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TELERAD

HARYANA CONTAINERS LIMITED

SARABHAI
SARABHAI CHEMICALS

suvik

SARABHAI M CHEMICALS

Sarabhai Campus

Ranoli, Gujarat

AERIAL VIEW OF MANUFACTURING FACILITY AT RANOLI – VADODARA _ GUJARAT (INDIA)

MANUFACTURING FACILITY AT RANOLI – VADODARA _ GUJARAT (INDIA)

MANUFACTURING FACILITY AT RANOLI – VADODARA _ GUJARAT (INDIA)

Major Features Of Own API Manufacturing Facility At Ranoli – Vadodara

Commissioned in June 2023

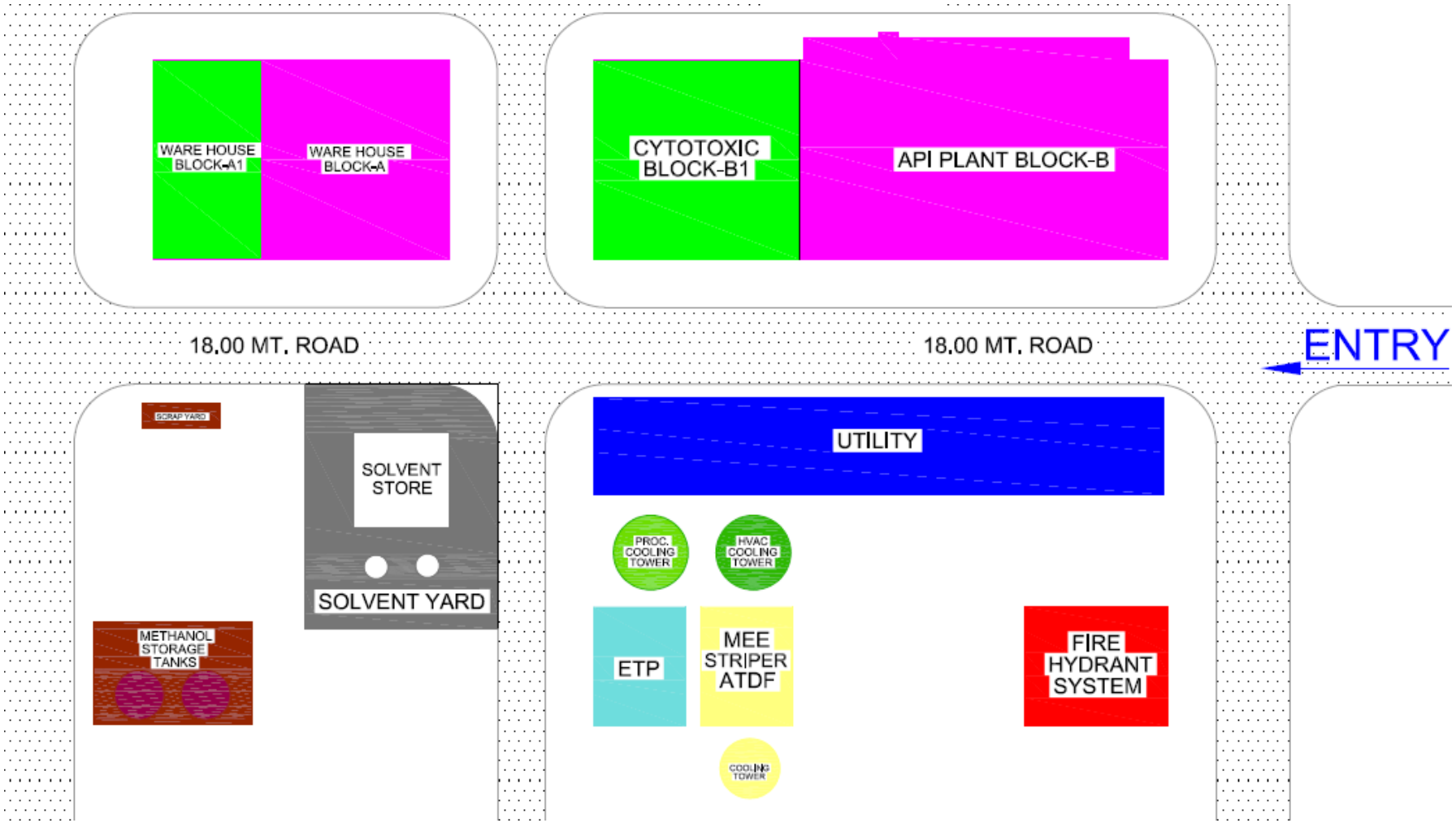
- This Site Consists Two Manufacturing Blocks (One for Oncology & another for General Synthetic APIs), Separate Block for High Value Low Volume (Solid & Liquid) Products , Utility Block , Solvent Yard , Full-fledged Q.C. Lab , PD Lab and Two separate Warehouse (One for Oncology & another for General Synthetic APIs) complying with cGMP and other regulatory authorities' requirement.

- Facility will have National & International Accreditation Like WHO , USFDA , EDQM , PMDA Etc…

- Spare Capacity for Contract Manufacturing is available in Both The Blocks .

- Plant is now operative for Crotamiton (API) & Hydroxy Urea (Oncology API) .

Ranoli Manufacturing Site Block Diagram



Ranoli Manufacturing Site Size

Sr. No.	Block	Area in Sq Mt
1	Manufacturing , Quality Dept & Process Development Lab	6000
2	Warehouse	870
3	Utility	500
4	ETP	200
5	Spare Area Available For Additional Oncology Product Manufacturing General APIs Manufacturing	 400 220

Major Manufacturing Equipment

Sr. No.	Equipment	Capacity Range	Total
1	S.S. 316 Reactors with Condenser & Receiver	0.5 KL - 5 KL	15
2	G.L. Reactors with Condenser & Receiver	0.5 KL - 5 KL	04
3	Centrifuges SS 316	36”	05
4	FBD SS 316	120 kg	02
5	RCVD SS 316	0.1 KL - 1 KL	04

Products to Manufacture
At
Manufacturing Site – Ranoli – Vadodara , Gujarat

Active Pharmaceutical Ingredients

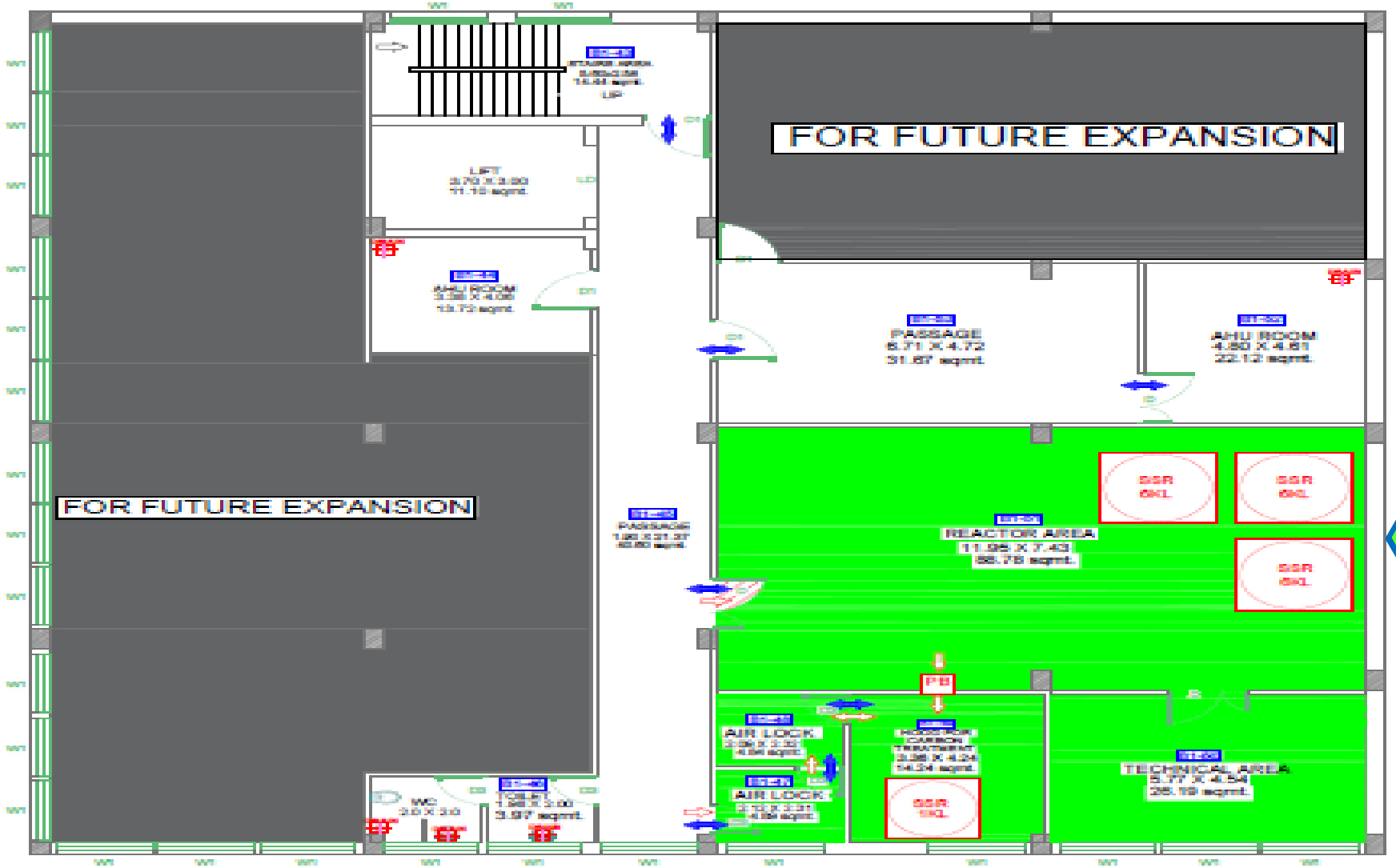
- Crotamiton BP/EP/USP/JP
  Status – Operative & Process Validation is Completed
- Acenocoumarol BP
  Process Validation – NOV-DEC 2024
- Bupivacaine HCL USP/BP/EP
  Process Validation – JAN-MAR 2025
- Ropivacaine HCL USP/BP/EP
  Process Validation – MAR-APR 2025
- Fluconazole USP/EP

Dedicated Manufacturing Plant For Oncology Product

- Hydroxy Urea
  Status – Operative & Process Validation is Completed
- Methotrexate
- Gemcitabine

ONCOLOGY PRODUCT MANUFACTURING BLOCK

Oncology Product Manufacturing Block



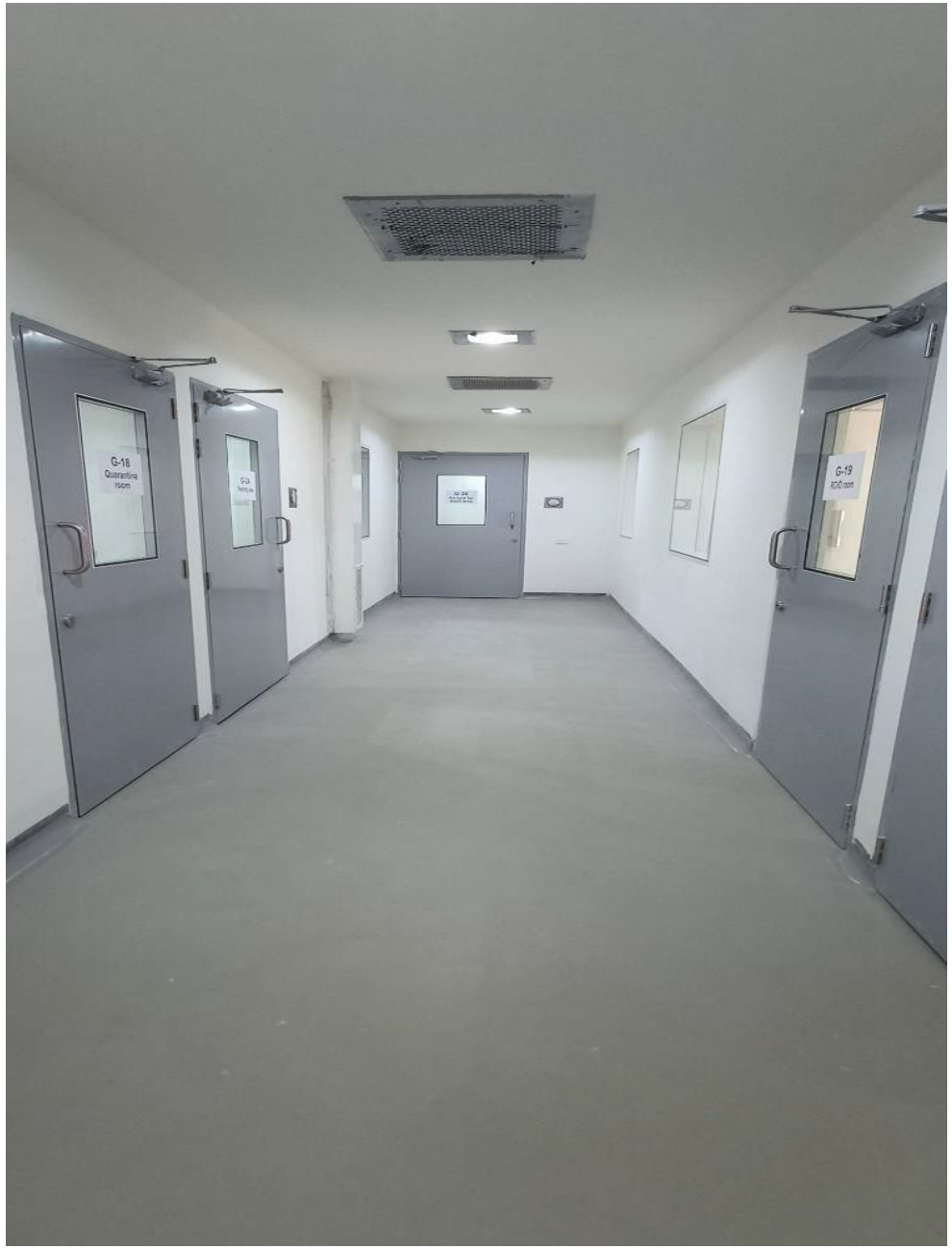
Hydroxycarbamide

Manufacturing Plant View

Entry Corridor For Oncology Products Manufacturing Block

Intermediate Stage Mfg. Area

Clean Zone (GMP) Area Corridor



Final Crystallization Area

Centrifuge

Rotocone Vacuum Dryer

Utilities Status

Sr. No.	Major Utilities	Total Cap.
1	Boiler	4 MT
2	HVAC System Refrigeration Load AHUs	 180TR 31
3	Purified Water System	10 M^3/Hr
4	Cooling Water System	250 TR
5	High Therm Unit	2 lacs KCal
6	High Vacuum System	Up to 760mmHg
7	ETP	40 KLPD

OTHER THAN ONCOLOGY PRODUCT MANUFACTURING BLOCK

Other Than Oncology Products Manufacturing Block

Liquid Product

Solid Product

Intermediate Stage Mfg. Area (First Floor & Ground Floor)

Liquid Product Mfg. Area

Liquid Product Mfg. Area

Warehouse Corridor

Purified Water System - CSRO

Purified Water System – HSRO

Fire Hydrant System

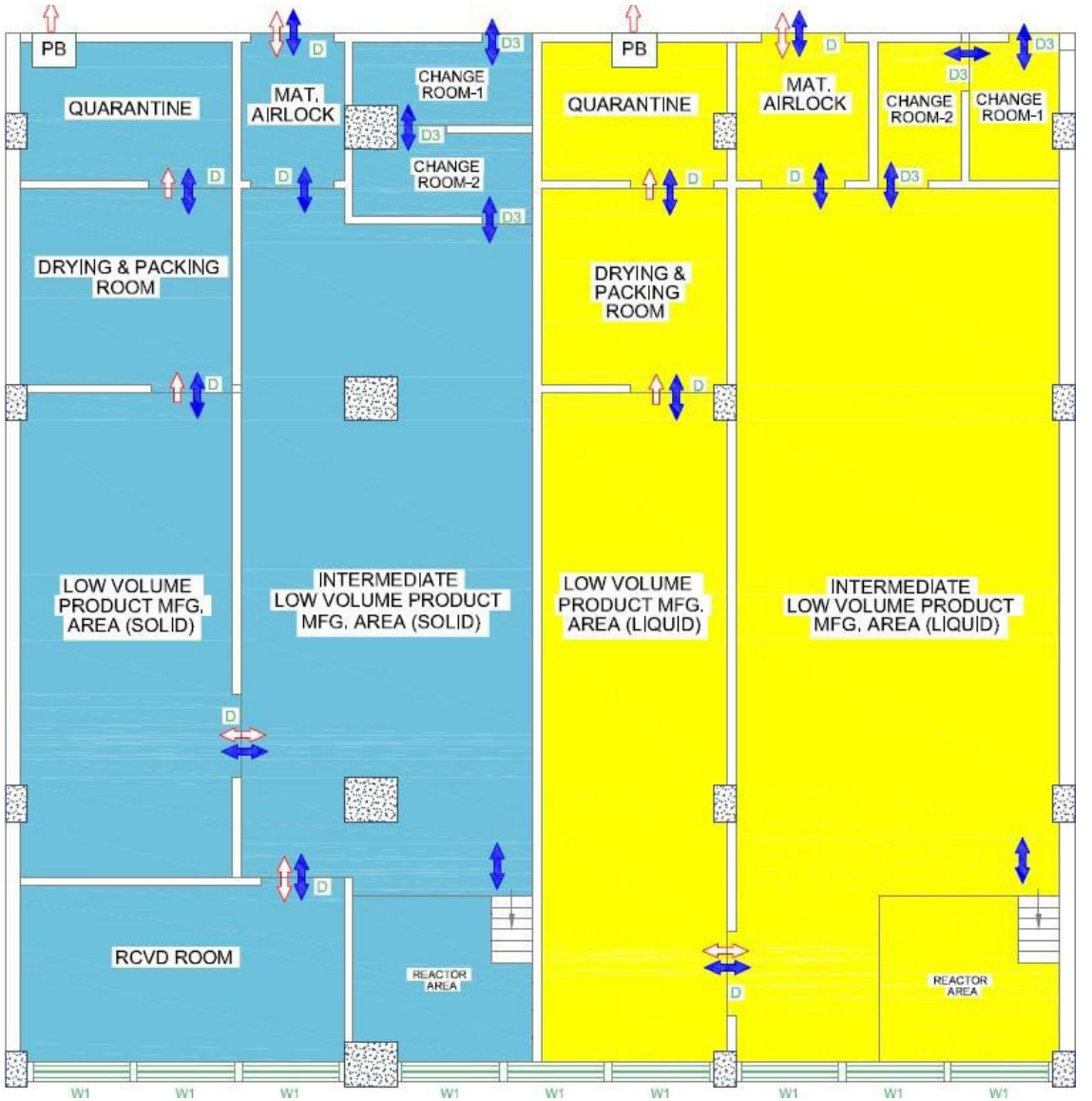
(MEE)Multi Effect Evaporation Plant

(MEE)Multi Effect Evaporation Plant

HIGH VALUE LOW VOLUME PRODUCTS MANUFACTURING BLOCK

High Value Low Volume Products Manufacturing Block

Solid Products



Liquid Products

Major Manufacturing Equipment For High Value Low Volume Products

Sr. No.	Equipment	Capacity Range	Total
1	S.S.Reactor	0.5 KL	02
2	Glass Assembly	0.020 KL- 0.2KL	05
3	RCVD (For Solid Product Drying)	0.1 KL	01
4	Nutch Filter	0.050 KL	03

Choice of products to Manufacture in
High Value Low Volume Products Manufacturing Block

- Fluphenazine Decanoate USP/BP/EP
  Status - Process Validation – JAN-MAR 2025
- Ascorbyl Palmitate BP/EP/USP
  Status - Process Validation – MAR-APR 2025

Spare Capacity Is also Available.

Liquid Product Mfg. Area

Glass assembly

Solid Product Mfg. Area

RCVD

Process Development Lab

Quality Control Laboratory

Sr. No.	Major Laboratory Instruments
1	High Performance Liquid Chromatograph (HPLC)
2	Gas Chromatograph With Head Space (GC)
3	Fourier Transform Infrared Spectroscopy (FTIR)
4	U.V. Spectrophotometer
5	Potentiometer
6	Analytical Balances
7	Stability Chambers
8	Laminar Air Flow
9	Other Indigenous Equipment

