

L.Dis.No:91753/TS/2022

Dated:21/06/2022
Valid until:19/06/2025

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: **17/06/2022**.
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:21-06-2022 11:47:59 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	Chlorhexidine Gluconate Solution USP		Chlorhexidine Gluconate Solution USP 20%v/v (eq. to Chlorhexidine Gluconate 4% w/v), Colour - FD & C Red 40 - Q.S., Purified Water USP - Q.S		Export
2	Hydrogen Peroxide Solution USP		Hydrogen Peroxide Solution USP 6% w/v (20 volumes) Excipients - Q.S.		Export
3	Povidone Iodine Topical Solution 10% solution		Povidone Iodine USP - 10% w/v, (Available Iodine - 1%), Purified Water USP - Q.S.		Export
4	Povidone Iodine Topical Solution 5% solution		Povidone Iodine USP - 5% w/v, (Available Iodine - 0.5%), Purified Water USP - Q.S.		Export
5	Povidone Iodine Topical Solution 7.5% solution		Povidone Iodine USP - 7.5% w/v, (Available Iodine - 0.75%), Non Ionic Surfactant - Q.S., Purified Water USP - Q.S		Export

6	Solution Chlorhexidine Gluconate USP, and Ethanol USP		Chlorhexidine Gluconate USP - 2.5% v/v, (eq. of Chlorhexidine Gluconate - 0.5% w/v), Ethanol USP - 70% v/v, Colour - Carmosine - Q.S., Purified Water USP - Q.S., With Emollients, Moisturizers	Export
7	Solution of 2 - Propanol USP, 1-Propanol and Mecetronium ethylsulphate		2- Propanol USP - 45% w/w, 1-Propanol - 30% w/w, Mecetronium ethylsulphate - 0.2%, Colour Brilliant Blue (f.c.f.) Q.S., Purified Water USP Q.S., Skin Protecting Substance.	Export
8	Solution of Chlorhexidine Gluconate USP and Cetrimide USP		Chlorhexidine Gluconate Solution USP 7.5%v/v, (eq to Chlorhexidine Gluconate - 1.5% w/v), Cetrimide USP - 15% w/v, Purified Water USP - Q.S., Tartarazine - Q.S	Export
9	Solution of Chlorhexidine Gluconate USP, Cetrimide USP and Isopropyl Alcohol USP		Chlorhexidine Gluconate Solution USP 7.5%v/v, (eq to Chlorhexidine Gluconate - 1.5% w/v), Cetrimide USP - 15% w/v, Isopropyl Alcohol USP - 7% v/v, Purified Water USP - Q.S., Colour - Sunset Yellow Tartarazine - Q.S.	Export
10	Solution of Chloroxylenol USP, Alcohol (denatured), Terpeneol		Chloroxylenol USP - 4.8% w/v, Alcohol (denatured) - 13.1% v/v, Terpeneol BP - 9% v/v, Purified Water USP - Q.S., Colour Caramel - Q.S.	Export
11	Solution of Ethanol, Isopropyl Alcohol USP, N-Propanol		Ethanol USP - 10% w/w, Isopropyl Alcohol USP - 9% w/w, N-Propanol - 6% w/w, Colour Brilliant Blue - Q.S., Purified Water USP - Q.S.	Export
12	Solution of Orthophthaldehyde		Orthophthaldehyde 0.55% w/w, Purified Water USP - Q.S.	Export

Manufacturer: **M/S M/s SANMED HEALTHCARE PVT.LTD,**
PLOT NO 56 BIOTECH PARK, PHASE III, KARKAPATLA VILLAGE, MARKOOK MANDAL, SIDDIKET DISTRICT, PINCODE 500081, TELANGANA STATE, INDIA

Drug License No: **5/MD/TS/2015/F/G,**
Dated: 04/08/2015 **Under Form 25**, valid upto **03/08/2025**

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

The Unit **M/S M/s SANMED HEALTHCARE PVT.LTD, PLOT NO 56 BIOTECH PARK, PHASE III, KARKAPATLA VILLAGE, MARKOOK MANDAL, SIDDIKET DISTRICT, PINCODE 500081, 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

