

L. Dis. No.3842/E1/2020

Dated: 18-08-2022

To

M/s.Credo Life Sciences Pvt Ltd
Sy.No.1613, Nandigama Village
Nandigama Mandal
Ranga Reddy District-509228
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: 19.10.2020
2. Joint Inspection report dt:22.02.2021 & 23.02.2021.

-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,



G.RAMDHAN, M.Pharm
Deputy Director-I & Licensing Authority

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

1. Duloxetine HCl EC Pellets 9% w/w
Each 1g enteric Coated Pellets Contains
Duloxetine HCl Ph. Eur-----90 mg
2. Duloxetine HCl EC Pellets 17% w/w
Each 1g enteric Coated Pellets Contains
Duloxetine HCl USP/Ph. Eur-----170 mg
3. Duloxetine HCl EC Pellets 20% w/w
Each 1g enteric Coated Pellets Contains
Duloxetine HCl USP/Ph. Eur-----200 mg
4. Esomeprazole Magnesium EC Pellets 22.5% w/w
Each 1g enteric coated Pellets contains
Esomeprazole 225mg as Esomeprazole magnesium USP/Ph.Eur

Manufacturer : M/s.Credo Life Sciences Pvt Ltd
Sy.No.1613, Nandigama Village
Nandigama Mandal
Ranga Reddy District-509228
Telangana State, India.

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

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

Drug Licence No. : 20/RR/TS/2017/F/G dated:10-07-2017
under Form - 25 & 28 valid upto 09-07-2027 .

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.Credo Life Sciences Pvt Ltd, Sy.No.1613, Nandigama Village,
Nandigama Mandal, Ranga Reddy District-509228, Telangana State, India was
jointly inspected by K.Naveen Reddy, Drugs Inspector, CDSCO, Hyderabad and
A.N.Kranthi Kumar, Drugs Inspector, Jinnaram(Mfg), Hyderabad on 22.02.2021 &
23.02.2021.

[Handwritten Signature]
18/08/2022



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(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 04 (Four) 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.



G.RAMDHAN, M.Pharm
Deputy Director-I & Licensing Authority