

**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,



*B. Venkateswarlu*  
26/07/19  
**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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|     |                             |
|-----|-----------------------------|
| 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.



Yours truly,



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



**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.),502325** is 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

**This Document is Digitally Signed. Signature is not required**