

Apostille



DRUGS CONTROL ADMINISTRATION
Government of Telangana



L. Dis. No.1199/E1/2019

Dated 29-06-2019

To

M/s. Neuland Laboratories Ltd
Unit-I, Sy.No.347, 473, 474, 490/2
Bonthapally Village, Veerabhadraswamy
Temple Road, Gummadidala Mandal
Sangareddy District-502313
Telangana State, India.

Sir,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of
World Health Organisation G.M.P. Certificate – Regarding.

Ref: 1. Your letter dated: 27.03.2019
2. Joint Inspection report dt:23.04.2019 to 25.04.2019.

-X-X-X-X-

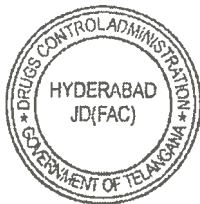
With reference to your application cited, I forward herewith **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Joint Inspection Report of the Officers of Drugs Control Administration, Telangana State and CDSCO, Zonal Office, Hyderabad vide reference 2nd cited.

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

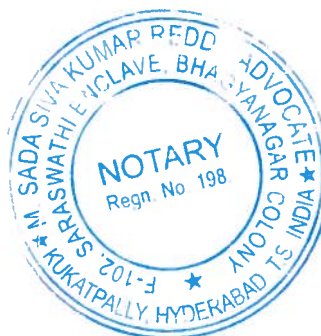
Yours faithfully,

B. Venkateswarlu
29/06/19

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



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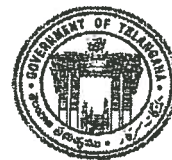




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DRUGS CONTROL ADMINISTRATION
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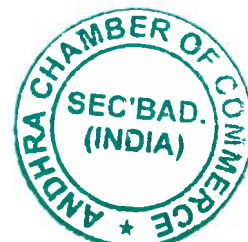
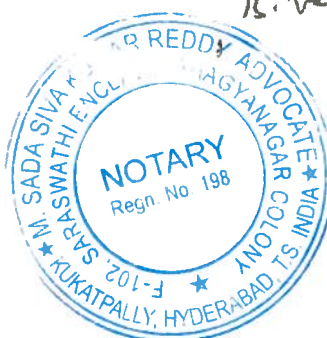
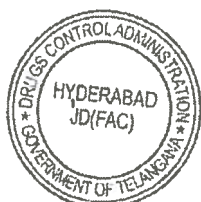
Dated: 29-06-2019



LIST OF PRODUCTS APPROVED UNDER WHO-GMP
CERTIFICATION SCHEME FOR EXPORT PURPOSE

| | | |
|----|----------------------------|----------------|
| 1 | Aripiprazole Lauroxil | IHS |
| 2. | Rotigotine | IHS |
| 3. | Albuterol | USP |
| 4 | Albuterol Sulfate | USP |
| 5 | Alcaftadine | IHS |
| 6 | Besifloxacin Hydrochloride | IHS |
| 7 | Bilastine | IHS |
| 8 | Ciprofloxacin | USP/Ph.Eur |
| 9 | Donepezil Hydrochloride | USP/IHS |
| 10 | Donepezil Base | IHS |
| 11 | Dorzolamide Hydrochloride | USP/Ph.Eur |
| 12 | Enalapril Maleate | USP/Ph.Eur/JP |
| 13 | Escitalopram Oxalate | USP/IHS |
| 14 | Ethacrynic acid | USP |
| 15 | Hydralazine Hydrochloride | USP |
| 16 | Ipratropium Bromide | USP/Ph.Eur |
| 17 | Itraconazole | USP/Ph.Eur/IHS |
| 18 | Labetalol Hydrochloride | USP/Ph.Eur |
| 19 | Levetiracetam | USP/Ph.Eur |
| 20 | Levofloxacin Hemihydrate | USP/IHS |
| 21 | Mirtazapine | Ph.Eur/USP |
| 22 | Moxifloxacin Hydrochloride | Ph.Eur/USP |
| 23 | Ofloxacin | Ph.Eur/USP |
| 24 | Olanzapine | USP/Ph.Eur |
| 25 | Paliperidone Palmitate | IHS |
| 26 | Palonosetron Hydrochloride | IHS |
| 27 | Paricalcitol | USP |
| 28 | Posaconazole | IHS |
| 29 | Rabeprazole Sodium | IHS |
| 30 | Ramipril | USP/Ph.Eur |
| 31 | Ropinirole Hydrochloride | USP/IHS |
| 32 | Ropinirole Base | IHS |
| 33 | Salbutamol | Ph.Eur |
| 34 | Salbutamol Sulphate | Ph.Eur |
| 35 | Salmeterol Xinafoate | Ph.Eur/USP |
| 36 | Sodium Phenyl acetate | IHS |
| 37 | Sotalol Hydrochloride | Ph.Eur/USP |

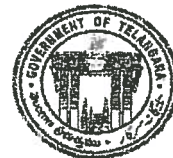
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DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No.1199/E1/2019 – WHO GMP CERTIFICATE

Manufacturer : M/s. Neuland Laboratories Ltd
Unit-I, Sy.No.347, 473, 474, 490/2
Bonthapally Village, Veerabhadraswamy
Temple Road, Gummadidala Mandal
Sangareddy District-502313
Telangana State, India.

When applicable detailed : Placing the product on the market as above.

It is certified that the above products had been authorized to be placed on the market for use in the Country and exporting countries.

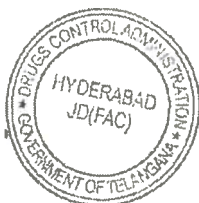
Drug Licence No. : 184/MD/AP/96/B/R, dated: 07.05.1986
under Form – 25 valid upto 31.12.2021.

It is also certified that (a) the manufacturing plant in which the product is produced is subject to inspection at suitable intervals.

The Unit M/s.Neuland Laboratories Ltd, Unit-I, Sy.No.347, 473, 474, 490/2, Bonthapally Village, Veerabhadraswamy Temple Road, Gummadidala Mandal, Sangareddy District-502313, Telangana State, India was inspected jointly by Mr. Bikramaditya Chowdhury and Mr. A.N.Kranthi Kumar, Drugs Inspector, Jinnaram(Mfg) on 23.04.2019 to 25.04.2019.

(b) The manufacturer conforms to requirements for Good Manufacturing Practices in the manufacturer and Quality Control (As recommended by the World Health Organisation) in respect of 37 (Thirty five) products to be sold or distributed with in the Country or origin (or to be exported).

This Certificate is valid for Three years from the date of issue.



B. Venka
28/06/19
Dr.B.VENKATESWARLU
Joint Director(FAC) & Licensing Authority



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

ATTESTED
[Signature]
G. DAYANAND
Asst. Secretary
Andhra Chamber of Commerce
Secunderabad-500 003 (India)

भारत सरकार
विदेश विभाग
नई दिल्ली

अभिष्टा/अपोस्टिल
(Convention de La Haye du 5 octobre 1961)

REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT

has been signed by
B. VENKATESWARLU

in the capacity of
Jt. Director

Andhra Chamber of Commerce
Andhra Pradesh

Certified

at NEW DELHI, INDIA the 01-Dec-2020

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. APHY0006725520

Seal / Stamp

is issued to NEULAND LABORATORIES LTD



Ministry of External Affairs, New Delhi
Copy Division
(Attestation)
(Signature)
(Seal)

79623x1
N/mf
cm

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