

**GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION**

L.Dis. No. 4797/P&B/2019

Dated: 21-10-2019

From:
M B R Prasad, M.Pharm, M.Phill, A.IC.
Director & Licensing Authority,
O/o. The Director General,
Drugs Control Administration,
Chuttugunta,
Guntur-522 004.

To
Dr.Reddy's Laboratories Ltd,
CTO-VI,
APIIC Industrial Estate,
Pydibhimavaram,
Ranasthalam Mandal,
Srikakulam District,
Andhra Pradesh-532 409.

Sir,

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

Ref:- 1. Your applications dated: 26.11.2018, 03.01.2019, 25.02.2019 and 23.05.2019.
2. Joint Inspection dated 20.08.2019 and 21.08.2019.
3. Ltr.No 5-6(031-A4)/2019/3536 dt 28.08.2019 of the Deputy Drug Controller (India) CDSCO, Zonal Office Hyderabad.

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, Andhra Pradesh, INDIA for **Export** purpose.

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

Yours faithfully

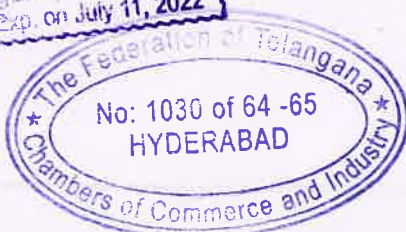


DIRECTOR& LICENSING AUTHORITY
DRUGS CONTROL ADMINISTRATION

17 MAR 2020

ATTESTED

T. SUJATHA
Deputy Chief Executive Officer





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 DIRECTOR

acting in the capacity of DIRECTOR

bears the seal/stamp of DY. CHIEF EXEC. OFFICER, CHAMBERS
OF COMMERCE & INDUSTRY, HYDERABAD

Certified

at NEW DELHI, INDIA the 20-Mar-2020

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. APHY0008194920

Signature

Seal / Stamp

is issued to DR. REDDYS LABORATORIES LTD.



(सुनील चनाप)
(SUNIL CHANAP)
सेक्शन ऑफिसर (ओ आई)
Section Officer (OI)
सी. पी. पी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs New Delhi

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



ATTESTED



**GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION**

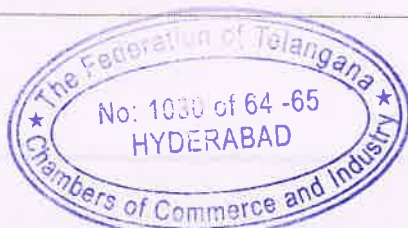
Office of the Director General,
Drugs control Administration,
Chuttugunta,
Guntur-522 004.

L.Dis. No.4797/P&B/2019

Date: 21-10-2019

CERTIFICATE OF PHARMACEUTICALS PRODUCTS FOR EXPORT

S.No	Name of the product
1.	Eslicarbazepine Acetate IH
2.	Sugammadex Sodium IH
3.	Mirabegron Amorphous IH
4.	Sitagliptin Hydrochloride monohydrate IH
5.	Sertraline Hydrochloride IH
6.	Sertraline Hydrochloride Ph.Eur
7.	Sertraline Hydrochloride USP
8.	Tolterodine Tartrate IH
9.	Nizatidine USP
10.	Nizatidine Ph.Eur.
11.	Olmesartan Medoxomil IH
12.	Olmesartan Medoxomil USP
13.	Irbesartan USP
14.	Irbesartan IH
15.	Irbesartan Ph.Eur.
16.	Divalproex Sodium IH
17.	Divalproex Sodium USP
18.	Pioglitazone Hydrochloride IH
19.	Pioglitazone Hydrochloride USP
20.	Quetiapine Fumarate IH
	Zafirlucast IH



21/10/19
DIRECTOR
Drugs Control Administration
Government of Andhra Pradesh
Chuttugunta, Guntur-522 004

INVESTIGATION OF THE FEDERAL BUREAU OF INVESTIGATION

Report of the
Investigator
Date: 10/10/54

Page 2 of 2

10/10/54

STATE OF NEW YORK - ALBANY COUNTY

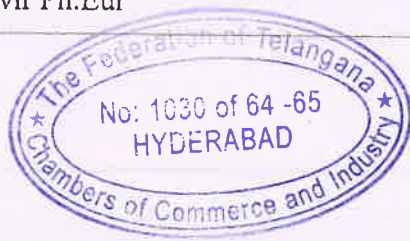
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L.Dis. No. 4797/P&B/2019

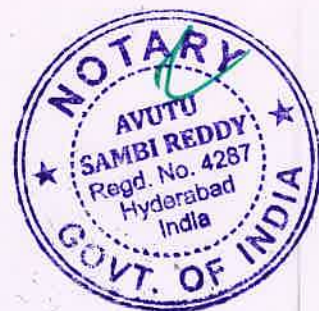
WHO GMP CERTIFICATE APPROVED FOR 111 PRODUCTS TO M/s Dr. Reddy's Laboratories Limited, CTO-VI, APIC Industrial Estate, Pydibhimavaram, Rajasulam Mandal, Srikakulam District, Andhra Pradesh. UNDER DRUG LICENCE BEARING No. 165/SK/AP/95/B/R in Form-25 dated 14.11.1991 Validity up to 31.12.2022.

22.	Lansoprazole USP
23.	Sildenafil citrate IH
24.	Sildenafil Citrate USP
25.	Sildenafil Citrate Ph.Eur.
26.	Amtolmetin Guacil IH
27.	Levetiracetam IH
28.	Levetiracetam Ph.Eur.
29.	Levetiracetam USP
30.	Voriconazole IH
31.	Voriconazole USP
32.	Voriconazole Ph.Eur.
33.	Letrozole USP
34.	Letrozole Ph.Eur.
35.	Valsartan IH
36.	Valsartan USP
37.	Valsartan Ph.Eur.
38.	Esomeprazole Magnesium Amorphous IH
39.	Esomeprazole Magnesium Trihydrate Ph.Eur.
40.	Palonosetron Hydrochloride IH
41.	Candesartan Cilexetil IH
42.	Candesartan Cilexetil Ph.Eur
43.	Candesartan Cilexetil USP
44.	Oxaprozin IH
45.	Oxaprozin USP
	Ritonavir USP
47.	Ritonavir Ph.Eur



21/11/18

DIRECTOR
Drugs Control Administration
Government of Andhra Pradesh
Guntur-522 004



THE UNIVERSITY OF CHICAGO LIBRARY

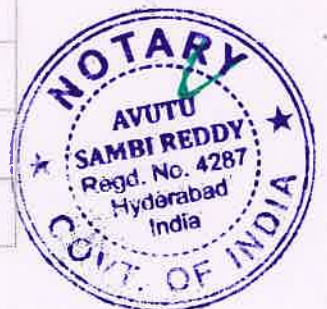
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L.Dis. No. 4797/P&B/2019

WHO GMP CERTIFICATE APPROVED FOR 111 PRODUCTS TO M/s Dr.Reddy's Laboratories Limited, CTO-VI, APIC Industrial Estate, Pydibhuvanapuram, Ramasthalam Mandal, Srikakulam District, Andhra Pradesh. UNDER DRUG LICENCE BEARING No. 165/SK/AP/95/B/R in Form-25 dated 14.11.1991 Validity up to 31.12.2022.

48.	Valganciclovir Hydrochloride IH
49.	Valganciclovir Hydrochloride USP
50.	Abacavir IH
51.	Escitalopram Oxalate IH
52.	Escitalopram Oxalate USP
53.	Eszopiclone IH
54.	Lenalidomide IH
55.	Fluconazole USP
56.	Fluconazole Ph.Eur.
57.	Fluconazole IH
58.	Desloratadine IH
59.	Naratriptan Hydrochloride USP
60.	Naratriptan Hydrochloride IH
61.	Bendamustine Hydrochloride IH
62.	Decitabine IH
63.	Ranolazine IH
64.	Paliperidone Palmitate IH
65.	Cinacalcet Hydrochloride IH
66.	Rasagiline Mesylate IH
67.	Ibandronate Sodium Monohydrate IH
68.	Febuxostat IH
69.	Quetiapine Fumarate Ph.Eur
70.	Quetiapine Fumarate USP
71.	Capecitabine IH
72.	Capecitabine USP
	Capecitabine Ph.Eur

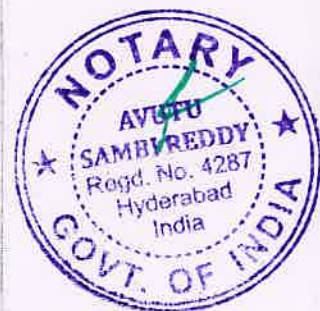
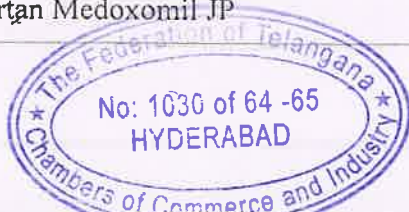


21/11/18
DIRECTOR
Drugs Control Administration
Government of Andhra Pradesh
Guntur-522 004

L.Dis. No. 4797/P&B/2019

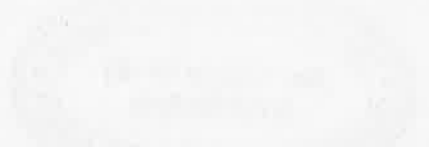
WHO GMP CERTIFICATE APPROVED FOR ALL PRODUCTS TO M/s Dr Reddy's Laboratories Limited CTO:VI, APPII Industrial Estate
Pydibhimanur, Ramanthapur Mandal, Srikakulam District, Andhra Pradesh, UNDER DRUG LICENCE BEARING No. 165/SK/AJ/95/R/R in
Form-25 dated 14.11.1991 Validity up to 31.12.2022.

74.	Granisetron IH
75.	Glatiramer Acetate IH
76.	Sitagliptin Hydrochloride IH
77.	Dabigatran Etxilate Mesylate IH
78.	Ticagrelor IH
79.	Pemetrexed Ditromethamine IH
80.	Vilazodone Hydrochloride IH
81.	Bivalirudin IH
82.	Enzalutamide IH
83.	Esomeprazole Magnesium Trihydrate IH
84.	Esomeprazole Magnesium USP
85.	Prasugrel (Base) IH
86.	Mirabegron IH
87.	Agomelatin Phosphoric acid IH
88.	Rivaroxaban IH
89.	Cabazitaxel IH
90.	Linagliptin IH
91.	Anastrozole USP
92.	Anastrozole Ph.Eur
93.	Anastrozole IH
94.	Duloxetine Hydrochloride USP
95.	Duloxetine Hydrochloride IH
96.	Udenafil IH
97.	Nateglinide IH
98.	Paliperidone IH
99.	Olmesartan Medoxomil Ph.Eur
100.	Olmesartan Medoxomil JP



21/5/19
DIRECTOR
Drug Control Administration
Government of Andhra Pradesh
600 004

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L.Dis. No. 4797/P&B/2019

WHO GMP CERTIFICATE APPROVED FOR 111 PRODUCTS TO M/s Dr Reddy's Laboratories Limited, CTO-VI, APIIC Industrial Estate, Pydibhimavaram, Ranasthalam Mandal, Srikakulam District, Andhra Pradesh, UNDER DRUG LICENCE BEARING No. 165/SK/AP/95/B/R in Form-25 dated 14.11.1991 Validity up to 31.12.2022.

101.	Prasugrel Hydrochloride IH
102.	Ezetimibe IH
103.	Ibandronate Sodium IH
104.	Metaraminol Bitartrate IH
105.	Rivastigmine IH
106.	Sitagliptin Phosphate IH
107.	Solifenacin Succinate IH
108.	Lurasidone Hydrochloride IH
109.	Fingolimod Hydrochloride IH
110.	Asenapine Maleate IH
111.	Rasagiline Hemi Tartrate IH

(111 Products Only)

Manufacturer

M/s Dr Reddy's Laboratories Limited.,
CTO-VI,
APIIC Industrial Estate,
Pydibhimavaram,
Ranasthalam Mandal
Srikakulam District,
Andhra Pradesh-532 409,
INDIA.

When applicable

Placing the product on the market as detail below :

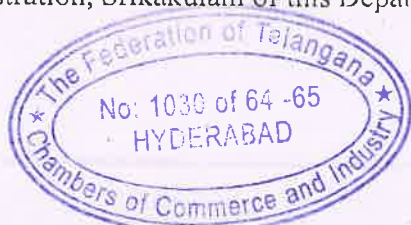
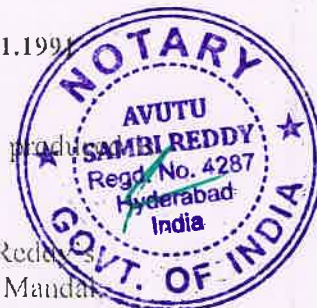
It is certified that the above products have been authorized to be placed on the market for use in the Country.

Drug Licence Nos.

: 165/SK/AP/95/B/R in Form-25 dated 14.11.1991
Validity up to 31.12.2022.

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 Limited, CTO-VI, APIIC Industrial Estate, Pydibhimavaram, Ranasthalam Mandal, Srikakulam District, Andhra Pradesh-532 409, INDIA., was inspected jointly by Mr. R. Srinivasan, ADC(I), CDSCO, Visakhapatnam, Mr. A. Lavanya, Drugs Inspector, Drugs Control Administration, Srikakulam of this Department.



21/10/19
DIRECTOR
Drugs Control Administration
Government of Andhra Pradesh
Guntur-522 004

L.Dis. No. 4797/P&B/2019

WHO GMP CERTIFICATE APPROVED FOR 111 PRODUCTS TO M/s Dr Reddy's Laboratories Limited, CTO-VI, APIIC Industrial Estate, Pydibhimavaram, Ranasthalam Mandal, Srikakulam District, Andhra Pradesh, UNDER DRUG LICENCE BEARING No. 165/SK/AP/952/H/R in Form-25 dated 14.11.1991 Validity up to 31.12.2022.

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 (111 Products) for export in the international market.

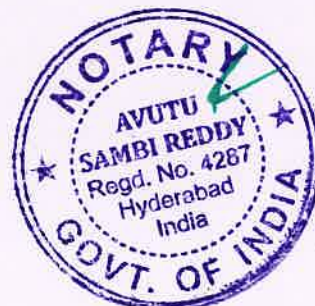
This certificate is valid for a period of Three years from the date of issue.

Yours faithfully



[Signature]
21/10/19
**DIRECTOR & LICENSING AUTHORITY
DRUGS CONTROL ADMINISTRATION**

TO,
M/s Dr Reddy's Laboratories Limited.,
CTO-VI,
APIIC Industrial Estate,
Pydibhimavaram,
Ranasthalam Mandal
Srikakulam District,
Andhra Pradesh-532 409,
INDIA.



ALL
APPROVED
DUE

RECEIVED
JULY 10 1964
U.S. DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION



ALL INFORMATION CONTAINED
HEREIN IS UNCLASSIFIED
DATE 10-10-80 BY 60322
UCBAW/STP

