LA ORGANIZACIÓN MUNDIAL DE LA SALUD para el producto recomendado por el Equipo de Inspección Conjunta que consiste de oficiales de la Organización de Control Estándar de Medicamentos Central y oficiales de la Administración de Control de Medicamentos, Telangana con el propósito de Exportación.

Este Certificado es válido por un período de Tres años desde la fecha de emisión.

Atentamente,

B. Venkateswarlu
29/05/19

Dr. B. VENKATESWARLU

Director Adjunto (FAC) & Autoridad Licenciadora



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[Signature]
Sanjay Singh
Assistant Secretary
PHD Chamber of Commerce and Industry
New Delhi (INDIA)



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Section Officer (OI)
विभाग प्रमुख, आई विभाग
Ministry of External Affairs, New Delhi

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**GOBIERNO DE TELANGANA
ADMINISTRACIÓN DE CONTROL DE MEDICAMENTOS**

Oficina del Director General,
Medicamentos y Derechos de Autor,
Administración de Control de Medicamentos,
Vengalraonagar, Hyderabad-,

L.Dis.No. 664/A3/2019

Fecha: 29.05.2019.

**LISTA DE PRODUCTOS APROBADOS BAJO EL ESQUEMA DE
CERTIFICACIÓN OMS-BPM CON EL PROPÓSITO DE EXPORTACIÓN**

S. No.	PRODUCTOS
1.	
2.	Desloratadina (Ph. Eur)
3.	Dextrometorfano (USP)
4.	Dextrometorfano Hidrobromuro (IP/USP/BP/Ph. Eur/JP/CP)
5.	Diltiazem HCl (IP/USP/BP/Ph. Eur/JP/CP)
6.	Fosfenitoína Sódica (USP)
7.	Iopamidol (USP/BP/Ph. Eur/JP)
8.	Levetiracetam (USP/BP/Ph. Eur)
9.	Nabumetona (USP/BP/Ph. Eur/JP)
10.	Naproxeno (IP/USP/BP/Ph. Eur/JP)
11.	Naproxeno Sódico (USP/Ph. Eur)
12.	Niacina (IP/USP/BP/Ph. Eur/JP)
13.	Proguanil Clorhidrato (IP/USP/BP/Ph. Eur)
14.	Quetiapina Fumarato (IP/Ph. Eur/USP/IHS)
15.	Tamsulosina Clorhidrato (IP/USP/BP/Ph. Eur/JP)
16.	Telmisartan (IP/USP/BP/Ph. Eur)
17.	Valaciclovir Clorhidrato (USP/BP/Ph. Eur/JP)
18.	Zolpidem Tartrato (IP/USP/BP/Ph. Eur/JP)

B.V. 29/05/19
Dr. B. VENKATESWARLU
Director Adjunto (FAC) & Autoridad Licenciadora

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Sanjay Singh
Assistant Secretary
PHD Chamber of Commerce and Industry
New Delhi (INDIA)

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Regn. No. 607
Delhi
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No DLND0004961021

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(सुनील घनाप)
(SUNIL CHANAP)
अनुमति अधिकारी (ओ.आई.)
Attestation Officer (OI)
ए.पी.डी. प्रमाण / C.P.V. Divisions
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi