

DRUGS CONTROL ADMINISTRATION GOVERNMENT OF TELANGANA



L.Dis.No.10300/E(J)/TS/2018

Dated: 170 -04-2018

To M/s. Sreepathi Pharmaceuticals Limited Plot No.163, Phase-V, IDA, Jeedimetla, Hyderabad, Telangana State

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: Nil received on dt: 22.08.2017

HYDERABAD

2. Inspection report of Drugs Inspector, Dated: 14.12.2017 & 15.12.2017

-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. This certificate is meant for Export of drugs only.

Yours faithfully,

JOINT DIRECTOR,
LICENSING & CONTROLLING AUTHORITY



DRUGS CONTROL ADMINISTRATION GOVERNMENT OF TELANGANA



Dated: 10-04-2018

L.Dis.No.10300/E(J)/TS/2018

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

1. Ciprofloxacin Hydrochloride

IP/BP/USP/Ph.Eur

2. Ciprofloxacin

IP/BP/USP/Ph.Eur

Manufacturer

M/s. Sreepathi Pharmaceuticals Limited

Plot No.163, Phase-V,

IDA, Jeedimetla,

Hyderabad, Telangana State

When applicable

Placing the products on the market as detailed

below.

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

Drug Licence No.

No.76/RR/AP/95/B/R, Dated: 09.06.1986

In Form-25 valid up to 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. Sreepathi Pharmaceuticals Limited situated at Plot No.163, Phase-V, IDA, Jeedimetla, Hyderabad, Telangana State, India was inspected by Smt.M.Shakuntala, Drugs Inspector, CDSCO, Hyderabad and Smt.Sree Bindu, Drugs Inspector, Drugs Control Administration on 14.12.2017 & 15.12.2017.

(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 02 (two) 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.

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JOINT DIRECTOR,
LICENSING & CONTROLLING AUTHORITY