



DRUGS CONTROL ADMINISTRATION
Government of Telangana



L. Dis. No.7964/E1/2018

Dated: 28-11-2018

To
M/s.Therapiva Private Limited
TU-II, Plot No.9/A, Phase-III, Jeedimetla(V)
Quthbullapur(M), Medchal-Malkajgiri District-500055
Telangana State, India.

Sir,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of
World Health Organisation G.M.P. Certificate – Regarding.

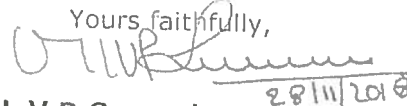
Ref: 1. Your letter dated: 16.11.2018
2. Joint Inspection report dt:01.08.2018 & 02.08.2018.

-X-X-X-X-

With reference to your application cited, 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, Telangana State and CDSCO, Zonal Office, Hyderabad vide reference 2nd cited.

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

Yours faithfully,


28/11/2018

M.L.V.P. Surendranath Sai
Joint Director & Licensing Authority(FAC)



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6892022 (L)

10/10/10



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

S. No	Name of the product
1.	Doxazosin Mesylate IH
2.	Doxazosin Mesylate Ph.Eur
3.	Doxazosin Mesylate USP
4.	Donepezil Hydrochloride IH
5.	Donepezil Hydrochloride USP
6.	Sumatriptan Succinate Ph. Eur
7.	Sumatriptan Succinate USP
8.	Ondansetron USP
9.	Ondansetron IH
10.	Ondansetron Hydrochloride Dihydrate Ph.Eur
11.	Ondansetron Hydrochloride Dihydrate USP
12.	Olanzapine USP
13.	Olanzapine Ph.Eur
14.	Olanzapine IH
15.	Montelukast Sodium IH
16.	Montelukast Sodium USP
17.	Montelukast Sodium Ph.Eur
18.	Topiramate USP
19.	Topiramate IH
20.	Escitalopram Oxalate IH
21.	Escitalopram Oxalate Ph.Eur
22.	Escitalopram Oxalate USP

Manufacturer

: M/s.Therapiva Private Limited
TU-II, Plot No.9/A, Phase-III,
Jeedimetla(V), Quthbullapur(M),
Medchal-Malkajgiri District-500055
Telangana State, India.

When applicable

: Placing the product on the market as
detailed above.

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

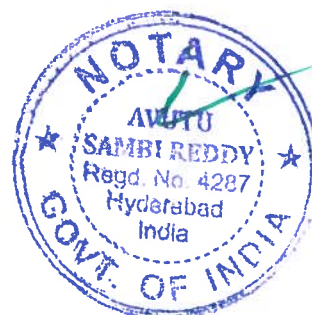
Drug Licence No.

: 89/RR/AP/95/B/CC, Dt:20.01.1984
under Form-25 valid upto 12-11-2023

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[Signature]
28/11/2018



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DRUGS CONTROL ADMINISTRATION
Government of Telangana



L. Dis. No.7964/E1/2018

Dated: 28/11-2018

Issue of WHO GMP Certificate to M/s.Therapiva Private Limited, TU-II, Plot No.9/A, Phase-III, Jeedimetla(V), Quthbullapur(M), Medchal-Malkajgiri District-500055, Telangana State, India.

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.Therapiva Private Limited, TU-II, Plot No.9/A, Phase-III, Jeedimetla(V), Quthbullapur(M), Medchal-Malkajgiri District-500055, Telangana State, India was inspected jointly by Sri.Naveen Yadav, Drugs Inspector, CDSCO, Hyderabad and Dr.J.Raju, Drugs Inspector, Drugs Control Administration, Hyderabad on 01.08.2018 & 02.08.2018.

(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 22 (Twenty two) products to be sold or distributed with in the Country or origin (or to be exported).

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


28/11/2018

M.L.V.P.Surendranath Sai
Joint Director & Licensing Authority(FAC)



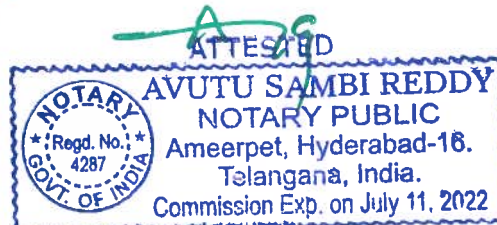
ATTESTED


G. DAYANAND

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



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

This public document of the type
COMMERCIAL DOCUMENT

is issued to THERAPIVA PRIVATE LIMITED

has been signed by G DAYANAND

with the seal / stamp of ASSTT SECRETARY, ANDHRA CHAMBER
OF COMMERCE, SECUNDERABAD

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 14-Feb-2019 at NEW DELHI, INDIA
with reference no. APHY0003665419

Seal Stamp

Signature

(भावना शर्मा)
(Bhavana Sharma)
अनुभाग अधिकारी (ओ आई)
Section Officer (OI)
सी. दी. पी. विभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

The Ministry of External Affairs
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MINISTRY OF EXTERNAL AFFAIRS
NEW DELHI
14 FEB 2019
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