

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

From:
M.B.R.Prasad, M.Pharm, M.Phil, A.I.C.,
Director & Licensing Authority,
O/o. Director General,
Drugs and Copyrights,
Drugs Control Administration,
SMC Campus, Gunadala ,
Vijayawada – 520008, Andhra Pradesh.

To:
Divi's Laboratories Limited, Unit-2,
Annaram Post, Chippada Village,
Bheemunipatnam Mandal,
Visakhapatnam District – 531 162,
Andhra Pradesh, India.

Sirs,

Sub: Drugs and Cosmetics Act 1940 and Rules made thereunder- Issue of **World Health Organisation Good Manufacturing Practice Certificate**– Regarding.

- Ref: 1. Your application dated: 16.02.2024
2. Joint Inspection Report Dated: 27.05.2024 and 28.05.2024.
3. File No: SZ-VSKP/WHO-GMP/005/2024-25/160, Dated:11.06.2024 of
Asst. Drugs Controller (I), CDSCO, Sub-Zone, Visakhapatnam.

I forward herewith **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE** Certificate for the products Recommended by the Joint Inspection team consisting of the officers of Drugs Control Administration, Andhra Pradesh and CDSCO, Hyderabad.

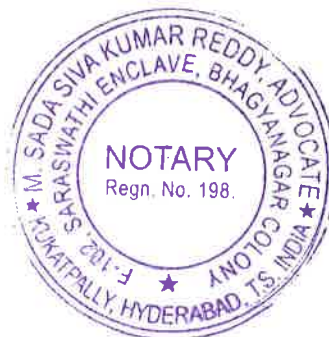
This Certificate is **valid for a period of three years** from the date of issue and this certificate is meant for Export of Drugs only.

Yours faithfully

Digitally signed by
BABU RAJENDRA
PRASAD MEESALA
Date: 2024.06.26
16:17:19 +05'30'



DIRECTOR AND LICENSING AUTHORITY
DRUGS CONTROL ADMINISTRATION



**GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION**

Office of the Director General,
Licensing & Approving Authority,
Drugs and Copyright,
Drugs Control Administration,
SMC Campus, Gunadala
Vijayawada – 520 008, Andhra Pradesh.

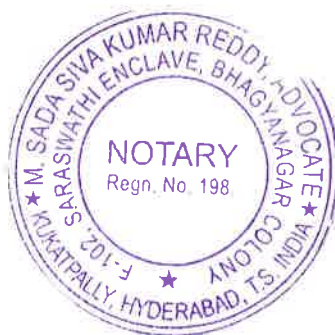
LIST OF PRODUCTS APPROVED UNDER WHO GMP CERTIFICATE

S. No.	NAME(S) OF THE PRODUCT(S)	SPECIFICATION
2.	Bupropion Hydrochloride	USP
3.	Capecitabine	USP/IP/Ph.Eur
4.	Carbamazepine	IH
5.	Carbidopa	IP/BP/USP/Ph.Eur/JP
6.	Gabapentin	USP/Ph.Eur
7.	Iohexol	USP/Ph.Eur/JP/BP
8.	Irbesartan	USP/Ph.Eur
9.	Lacosamide	Ph.Eur
11.	Levodopa	BP/JP/Ph.Eur/USP/IP
12.	Losartan Potassium	USP/Ph.Eur/IP/JP
13.	Mesalamine	IP/USP/BP/Ph.Eur
14.	Naproxen	IP/BP/USP/Ph.Eur/JP
15.	Naproxen Sodium	USP/Ph.Eur/BP
16.	Olmesartan Medoxomil	Ph.Eur/USP
17.	Orlistat	USP/IH
18.	Phenylephrine Hydrochloride	BP/Ph.Eur/USP/JP/IP
19.	Pregabalin	IP/USP/Ph.Eur/BP
21.	Ranolazine	IH
22.	Sacubitril Valsartan Sodium Hydrate	IH
27.	Ticagrelor	IP/Ph.Eur/IH
28.	Triprolidine Hydrochloride	BP/USP/IP
29.	Valsartan	USP/Ph.Eur/IP
30.	Venlafaxine Hydrochloride	Ph.Eur/USP/BP
31.	Vigabatrin	BP/Ph.Eur



Digitally signed by BABU
RAJENDRA PRASAD MEESALA
Date: 2024.06.26 16:17:28 +05'30'

**DIRECTOR AND LICENSING AUTHORITY
DRUG CONTROL ADMINISTRATION**



GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

Manufacturer : M/s. Divi's Laboratories Limited, Unit-2,
Annaram Post, Chippada Village,
Bheemunipatnam Mandal,
Visakhapatnam District – 531 162,
Andhra Pradesh, India.

Drug License No. in form-25: **02/VP/AP/2003/B/R, Dated:18.01.2003**
Valid up to 17-01-2028, 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 Ltd., Unit-2, Annaram (Post), Chippada (V), Bheemunipatnam (M), Visakhapatnam District-531 162, Andhra Pradesh, India was jointly inspected by Mr. Vikram Mengana, Drugs Inspector, CDSCO, Sub-Zonal Office, Visakhapatnam and Mrs. N. Kalyani, Drugs Inspector, Drugs Control Administration, Andhra Pradesh on dated:27.05.2024 and 28.05.2024.

- b) The Manufacturer conforms to requirement for good manufacturing practice in the manufacture and quality (as recommended by the World Health Organisation) in respect of product mentioned above (Thirty-One 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.

Digitally signed by BABU
RAJENDRA PRASAD MEESALA
Date: 2024.06.26 16:17:37 +05'30'

DIRECTOR AND LICENSING AUTHORITY
DRUG CONTROL ADMINISTRATION

To
M/s. Divi's Laboratories Limited, Unit-2,
Annaram Post, Chippada Village,
Bheemunipatnam Mandal,
Visakhapatnam District – 531 162,
Andhra Pradesh, India.



ATTESTED

G. RAMANJANEYULU
Deputy secretary
Andhra Chamber of Commerce
Secunderabad-500 063 (India)

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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 **BABU RAJENDRA PRASAD MEESALA**
acting in the capacity of **DIRECTOR**
bears the seal/stamp of **ANDHRA CHAMBER OF COMMERCE, HYDERABAD**

Certified
at **NEW DELHI, INDIA** the **01-Jul-2024**
by **SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS**
No. **MHMC0003875624**

Seal / Stamp
is issued to **DIVIS LABORATORIES LIMITED**

01 2298942



(बी.एस.एस.वी. नारायण मुर्ति)
(B.S.S.V. Narayana Murthy)
अनुभाग अधिकारी (विवरण / ओ.आई.)
Section Officer (Attestation/O.I.)
सी.पी.वी. विभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi