

Metahel Cure Private Limited

(A WHO-GMP & ISO 9001: 2015 Certified Company)

WELCOME

Plot No. 94M2, Sector-6A, IIE,
SIDCUL, Haridwar-249403 Uttarakhand, INDIA

Metahel Cure Private Limited



Metahel Cure Private Limited

COMPANY PROFILE

- **Metahel Cure Pvt. Ltd. is a professionally managed company for the manufacturing of quality pharmaceuticals range of products.**
- **The Formulation unit is located in SIDCUL, Integrated Industrial Estate Haridwar, Uttarakhand.**
- **Metahel Cure Pvt. Ltd. was issued license to manufacture for sale by Drug Controlling & Licensing authority Uttarakhand on 06 March 2024.**
- **The facility is developed to manufacture Solid Oral Dosage (Tablets & Capsules) and Liquid Oral Dosage form.**
- **Metahel Cure Pvt. Ltd. is co-promoted by Mr. Rahul Dev Sharma a well-known industrialist having more than 25 years of experience in FMCG Business.**

Metahel Cure Private Limited

Location of Activities

Registered Office for Business Development is located at: Metahel Cure Pvt. Ltd., D-366 , Main Road , Bhajanpura, North East Delhi-110053, INDIA

Manufacturing Facility at : Plot No.94M2, Sector-6A, IIE ,SIDCUL,Haridwar-249403 Uttarakhand

The Manufacturing site is easily accessible by Rail and Road and the nearest Air port is Dehradun.

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- Land Area of Metahel Cure Pvt. Ltd. is 2000 square meter and total Built up Area is approx. 50,000 square meter (with Mezzanine Floor).
- The facility is equipped to undertake the manufacturing for Tablets, Capsules and Liquid Orals
- The manufacturing current capacity per shift of different dosage form is,

Production Capacity (All units are in Million)					
S. No.	Dosage Form	Per Shift	Per Day	Per Month	Per Year
1.	Tablets	2.5	7.5	225	2700
2.	Capsules	0.32	0.96	24.96	299.52
3.	Oral Liquids	0.03	0.09	2.34	28.08

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Facility started in the year March, 2024 for

- ▶ Tablets, Capsules and Oral Liquids License issued on 06/03/2024 by Drug Controlling & Licensing Authority Uttarakhand**
- ▶ On Form 25 Mfg Lic. No. : 8/UA/2024**
- ▶ On Form 28 Mfg Lic. No. : 8/UA/SC/P-2024**

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- ▶ **CGMP standards have been followed as the basic skeleton of the manufacturing facility.**
- ▶ **Unidirectional flow for Man & Material has been followed.**
- ▶ **All the rooms are Identified and have been allotted to carry out specific activities.**
- ▶ **Required Temperature and Humidity has been provided wherever applicable in the facility for product processing and packing.**
- ▶ **Warehouse “Raw material, Primary Packing material & Finished products” are maintained at controlled temperature/RH conditions as per requirements.**

Some pictures of the plant premises
STORE AREA



PRODUCTION CORRIDOR



TABLETS GRANULATION AREA



COMPRESSION AREA



BLISTER PACKING AREA



CAPSULE FILLING AREA



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Quality Control

- ❖ **The Quality Control laboratory is established to ensure that the products are safe and effective and is released only after thorough analysis as per approved specifications, methods and procedures developed in line with inhouse or Pharmacopeial requirements.**
- ❖ **Quality Control Lab. is supported by all requisite instrumentation to carry out the analysis of the products.**

Quality Control is an independent unit and responsible to carry out the analysis of Raw Materials, Packaging Materials, In-process Samples and Finished Products and ensure documentation of the same.

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Quality Control

- **Labs Divided into Subsection Like.....**
 - ❖ **Chemical : Titrimetry, Limit Test, Dissolution's etc.**
 - ❖ **Instrumental : HPLC, UV Spectrophotometer, IR etc.**
 - ❖ **Microbiological : Microbial Limit Tests, Environmental Monitoring, Water Monitoring.**
- **Separate area for Microbiology Lab is provided in QC with dedicated Air handling units.**
- **Laminar Air Flow and Biosafety Cabinet is kept in cubicles with ISO 6 background.**
- **Separate entry and exit route is given in sterile area in Microbiology lab.**

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Quality Assurance & Quality Management System

- ❖ **Separate independent Quality Assurance department with well qualified & experienced personnel is adhering to get continuous improvement in the quality.**
- ❖ **Quality systems are based on Schedule 'M', WHO TRS's guidelines and ICH Guidelines.**

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Quality Systems

- **For Maintaining Quality standards following Systems are maintained:**
- **Validations & Qualifications**
- **Documents Control Procedure**
- **Change Control and Deviations Procedure**
- **Procedure for Handling of Market Complaints**
- **CAPA Procedure**
- **Annual Product Quality Review (APQR)**
- **Stability Studies facility at site**
- **Self Inspection**
- **Training**
- **Trend Analysis – (Environment Monitoring & Water Monitoring)**
- **Risk Assessment.**

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Qualification / Requalification :

- **Area**
- **Equipment**

Validation :

- **Process**
- **Cleaning**
- **Analytical Methods**
- **Systems**

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Documentation Control

- ▶ **Standard Operating Procedures(SOP's)**
- ▶ **Standard Test Procedures**
- ▶ **Master Batch Manufacturing/Packing Records (BMR/BPR)**
- ▶ **Specifications**
- ▶ **Analytical Test Methods**
- ▶ **Validation Protocols**
- ▶ **Art Works**
- ▶ **Log Books**

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Other QA Activities

- ▶ **In-Process Checks**
- ▶ **Line Clearances**
- ▶ **Gap Analysis**
- ▶ **Batch Record and Other Documents Review**
- ▶ **Document Issuance & Retrieval**
- ▶ **Batch Release**

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Air Handling System

Air to all production cubicles is supplied through dedicated AHUs.

All AHUs are equipped with a pre-filter of 10 microns followed by fine filter of 3 micron and finally through terminal HEPA filter.

The process areas have been designed for a minimum of 20 air changes per hour.

Total Number of AHUs in the facility is 41

Warehouse- 04

Liquid Oral – 09

Tablet Section- 25

Quality Control-03

Each operational area has been supplied with a separate AHU/ terminal HEPA filters to avoid any cross contamination.

Corridor is supplied with a separate AHU and The required differential pressure are maintained between the adjacent area with respect to Corridor.

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Water System

Bore well is the source of raw water. The water is chlorinated through dosing and passed through MGF-I then dechlorinated. The water is feed to CSRO after antiscalent dosing.

The CSRO passed water is collected in 2000Ltr. Tank and then fed to MGF-II and then through Softener unit.

The soft water is collected in 3000ltr tank and fed to Multipurpose tank and further through HSRO and EDI unit.

The purified water produced is passed through UV light and stored in 3000 ltr. SJ tank.

The water distribution is through a close loop from jacketed storage tank 3000 Ltrs.

Total 32 user points including return is provided on distribution loop.

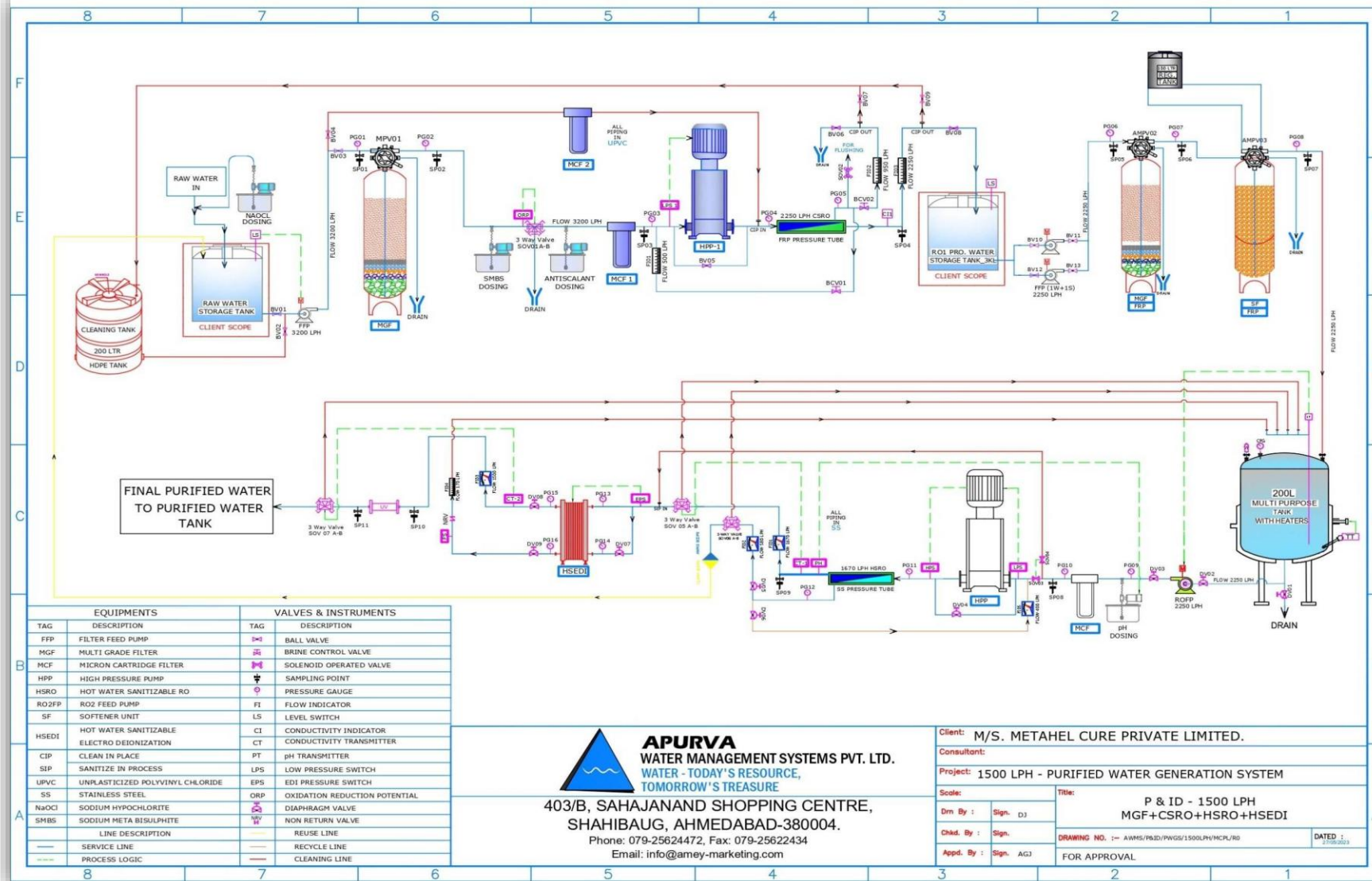
Purified water finally passed through the UV light before distribution to production areas.

The water system is qualified and continually evaluated as per defined schedule.

Trend results are prepared for regularly monitoring of the water quality.

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Water System (Schematic Diagram)



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Effluent Treatment Plant

- **Effluent treatment plant is provided for treatment of waste water .**

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Quality Policy

Metahel Cure Private Limited manufacturing pharmaceutical products to the satisfaction of its customers and is committed to maintain the belief of “Creating a Healthier Tomorrow” by maintain unrivalled levels of quality in manufacturing of drug formulation.

Our Quality policy comprises of :

Manufacturing & supplying quality drugs consistently to meet the needs of esteemed clients and for the mankind in general.

Ensuring strict compliance with cGMP guidelines, prevailing national and international standards governing the pharmaceuticals industry.

The quality policy is communicated and well understood at all appropriate levels.

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Key Personnel

Name	Department	Designation	Qualification	Experience
Rahul Dev Sharma	-	MD	B.Com	33 years
Rohan Sharma	-	Director	B.LLB	3 Years
Suresh Kumar Nair	Quality Assurance	Quality Head	B.Sc (Chemistry Hons.)	35 Years
Laxman Singh	Production	Manager	M.Sc	24 Years
Vijay Pal	Engineering	Manager	B.Tech	22 Years
Harsh Vardhan	Quality Control	QC. Manager	B.Sc	16 Years
Navendu Kumar	Warehouse	Store Incharge	B.Com	12 Years

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Training

Training needs are identified in the beginning of the year based on the activities. performed by the personnel and evaluation by the dept. in charge.

