DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L. Dis. No. 10081/ A3 / 2015 **Date:** -10-2015

TO

DR.Reddy's Laboratories Limited

Unit-III,116,IDA,

Bollaram(Village),Jinnaram Mandal,

Medak District,

Telangana.

Sir,

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

Ref:- 1. Your applications dated 11-05-2015 & 21-07-2015

2. Jt. Inspection Report dated 14-07-2015.

I forward herewith **W.H.O. Good Manufacturing Practice Certificate** for the products mentioned by the Joint.Inspection team consisting of Officers of Drugs Control Administration,CDSCO, Telangana, INDIA..

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

HYDERABAD

of Officer

Yours faithfully

& LO 1204

M.AMRUTH RAO

LICENSING & CONTROLLING AUTHORITY

The Federation of Telangana & Andhra Pradesh
No. 1030 of 64 - 65
HYDERABAD

M. SIVA KUMAR REDDY ADVOCATE ★ INDIA
ENCLAVE, BHAGYANAGAR COLONY
NOTARY
Regn. No. 198

ATTESTED
04 JUL 2017
M. SADA SIVA KUMAR REDDY, B.Com., B.L

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis. No.10081 / A-3 / 2015

WHO GMP CERTIFICATE APPROVED FOR FORTY NINE PRODUCTS TO DR.REDDY'S LABORATORIES LTD, UNIT III, 116,IDA BOLLARAM VILLAGE,JINNARAM MANDAL,MEDAK DISTRICT UNDER DRUG LICENSE IN FORMS 25 BEARING NO.11/MD/AP/95/B/R; DATED 24.11.1993 VALID UPTO 31.12.2017.

LIST OF PRODUCTS APPROVED UNDER WHOGMP

CERTIFICATION SCHEME FOR EXPORT PURPOSE

S. No	Name of the product(s)	Specification
1.	Alendronate Sodium Trihydrate	IH
2.	Alendronate Sodium	USP
3.	Sodium Alendronate Trihydrate	Ph.Eur
4.	Amlodipine Besylate	IH
5.	Amlodipine Besilate	JP
6.	Amlodipine Besilate	Ph.Eur
7.	Amlodipine Besilate	BP
8.	Amlodipine Besylate	USP
9.	Amlodipine Maleate	IH
10.	Aprepitant	IH
11.	Atomoxetine Hydrochloride	IH
12.	Atomoxetine Hydrochloride	USP
13.	Enalapril Maleate	Ph.Eur
14.	Esomeprazole Magnesium	IH
15	Esomeprazole Magnesium Dihyrate	IH
16.	Lacidipine	IH

Sixteen Products Only

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

The Federation of Telangana & Andhra Pradesh No. 1030 of 64 - 65 HYDERABAD

ATTESTED 04 JUL 2017

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis. No.10081 /A-3 / 2015

WHO GMP CERTIFICATE APPROVED FOR FORTY NINE PRODUCTS TO DR.REDDY'S LABORATORIES LTD.,UNIT-III, 116,IDA BOLLARAM VILLAGE,JINNARAM MANDAL,MEDAK DISTRICT UNDER DRUG LICENSE IN FORMS 25 BEARING NO.11/MD/AP/95/B/R; DATED 24.11.1993 VALID UPTO 31.12.2017.

LIST OF PRODUCTS APPROVED UNDER WHOGMP

CERTIFICATION SCHEME FOR EXPORT PURPOSE

17	Lacidipine	BP
18	Levocetirizine Di Hydrochloride	IH
19	Omeprazole Magnesium	Ph.Eur
20	Omeprazole Magnesium	IH
21	Omeprazole Magnesium	USP
22	Omeprazole	Ph.Eur
23	Omeprazole	USP
24	Omeprazole	BP
25	Omeprazole Sodium	Ph.Eur
26	Omeprazole Sodium	BP
27	Pamidronate Disodium Pentahydrate	Ph.Eur
28	Pamidronate Disodium Pentahydrate	BP
29	Pamidronate Disodium Pentahydrate	IH

Thirteen Products only

The Federation of Telangana & Andhra Pradesh Chambers of Commerce & Industry
No. 1030 of 64 - 65
HYDERABAD

M. SADA SIVA KUMAR REDDY ADVOCATE, B.Com., B.L.

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis. No.10081 / A-3 / 2015

WHO GMP CERTIFICATE APPROVED FOR FORTY NINE PRODUCTS TO DR.REDDY'S LABORATORIES LTD.,UNIT-III, 116,IDA BOLLARAM VILLAGE,JINNARAM MANDAL,MEDAK DISTRICT UNDER DRUG LICENSE IN FORMS 25 BEARING NO.11/MD/AP/95/B/R; DATED 24.11.1993 VALID UPTO 31.12.2017.

