DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No. 1113 / Stores / 2019 **Dated: 19-10-2019**

To
Dr. Reddy's Laboratories Limited
Chemical Technical Operations - Unit-III,
Plot No. 116, Sri Venkateswara Co-operative Industrial Estate,
IDA, Bollaram, Jinnaram (Mandal),
Sangareddy District, Telangana,
INDIA - 502 325

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/0346-18 dt. 26.02.2019
2. Inspection Report dated 09.07.2019 & 10.07.2019.
3. CDSCO recommendation letter no. 5-6(036-A3)/2019/3883 dt. 09.09.2019

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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, Telangana and CDSCO, Hyderabad, INDIA for **Export** purpose.

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

Yours faithfully

19/10/19

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

DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No. 1113 / Stores / 2019 Dated: 19 - 10 - 2019

CERTIFICATE OF PHARMACEUTICALS PRODUCTS FOR EXPORT

S. No	Name of the product
1.	Alendronate Sodium Trihydrate IH
2.	Alendronate Sodium USP
3.	Sodium Alendronate Ph. Eur.
4.	Amlodipine Besilate 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.	Aprepitant USP
12.	Atomoxetine Hydrochloride IH
13.	Atomoxetine Hydrochloride USP
14.	Enalapril Maleate Ph. Eur.
15.	Esomeprazole Magnesium IH
16.	Esomeprazole Magnesium Dihyrate IH
17.	Esomeprazole Magnesium Trihydrate Ph. Eur.
18.	Esomeprazole Magnesium USP
19.	Lacidipine IH
20.	Lacidipine BP
21.	Levocetirizine Di Hydrochloride IH
22.	Levocetirizine Di Hydrochloride USP
23.	Omeprazole BP
24.	Omeprazole Magnesium IH
25.	Omeprazole Magnesium Ph.Eur

DRUGS CONTROL ADMINISTRATION GOVERNMENT OF TELANGANA HYDERABAD JD(FAC)

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

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

Sl.No	Name of the product
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L.Dis.No. 1113 / Stores / 2019 **Dated: 19 - 10 - 2019**

26.	Omeprazole Magnesium USP
27.	Omeprazole Ph. Eur.
28.	Omeprazole USP
29.	Omeprazole Sodium BP
30.	Omeprazole sodium Ph. Eur.
31.	Palonosetron Hydrochloride IH
32.	Pamidronate Disodium Pentahydrate Ph. Eur.
33.	Pamidronate Disodium Pentahydrate BP
34.	Pamidronate Disodium Pentahydrate IH
35.	Pantoprazole Sodium IH
36.	Pantoprazole Sodium Sesquihydrate BP
37.	Pantoprazole Sodium Sesquihydrate Ph. Eur.
38.	Pantoprazole Sodium USP
39.	Rabeprazole Sodium Hydrate Ph. Eur.
40.	Rabeprazole Sodium IH
41.	Rabeprazole Sodium USP
42.	Ramipril BP
43.	Ramipril CP
44.	Ramipril IH
45.	Ramipril Ph. Eur.
46.	Ramipril USP
47.	Ropinirole Hydrochloride IH
48.	Ropinirole Hydrochloride USP
49.	Terbinafine Hydrochloride IH
50.	Terbinafine Hydrochloride Ph. Eur.
51.	Terbinafine Hydrochloride BP
52.	Terbinafine Hydrochloride USP
53.	Terbinafine Hydrochloride JP

DRUGS CONTROL ADMINISTRATION HYDERABAD JD(FAC) GOVERNMENT OF TELANGANA

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

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

19/10/19

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DRUGS CONTROL ADMINISTRATION
Government of Telangana

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DRUGS CONTROL ADMINISTRATION TELANGANA

L.Dis.No. 1113 / Stores / 2019 **Dated:** 19 - 10 - 2019

54.	Tizanidine Hydrochloride IH
55.	Tizanidine Hydrochloride USP
56.	Tizanidine Hydrochloride Ph. Eur.
57.	Zoledronic Acid Monohydrate IH
58.	Alendronate Sodium IH
59.	Gatifloxacin Anhydrous

