



Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-03 Jun 2025

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.

(General instructions and explanatory notes attached).

Certificate No.: **NEW-WHO-GMP/CERT/KD/151074/2025/11/55399**

On the basis of the inspection carried out on **13.02.2025 to 14.02.2025**, we certify that the site indicated on this Certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1.

1. Name of the Firm : **RANK ORGANICS CHEMICAL PRIVATE LIMITED**
Address : **PLOT NO. N 85 & 86, MIDC TARAPUR,
TALUKA : PALGHAR DISTRICT : PALGHAR
PALGHAR 401506 MAHARASHTRA STATE,
INDIA**
2. Licence No. : **KD202 In Form 25**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 02 Jun 2028 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1NAR10615107420250603
RANK ORGANICS CHEMICAL PRIVATE LIMITED
NEW-WHO-
GMP/CERT/KD/151074/2025/11/55399

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:03 Jun 2025



Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.
2. The certification number should be traceable within the regulatory authority issuing the certificate.
3. Where the regulatory authority issues a licence for the site, this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.
4. Table 1
List the dosage forms, starting materials, categories and activities. Examples are given below.

Example -1

Pharmaceutical Product (s) ¹	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

Example - 2.

Pharmaceutical Product (s) ¹	Category (ies)	Activity (ies)
Starting material (s) ²		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals, a compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2, 1999. World Health Organization, Geneva and subsequent updates.



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO- VALID UP TO :02 Jun 2028
GMP/CERT/KD/151074/2025/11/55399
Name of Manufacturing Firm : RANK ORGANICS CHEMICAL PRIVATE
LIMITED
PLOT NO. N 85 & 86, MIDC TARAPUR, TALUKA :
PALGHAR DISTRICT : PALGHAR PALGHAR
401506 MAHARASHTRA STATE, INDIA
Drug License No : KD202 In Form 25

Sr.No.	Name of the Product	Composition
1	IRON (III) HYDROXY POLYMALTOSE	
2	NAPHAZOLINE HYDROCHLORIDE Ph.Eur.	
3	NAPHAZOLINE HYDROCHLORIDE USP	
4	SODIUM STEARYL FUMARATE B.P.	
5	SODIUM STEARYL FUMARATE JPE	
6	SODIUM STEARYL FUMARATE Ph Eur	
7	Sodium Stearyl Fumarate USP	
8	TRIPROLIDINE HYDROCHLORIDE BP	



12

Address of certifying authority :
Food & Drug Administration, M.S.

Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.

Tel: +91-22-26592363/64

Fax: +91-22-26591959

1NAR10615107420250603

RANK ORGANICS CHEMICAL PRIVATE LIMITED -

NEW-WHO-

GMP/CERT/KD/151074/2025/11/55399

Name of the Authorised person : D. R. GAHANE

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai.

Maharashtra State, India

Date:03 Jun 2025

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO- VALID UP TO :02 Jun 2028
GMP/CERT/KD/151074/2025/11/55399
Name of Manufacturing Firm : RANK ORGANICS CHEMICAL PRIVATE
LIMITED
PLOT NO. N 85 & 86, MIDC TARAPUR, TALUKA :
PALGHAR DISTRICT : PALGHAR PALGHAR
401506 MAHARASHTRA STATE, INDIA
Drug License No : KD202 In Form 25

Sr.No.	Name of the Product	Composition
9	TRIPROLIDINE HYDROCHLORIDE IP	
10	TRIPROLIDINE HYDROCHLORIDE USP	
12		

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1NAR10615107420250603
RANK ORGANICS CHEMICAL PRIVATE LIMITED -
NEW-WHO-
GMP/CERT/KD/151074/2025/11/55399

Name of the Authorised person : D. R. GAHANE

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:03 Jun 2025