GMP Training : A yearly calendar is prepared by QA and monthly training is provided to all employee. The record is maintained by QA.

Induction Training : The induction training is given to newly appointed employee & recorded.

On Job Training: To make the training more effective – workers are given on job training at the place of activity.

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Medical Checkup

- **All the employee's involved in Core area ,Sampling and Dispensing under go medical check-up Periodically through an Authorized Medical Officer.**

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Visitor Notification

Please observe the following site safety rules:

- This is a Non Smoking Site.
- Please leave your jewelry, wallet, watch and goggles etc in the conference area or else keep it in pocket or lockers.
- In case of emergency alarm the person accompanying you will directly take you to the nearest assembly point.
- Necessary Gowning & Personal Protective Equipment will be provided wherever required during plant visit.

FOOD SAFETY & DRUGS ADMINISTRATION AUTHORITY
DIRECTORATE GENERAL OF MEDICAL HEALTH AND FAMILY WELFARE,
SAHASTRADHARA ROAD, DEHRADUN
F.no.26/0/Drug/144/2023/ 18729 Date: 27 September 2024
CERTIFICATE OF GOOD MANUFACTURING PRACTICES

Certificate no.: 26/0/Drug/144/2023/

On the basis of the Joint Inspection carried out with CDSCO, North Zone on Dated 11-09-2024 and Futher inspected by I.D Haridwar on Dated 26-09-2024, 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

Name & Address of site:

M/s METAHEL CURE Pvt.Ltd,
Plot No-94M2, Sector-6A, IIE, SIDCUL,
Distt. Haridwar-249403 Uttarakhand (India)

Manufacturer's license number:

Form 25- 8/UA/2024

Form 28- 8/UA/SC/P-2024

1- Table 1:

Dosage form(s)	Category(ies)	Activity(ies)
Tablets	(Non Beta Lactam)	Manufacturing
Capsules	(Non Beta Lactam)	Manufacturing
Oral Liquid	(Non Beta Lactam)	Manufacturing

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 26-09-2027 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.

The firm is following Good Manufacturing Practices as per World Health Organization(WHO)TRS Guide Lines, in the Manufacturing & testing of the said categories of Products and Items in respect of which the Certificates of Pharmaceuticals products have been issued.

Address of certifying Authority:

Directorate General of Medical Health & Family Welfare, Sahastradhara Road, Dehradun (Uttarakhand) INDIA.

Name & function of responsible person:

Shri Tajber Singh
Additional Commissioner
Food Safety & Drug Administration
Uttarakhand.
Email: drugscontroluk@gmail.com
Tel.no. NA
Fax. no. 0135260874




(Tajber Singh)
Additional Commissioner
Food Safety & Drug Administration
Uttarakhand
TAJBER SINGH
ADD. COMMISSIONER
FOOD SAFETY &
DRUG ADMINISTRATION (U.K.)

WHO-GMP Certificate



Certificate Of Registration

WRG Certifications hereby certifies that the Quality Management System of:

METAHEL CURE PVT. LTD.

Plot No - 94M2, Sector - 6A, IIE, SIDCUL, Distt. Haridwar - 249403, Uttarakhand, India.

has been assessed and found to operate in compliance and meets the requirement of following standard

ISO 9001:2015

for the scope of

Manufacturing and Supply of Tablets, Capsules and Oral Liquids

Initial date of certification : Oct 07, 2024
Current date of certification : Oct 07, 2024
Date of expiry : Oct 06, 2027

(Subject to surveillance mark present)

1st Surveillance Date : Sep 2025



2nd Surveillance Date : Sep 2026



Certificate Number : GMS-MMXXIV-10-15026

NACE Code : DG-24.40



Registry information can be found at: www.wrgcert.com/registry

This certificate remains the property of American International Accreditation Organization - Bureau of Accredited Registrars, (AIAO-BAR) & World Registrar Group Certification, (WRG Certifications). This certificate is valid for three years from the date of its issuance. Must be returned, if certificate is withdrawn. Compliance & Accreditation by AIAO-BAR, www.aiao-bar.org. Registration No - AIAO-BAR-0305131-1

ISO 9001:2015

ISO 9001

ISO 9001:2015 Certificate

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