The Unit M/s. Dr. Reddy's Laboratories Limited at the premises situated at Chemical Technical Operations - Unit-III, Plot No. 116, Sri Venkateswara Co-operative Industrial Estate, IDA, Bollaram, Jinnaram (Mandal), Sangareddy District, Telangana, INDIA-502 325, was inspected by Mrs. K. Bhuvaneswari, Drugs Inspector, CDSCO and A.N. Kranthi Kumar, Drugs Inspector, Drugs Control Administration, Telangana on 09.07.2019 & 10.07.2019.

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 above mentioned **Fifty Nine (59) Products** for export in the international market.

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

Yours faithfully

DRUGS CONTROL ADMINISTRATION GOVERNMENT OF TELANGANA HYDERABAD JD(FAC)

19/10/19

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

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

ATTESTED

- 1 NOV 2019

R. KULKARNI
Joint Director

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

ATTESTED 23.10.2019

M. SADA SIVA KUMAR REDDY, B.Com., B.L.,
ADVOCATE & NOTARY
Appointed by Govt. of A.P., India
G.O.Ms.No.198, Rev (Regn-II), dt. 11.04.2000
102, Saraswathi Enclave, Bhagyanagar Colony,
Kukatpally, Hyderabad, A.P., India (Ph: 98480 44395)

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

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 B VENKATESWARLU

acting in the capacity of JT. DIRECTOR

bears the seal/stamp of JT. DIRECTOR, CHAMBERS OF COMMERCE & INDUSTRY, HYDERABAD

Certified

at NEW DELHI, INDIA the 13-Nov-2019

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No APHY0021596219

Signature

Seal / Stamp

is issued to DR. REDDYS LABORATORIES LTD.

विदेश मंत्रालय MINISTRY OF EXTERNAL AFFAIRS भारत सरकार, नई दिल्ली GOVT. OF INDIA, NEW DELHI

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

ADMINISTRACION DE CONTROL DE MEDICAMENTOS
GOBIERNO DE TELANGANA

L.Dis.No. 1113/Archivo/2019 **Fecha: 19-10-2019**

A:
Dr. Reddy's Laboratories Limited
Chemical Technical Operation – Unit III
Plot No 116, Sri Venkateswara Co-operative Industrial Estate
IDA, Bollaram, Jinnaram (Mandal),
Sangareddy District, Telengana
INDIA – 502 325

Señor,

Tema: Ley de Medicamentos y Cosméticos, 1940 y Regulaciones para la misma – Emisión del Certificado de Buenas Prácticas de Manufactura por la Organización Mundial de la Salud – Reg.

Ref: 1. Su solicitud N° DRL/NRA/0346-18 de fecha 26-02-2019
2. Reporte de inspección de fecha 09-07-2019 y 10-07-2019
3. Carta de recomendaciones CDSCO N° 5-6(036-A-3)/2019/3883 de fecha 09-09-2019

Reenvío a usted el **Certificado de Buenas Prácticas de Manufactura** de la OMS para los productos mencionados por parte del equipo de Inspección Conjunta que consta de funcionarios de la Adminstración de Control de Medicamentos, CDSCO, Hyderabad, INDIA para propósitos de **Exportación.**

Este certificado es válido hasta tres años desde la fecha de emisión.

