

L.Dis.No:104951/TS/2022

Dated:21/12/2022
Valid until:19/12/2025

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:29/11/2022.
2. Joint Inspection report .

-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 & Drugs Inspector, CDSCO, Hyderabad vide reference 2nd cited.

Digitally Signed By
RAMDHAN GUGULOTH
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:21-12-2022 15:04:14 PM

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

| S.No | Generic Name | Brand Name | Composition | PackSize | Market |
|------|--|------------|---|----------|--------|
| 1 | Itraconazole IR Pellets 20% w/w | | Each 1 gram IR pellets contains Itraconazole Ph.Eur/USp..200 mg | | Export |
| 2 | Itraconazole IR Pellets 22% w/w | | Each 1 gram IR pellets contains Itraconazole Ph.Eur/USp..220 mg | | Export |
| 3 | Tamsulosin HCl SR pellets 0.20% w/w | | Each 1 gram SR Pellets contains Tamsulosin HCl IP/USP/Ph.Eur...2.00 mg Dissolution Profile: Medium -500 ml, 0.1N HCl, Apparatus-2, 100 RPM for 2 hrs & Medium-500ml, 3rd and 8th hour pH7.2 Phosphatte buffer, RPM 100 After 2nd hour-13 to 34%, After 3rd hour - 47 to 68%, After 8th hour - NLT 80% | | Export |

Manufacturer: M/S M/s CREDO LIFE SCIENCES PRIVATE LIMITED,
SY.NO.1613, NANDIGAMA VILLAGE AND MANDAL, RANGA REDDY DISTRICT,
TELANGANA, NANDIGAMA VILLAGE, NANDIGAMA MANDAL, RANGA REDDY
DISTRICT,PINCODE 509228,TELANGANA STATE,INDIA

Drug License No: **20/RR/TS/2017/F/G,**
Dated:10/07/2022 **Under Form 25&28** ,valid upto **09/07/2027**

When applicable Placing the product on the market as detailed below.

The Unit M/S M/s CREDO LIFE SCIENCES PRIVATE LIMITED, SY.NO.1613, NANDIGAMA VILLAGE AND MANDAL, RANGA REDDY DISTRICT, TELANGANA, NANDIGAMA VILLAGE, NANDIGAMA MANDAL, RANGA REDDY DISTRICT,PINCODE 509228,TELANGANA STATE,INDIA Telangana State,India was inspected jointly by

It is certified that:

- The above products had been authorized to be placed on the market for use in the country and exported countries
- The manufacturing plant in which the product is produced is subject to inspection at suitable intervals.
- The manufacturer conforms to requirements for Good Manufacturing Practices in the manufacture and Quality Control (As recommended by the World Health Organisation) in respect of **#Error** products to be sold or distributed with in the Country of origin (or to be exported).



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This Document is Digitally Signed. Signature is not required