

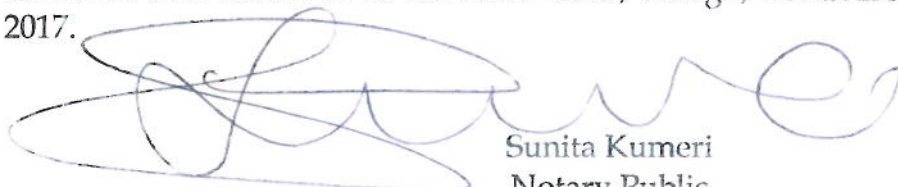


BE IT KNOWN that I, Sunita Kumeri of, 18-24 Stoke Road, Slough, Berkshire United Kingdom a duly authorised Notary Public

CERTIFY that

1. The signature set and subscribed to the certificate at the foot of the first page of the copy document annexed hereto is genuine having been subscribed thereto by Zoe Bruce whose identity I the Notary attest and who is duly authorised by Pfizer Limited ("the Company") to represent them in this matter, and
2. Zoe Bruce has thereby certified on behalf of the Company that the copy Good Manufacturing Practice Certificate for M/s. Neuland Laboratories Ltd annexed hereto is a true copy of the original document.

SIGNED and sealed at 18-24 Stoke Road, Slough, Berkshire aforesaid on 7th July 2017.


Sunita Kumeri
Notary Public
England and Wales



Protocol No. 9/117

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. **Country:** United Kingdom of Great Britain and Northern Ireland
Pays / Pais:

This public document

Le présent acte public / El presente documento público

2. **Has been signed by**
a été signé par Sunita Kumeri
ha sido firmado por

3. **Acting in the capacity of**
agissant en qualité de Notary Public
quien actúa en calidad de

4. **Bears the seal / stamp of**
est revêtu du sceau / timbre de The Said Notary Public
y está revestido del sello / timbre de

Certified

Attesté / Certificado

5. **at** London
à / en
6. **the** 11 July 2017
le / el día

7. **by** Her Majesty's Principal Secretary of State
par / por for Foreign and Commonwealth Affairs

8. **Number** APO-431778
sous no / bajo el numero

9. **Seal / stamp**
Sceau / timbre
Sello / timbre



10. **Signature** J. Royes
Signature
Firma

This Apostille is not to be used in the UK and only confirms the authenticity of the signature, seal or stamp on the attached UK public document. It does not confirm the authenticity of the underlying document. Apostilles attached to documents that have been photocopied and certified in the UK confirm the signature of the UK official who conducted the certification only. It does not authenticate either the signature on the original document or the contents of the original document in any way.



DRUGS CONTROL ADMINISTRATION
Government of Telangana



L. Dis. No.6796/E(S)/TS/2017

Dated: -06-2017

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: 29.04.2017
2. Joint Inspection report dt:30.05.2017 & 31.05.2017.

-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 vide reference 2nd cited.

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

Yours faithfully,

M AMRUTH RAO
Joint Director & Licensing Authority





DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No.6796/E(S)/TS/2017

Dated: -06-2017

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

1	Albuterol	USP
2	Albuterol Sulfate	USP
3	Alcaftadine	IHS
4	Besifloxacin Hydrochloride	IHS
5	Bilastine	IHS
6	Ciprofloxacin	USP/Ph.Eur
7	Donepezil Hydrochloride	USP/IHS
8	Donepezil Base	IHS
9	Dorzolamide Hydrochloride	USP/Ph.Eur
10	Enalapril Maleate	USP/Ph.Eur/JP
11	Escitalopram Oxalate	USP/IHS
12	Ethacrynic acid	USP
13	Hydralazine Hydrochloride	USP
14	Ipratropium Bromide	USP/Ph.Eur
15	Itraconazole	USP/Ph.Eur
16	Labetalol Hydrochloride	USP/Ph.Eur
17	Levetiracetam	USP/Ph.Eur
18	Levofloxacin Hemihydrate	USP/IHS
19	Mirtazapine	Ph.Eur/USP
20	Moxifloxacin Hydrochloride	Ph.Eur/USP
21	Ofloxacin	Ph.Eur/USP
22	Olanzapine	USP/Ph.Eur
23	Paliperidone Palmitate	IHS
24	Palonosetron Hydrochloride	IHS
25	Paricalcitol	USP
26	Posaconazole	IHS
27	Rabeprazole Sodium	IHS
28	Ramipril	USP/Ph.Eur
29	Ropinirole Hydrochloride	USP/IHS





DRUGS CONTROL ADMINISTRATION
Government of Telangana



L.Dis.No.6796/E(S)/TS/2017 - WHO GMP CERTIFICATE

30	Ropinirole Base	IHS
31	Salbutamol	Ph.Eur
32	Salbutamol Sulphate	Ph.Eur
33	Salmeterol Xinafoate	Ph.Eur/USP
34	Sodium Phenyl acetate	IHS
35	Sotalol Hydrochloride	Ph.Eur/USP

Manufacturer

: M/s.Neuland Laboratories Ltd
Unit-I, Sy.No.347, 473, 474, 490/2
Bonhapally 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.

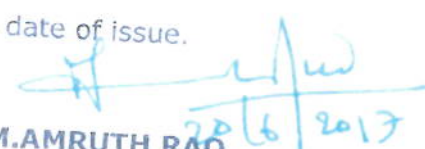
It is also certified that (a) the manufacturing plant in which the product is
produced is subject to inspection at suitable intervals.

The Unit M/s.Neuland Laboratories Ltd, Unit-I, Sy.No.347, 473, 474, 490/2,
Bonhapally Village, Veerabhadraswamy Temple Road, Gummadidala Mandal,
Sangareddy District-502313, Telangana State, India was inspected jointly by Mr.
G.Srinivas, Assistant Director-I(Mfg) and Mr. A.N.Kranthi Kumar, Drugs Inspector,
Jinnaram(Mfg) on 30.05.2017 & 31.05.2017.

(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 35 (Three five) products to be sold or
distributed with in the Country or origin (or to be exported).

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




M.AMRUTH RAO
Joint Director & Licensing Authority

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