

L.Dis.No:104282/TS/2023

Dated:09/06/2023  
Valid until:07/06/2026

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: **22/11/2022**.  
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  
**C RAJAVARDHANA CHARY**  
**Deputy Director and Certifying Authority**  
DRUGS CONTROL ADMINISTRATION  
TELANGANA STATE  
Date:09-06-2023 11:30:45 AM

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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	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE PELLETS 22.0% W/W		Each One Gram of Enteric coated Pellets Contains Esomeprazole Magnesium Trihydrate IHS/IP/BP. Equivalent to Esomeprazole 220mg. Approved Colours Used.		Domestic & Export
2	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE PELLETS 22.5% W/W		Each One Gram of Enteric coated Pellets Contains Esomeprazole Magnesium Trihydrate IHS/IP/BP. Equivalent to Esomeprazole 225mg. Approved Colours used.		Domestic & Export
3	ESOMEPRAZOLE PELLETS 8.5% W/W		Each One Gram of Enteric coated Pellets Contains Esomeprazole Magnesium Trihydrate IP/BP/USP. Equivalent to Esomeprazole - 85mg, Approved Colours used.		Domestic & Export
4	ITRACONAZOLE PELLETS 22.0% W/W		Each one gram of Pellets contains Itraconazole BP 220mg. Approved Colours used		Domestic & Export

5	LANSOPRAZOLE PELLETS 8.5% W/W		Each One Gram of Enteric coated Pellets Contains Lansoprazole IP/BP/USP - 85mg. Approved Colours Used	Domestic & Export
6	OMEPRAZOLE PELLETS 7.5% W/W		Each one gram of Enteric Coated Pellets contains Omeprazole IP/BP/USP 75mg. Approved colours used.	Domestic & Export
7	OMEPRAZOLE PELLETS 8.5% W/W		Each One Gram of Enteric coated Pellets Contains Omeprazole IP/BP/USP - 85mg. Approved Colours Used.	Domestic & Export
8	PANTOPRAZOLE PELLETS 22.0% W/W		Each one gram of Enteric Coated Pellets contains Pantoprazole Sodium IP/USP equivalent to Pantoprazole 220mg. Approved Colours used.	Domestic & Export
9	RABEPRAZOLE SODIUM ENTERIC COATED PELLETS 11.0% W/W		Each one gram of Enteric Coated Pellets contains Rabeprazole Sodium IP 110mg. Approved Colours Used.	Domestic & Export
10	RABEPRAZOLE SODIUM ENTERIC COATED PELLETS 15.0% W/W		Each one gram of Enteric Coated Pellets contains Rabeprazole Sodium IP 150mg. Approved Colours Used.	Domestic & Export
11	TAMSULOSIN HYDROCHLORIDE SR PELLETS 0.12% W/W		Each one gram of Sustained Release Pellets contains Tamsulosin HCl IP/USP 1.2mg. Approved Colours used.	Domestic & Export

Manufacturer: **M/S M/s RAVOOS LABORATORIES LTD,  
SY NO 542 TO 544 CHIVEMLA (VILLAGE & MANDAL) SURYAPET DIST,  
CHIVEMLA VILLAGE, CHIVEMLA MANDAL, SURYAPET DISTRICT,PINCODE  
508213,TELANGANA STATE,INDIA**

Drug License No: **44/NL/AP/2009/F/R,**  
Dated:18/11/2014 **Under Form 25&28** ,valid upto **17/11/2024**

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

The Unit **M/S M/s RAVOOS LABORATORIES LTD, SY NO 542 TO 544 CHIVEMLA (VILLAGE & MANDAL) SURYAPET DIST, CHIVEMLA VILLAGE, CHIVEMLA MANDAL, SURYAPET DISTRICT,PINCODE 508213,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 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