LIST OF PRODUCTS APPROVED UNDER WHOGMP

CERTIFICATION SCHEME FOR EXPORT PURPOSE

30	Pantoprazole Sodium	IH
31	Pantoprazole Sodium	USP
32	Pantoprazole Sodium Sesquihydrate	Ph.Eur
33	Pantoprazole Sodium Sesquihydrate	BP
34	Rabeprazole Sodium	IH
35	Ramipril	Ph.Eur
36	Ramipril	USP
37	Ramipril	BP
38	Ramipril	IH
39	Ropinirole Hydrochloride	IH
40	Ropinirole Hydrochloride	USP
41	Terbinafine Hydrochloride	IH
42	Terbinafine Hydrochloride	Ph.Eur
43	Terbinafine Hydrochloride	BP
44	Terbinafine Hydrochloride	USP
45	Terbinafine Hydrochloride	JP
46	Tizanidine Hydrochloride	IH
47	Tizanidine Hydrochloride	USP
48	Tizanidine Hydrochloride	Ph.Eur
49	Zoledronic Acid monohydrate	IH

Twenty Products only

HYDERABAD The Federation of Telangana & Andhra Pradesh No. 1030 of 64 - 65 HYDERABAD

ATTESTED

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

DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L.Dis. No.10081/ A-3 /~~2013~~ 2017

WHO GMP CERTIFICATE APPROVED FOR FORTY NINE PRODUCTS TO DR.REDDY'S LABORATORIES LTD.,UNIT-III, 116,IDA BOLLARAM VILLAGE,JINNARAM MANDAL,MEDAK DISTRICT UNDER DRUG LICENSE IN FORMS 25 BEARING NO.11/MD/AP/95/B/R; DATED 24.11.1993 VALID UPTO 31.12.2017.

Manufacturer	Dr.Reddy's Laboratories Limited,Unit-III 116,IDA Bollaram Village, Jinnaram Mandal, Medak Dist.Telangana.,India.
When applicable	Placing the product on the market as detailed above.
Drug Licence No.	11/MD/AP/95/B/R **Date 24-11-1993** **in form 25 valid upto 31-12-2017**

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.Dr Reddy's Laboratories Ltd., at the premises situated at M/s. DR. Reddy's Laboratories Ltd., Unit -III, IDA BOLLARAM village,Jinnaram Mandal, Medak Dist.Telangana was inspected jointly by Mr.Vivekananda Reddy,Drug Inspector, Drugs Control Administration;Hyderabad and Mr.Chandra Sekhar,DrugInspector,CDSCO,Hyderabad on 13-07-2015&14-7-2015.

The manufacturer confirms 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 (Seventeen Products) for export in the international market.

This certificate is valid for a period of Two years from the date of issue and this certificate is meant for EXPORT of Drugs only.

HYDERABAD

M.AMRUTH RAO 8/10/2014 JUL 2017

LICENSING &CONTROLLING AUTHORITY

To,

M/s Dr.Reddy's Laboratories Limited, Officer

Unit-III,116,IDA Bollaram (Village),Jinnaram Mandal,

Medak Dist.,Telangana.

ATTESTED

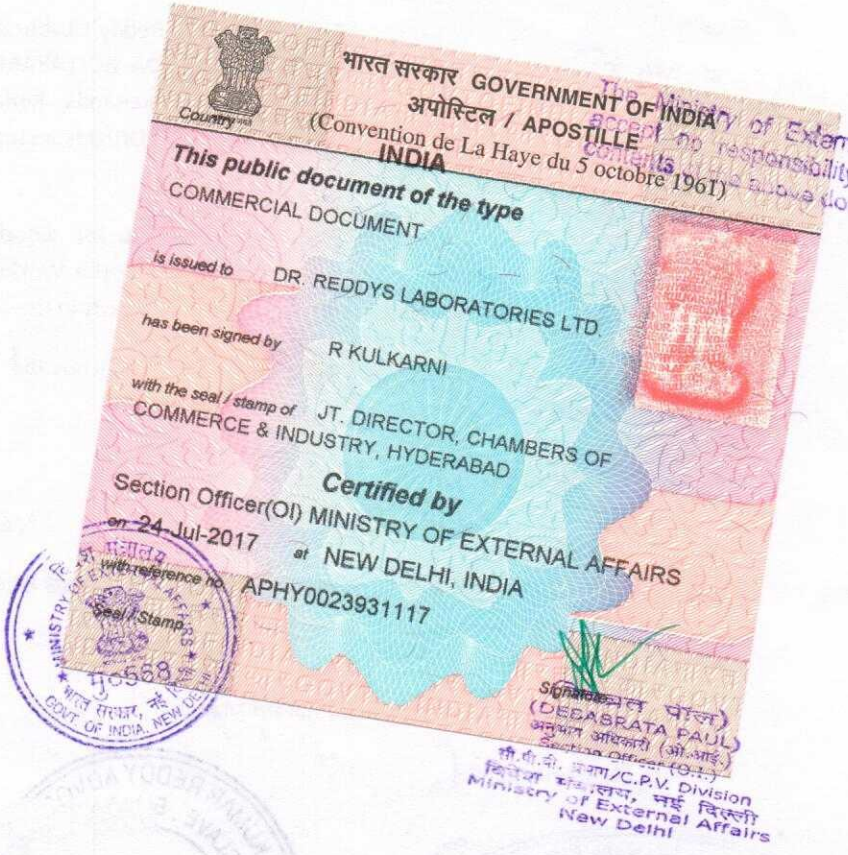
R. KULKARNI
Joint Director

The Federation of Telangana & Andhra Pradesh Chambers of Commerce & Industry
No. 1030 of 64 - 65
HYDERABAD

M. SADA SIVA KUMAR REDDY ADVOCATE NOTARY Regn. No.198 SWATHI ENCLAVE, BHAGYANAGAR COLONY INDIA

ATTESTED
04 JUL 2017
M. SADA SIVA KUMAR REDDY, B.Com., B.L.,

Srinivas Reddy
Poreddy
CMA - ISA



The Ministry of External Affairs accept no responsibility for the contents of the above documents

R. KULKARNI
Joint Director