Atentamente,

(firma ilegible)
Dr. B. VENKATESWARLU
DIRECTOR ADJUNTO
AUTORIDAD LICENCIANTE & DE CONTROL

ADMINISTRACION DE CONTROL DE MEDICAMENTOS
GOBIERNO DE TELANGANA

L.Dis.No. 1113/Archivo/2019 **Fecha: 19-10-2019**

CERTIFICADO DE PRODUCTOS FARMACEUTICOS PARA EXPORTACIÓN

S. No.	Nombre del producto
1.	Alendronato de sodio trihidrato IH
2.	Alendronato de sodio USP
3.	Sodio alendronato Ph. Eur.
4.	Amlodipino besilato IH
5.	Amlodipino besilato JP
6.	Amlodipino besilato Ph. Eur.
7.	Amlodipino besilato BP
8.	Amlodipino besilato USP
9.	Amlodipino maleato IH
10.	Aprepitant IH
11.	Aprepitant USP
12.	Atomoxetina clorhidrato IH
13.	Atomoxetina clorhidrato USP
14.	Enalapril maleato Ph. Eur.
15.	Esomeprazol magnesio IH
16.	Esomeprazol magnesio dihidrato IH
17.	Esomeprazol magnesio IH trihidrato Ph. Eur
18.	Esomeprazol magnesio USP
19.	Lacipidino IH
20.	Lacipidino BP
21.	Levocetirizina diclorhidrato IH
22.	Levocetirizina diclorhidrato USP
23.	Omeprazol BP
24.	Omeprazol magnesio IH
25.	Omeprazol magnesio Ph Eur
26.	Omeprazol magnesio USP
27.	Omeprazol Ph. Eur
28.	Omeprazol USP
29.	Omeprazol sódico BP
30.	Omeprazol sódico Ph Eur
31.	Palonosetron clorhidrato IH
32.	Palonosetron disodio pentahidrato Ph Eur
33.	Palonosetron disodio pentahidrato BP
34.	Palonosetron disodio pentahidrato IH
35.	Pantoprazol sódico USP
36.	Pantoprazol sódico sesquihidrato BP
37.	Pantoprazol sódico sesquihidrato Ph Eur
38.	Pantoprazol sódico USP
39.	Rabeprazol sodio hidrato Ph Eur
40.	Rabeprazol sodio IH

ADMINISTRACION DE CONTROL DE MEDICAMENTOS
GOBIERNO DE TELANGANA

L.Dis.No. 1113/Archivo/2019 **Fecha: 19-10-2019**

41.	Rabeprazol sodio USP
42.	Ramipril BP
43.	Ramipril CP
44.	Ramipril IH
45.	Ramipril Ph Eur
46.	Ramipril USP
47.	Ropirinol clorhidrato IH
48.	Ropirinol clorhidrato USP
49.	Terbinafina clorhidrato IH
50.	Terbinafina clorhidrato Ph Eur
51.	Terbinafina clorhidrato BP
52.	Terbinafina clorhidrato USP
53.	Terbinafina clorhidrato JP
54.	Tizanidina clorhidrato IH
55.	Tizanidina clorhidrato USP
56.	Tizanidina clorhidrato Ph Eur
57.	Ácido zoledrónico monohidrato IH
58.	Alendronato de sodio IH
59.	Gatifloxacino anhidro

La unidad M/s. Dr. Reddy's Laboratories Ltd., en las instalaciones situadas en Chemical Technical Operation – Unit III, Plot No 116, Sri Venkateswara Co-operative Industrial Estate, IDA, Bollaram, Jinnaram (Mandal), Sangareddy District, Telengana, INDIA – 502 325 fue inspeccionada por Sra. K. Bhuvaneswari, Inspector de medicamentos, CDSCO y A.N. Kranthi Kumar, Inspector de medicamentos, Administración de Control de Medicamentos, Telengana, el 09-07-2019 y 10-07-2019.

El fabricante se ajusta a los requerimientos de las Buenas Prácticas de Manufactura en cuanto a la elaboración y control de calidad (según las recomendaciones de la Organización Mundial de la Salud) respecto a los productos mencionados anteriormente **Cincuenta y nueve (59) productos** para exportación al mercado internacional.

Este certificado es válido por un periodo de tres años desde la fecha de emisión.

(firma ilegible)
Dr. B. VENKATESWARLU
DIRECTOR ADJUNTO
AUTORIDAD LICENCIANTE & DE CONTROL

Declaro que esta traducción es fiel a la original

Garin Hoyng Bernardita

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Bernardita Garin
Director Técnico
Novartis Chile S.A