

# DRUGS CONTROL ADMINISTRATION Government of Telangana



L.Dis.No. 8991 / Stores / 2018

Dated: 26 - 07 - 2019

To
Dr. Reddy's Laboratories Limited
Chemical Technical Operations – Unit II
Plot No.1, 75A, 75B, 105, 110, 111 & 112,
Sri Venkateswara Co-operative Industrial Estate,
Bollaram Village, Jinnaram Mandal,
Sangareddy District,
Telangana-502325

Sir,

- Sub:- Drugs and Cosmetics Act, 1940 and Rules made thereunder Issue of World Health Organization Good Manufacturing Practice Certificate Reg.
- Ref:- 1. Your application no. DRL/NRA/2337-18 dated 20.12.2018 & subsequent correspondence.
  - 2. CDSCO Inspection dated 09.01.2019 & 10.01.2019.
  - 3. CDSCO Recommendation letter no. 5-6(109)/2019/1551 dt. 06.06.2019

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I forward herewith **W.H.O.** Good Manufacturing Practice Certificate for the products recommended by the CDSCO, Zonal Office Hyderabad referred above for **Export** purpose.

This certificate is valid upto three years (3) from the date of issue.



Yours truly,

Dr. B. VENKATESWARLU

Joint Director (FAC)

Licensing & Controlling Authority



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### **CERTIFICATE OF PHARMACEUTICALS PRODUCTS FOR EXPORT**

S. No	Name of the product
1	Ciprofloxacin Hydrochloride USP
2.	Ciprofloxacin Hydrochloride Ph.Eur
3.	Ketorolac Tromethamine USP
4.	Ketorolac Trometamol Ph.Eur
5.	Finasteride USP
6.	Finasteride Ph.Eur
7.	Raloxifene Hydrochloride IH
8.	Raloxifene Hydrochloride Ph.Eur
9.	Raloxifene Hydrochloride USP
10.	Moxifloxacin Hydrochloride Ph.Eur
11.	Moxifloxacin Hydrochloride USP
12.	Glimepiride USP
13.	Glimepiride Ph.Eur
14.	Atorvastatin Calcium IH
15.	Atorvastatin Calcium Trihydrate IH
16.	Atorvastatin Calcium USP
17.	Atorvastatin Calcium Trihydrate Ph.Eur
18.	Dutasteride IH
19.	Metoprolol Succinate USP
20.	Telmisartan Ph.Eur
21.	Telmisartan USP
22.	Rizatriptan Benzoate USP
23.	Rizatriptan Benzoate Ph.Eur
24.	Levofloxacin Hemihydrate IH
25.	Levofloxacin USP
26.	Memantine Hydrochloride IH
27.	Fondaparinux Sodium IH
28.	Ciprofloxacin Ph.Eur
29.	Ciprofloxacin USP





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Dated:	26-	07 -	2019
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30.	Repaglinide USP	
31.	Repaglinide Ph.Eur	
32.	Paliperidone USP	
33.	Fondaparinux Sodium USP	
34.	Memantine Hydrochloride USP	
35.	Dutasteride USP	

The Unit M/s. Dr. Reddy's Laboratories Limited at the premises situated at Chemical Technical Operations – Unit II, Plot No. 1, 75A, 75B, 105, 110, 111 & 112, Sri Venkateswara Co-operative Industrial Estate, Bollaram Village, Jinnaram Mandal, Sangareddy District, Telangana – 502325, was inspected by Mr. G Narendra Kumar, Drugs Inspector, Zonal Office, CDSCO, Hyderabad on 09.01.2019 & 10.01.2019.

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 **Thirty Five (35) Products** for export in the international market.

This certificate is valid for a period of three (3) years from the date of issue.

HYDERABAD JD(FAC)

Yours truly,

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

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### DRUGS CONTROL ADMINISTRATION **Government of Telangana**



L.Dis.No:25473/TS/2019 Dated:11/09/2019

Valid until:10/09/2020

#### GOOD MANUFACTURING PRACTICES CERTIFICATE

This is to certify that M/s DR. REDDYS LABORATORIES LIMITED situated at address CHEMICAL TECHNICAL OPERATIONS - UNIT II, PLOT NOS., 1, 75A, 75B, 105, 110, 111 & 112, SRI VENKATESWARA CO-OPERATIVE INDUSTRIAL ESTATE, BOLLARAM(V), JINNARAM(M), SANGAREDDY(DIST.),502325is holding Drug Manufacturing Licence in Form 25 bearing No. 91/MD/AP/95/B/R Date.01/01/2013 Valid upto 31/12/2022 for manufacture for sale or distribution of drugs approved by this Department. The firm is subjected to periodical inspection by this Department.

The firm is following GOOD MANUFACTURING PRACTICES as stipulated under the provisions of Schedule "M" of the Drugs and Cosmetics Rules, 1945.

The firm should however carry out self inspection from time to time to ensure that the requirements of Good Manufacturing Practices are complied with.

Digitally Signed By

DR BOLLAM VENKATESWARLU **Deputy Director and Certifying Authority DRUGS CONTROL ADMINISTRATION** 

**TELANGANA STATE** 

Date:11-09-2019 12:34:50 PM

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