DRUGS CONTROL ADMINISTRATION
Government of Telangana

DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

L. Dis. No.12702/E1/2017 Dated: 10 -10-2018

To

M/s.Rakshit Drugs Private Limited,
Sy.No.10/B, IDA, Gaddapotharam Village,
Jinnaram Mandal, Sangareddy Dist-502319,
Talangana 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: 23.11.20176.
2. Joint Inspection report dt:25.07.2018 & 26.07.2018.

-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,

16/10/2018

M.L.V.P.Surendernath Sai
Joint Director & Licensing Authority(FAC)

NOTARY GOVT. OF INDIA Santosh Mishra GREATER MUMBAI Regn. No.6814

DRUGS CONTROL ADMINISTRATION HYDERABAD GOVERNMENT OF TELANGANA

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY 1836

A copy of this document / LETTER has been recorded with the Chamber

Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No...23072...Date

TRUE COPY
02-11-18
SANTOSH MISHRA
Advocate & Notary
Govt. Of India

MR. SAMIR PAUL PINTO
ASSISTANT MANAGER
2 NOV 2018

NOTARY SANTOSH MISHRA MUMBAI (MAHARASHTRA) REGN. NO. 6814 GOVERNMENT OF INDIA

NOTARIAL NOTARIAL NOTARIAL NOTARIAL NOTARIAL

The Signature of Shri. Santosh Mishra is hereby certified Home Department, Maharashtra accepts no responsibility for the contents of the document.

Home Department Government of Maharashtra

Section Officer
Home Department
Government of Maharashtra
Mantralaya, Mumbai

2 NOV 2018

DRUGS CONTROL ADMINISTRATION
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L.Dis.No.12702/E1/2017 Dated: 10-10-2018

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

1. **Sildenafil Citrate**	**IP/BP/EP/USP**
2. **Amlodipine Besylate**	**IP/BP/EP/USP**
3. **Cinnarizine**	**IP/BP/EP**
4. **Famotidine**	**IH/IP/EP/USP**
5. **Pantoprazole Sodium Sesquihydrate**	**USP/EP/BP**
6. **Diacerein**	**IP/EP**

Manufacturer : M/s.Rakshit Drugs Private Limited, Sy.No.10/B, IDA, Gaddapotharam Village, Jinnaram Mandal, Sangareddy Dist-502319, Talangana 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. : 67/MD/AP/2000/B/R, dt:18.12.2000 valid upto 31.12.2021 in Form-25

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.Rakshit Drugs Private Limited, Sy.No.10/B, IDA, Gaddapotharam Village, Jinnaram Mandal, Sangareddy Dist- 502319, Talangana State, India was inspected jointly by Mr.Naveen Yadav, Drugs Inspector, CDSCO, Hyderabad, Mr.Jay Jyothi Roy, Drugs Inspector, CDSCO, Hyderabad and Mr.A.N.Kranthi Kumar, Drugs Inspector, Jinnaram(Mfg), Drugs Control Administration, Telangana on 25.07.2018 & 26.07.2018.

(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 06 (Six) 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.

10/10/2018

M.L.V.P.Surendernath Sai
Joint Director & Licensing Authority(FAC)

TRUE COPY
02.11.18
SANTOSH MISHRA
Advocate & Notary
Govt. Of India

The Signature of Shri Santosh Mishra is hereby certified
Home Department, Maharashtra accepts
no responsibility for the contents
of the document.

Section Officer
Home Department
Government of Maharashtra
Mantralaya, Mumbai

2 NOV 2018

NOTARIAL

MR. SAMIR PAUL PINTO
ASSISTANT MANAGER

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has been recorded with the Chamber

Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 23071 Date 2 NOV 2018

MR. SAMIR PAUL PINTO
ASSISTANT MANAGER