Q.C. Lab Corridor

Wet Analysis Lab with Indigenous Equipment & Reagents

Instrument Room – HPLC , Potentiometer

Instrument Room –
U.V. & FTIR

Gas Chromatograph Room

Stability Chambers

Microbiological Lab

Media Preparation

Incubation Room

Laminar Flow in Microbiological Lab


Quality
Management
System

Quality Management System (QMS)	
Sr. No.	Document
01	Facility Qualification
02	Equipment & Systems Qualification
03	URS of Equipment & Instruments
04	Design Qualification
05	Installation Qualification
06	Statutory Licenses

Quality Management System (QMS)	
Sr. No.	Document
07	Standard Operating Procedures
08	Training
09	Specifications & Test Procedures
10	Validations
11	Vendor Qualification
12	Site Master File

Statutory Licences

Manufacturing License From National FDA for Oncology Products

FORM 28

Fresh License

(See Rule 76)

Licence to manufacture for sale (or for distribution of) drugs specified in Schedules C, C (1) [excluding those specified in schedule X]

Number of licence and date of issue No G/28/1882 Date: 26-Jul-2022

1. Directors

of M/s. ASENCE PHARMA PVT.LTD. is hereby licence to manufacture at the premises situated at the SURVEY NO. 591, 592, 593, 594, 595/A, 596, 597, 598, 606, 607, 608, 609/A, 610/A, 611/A, 612/A, 613, OPP. RANOLI RAILWAY STATION, VILLAGE RANOLI, VADODARA - 391 350 the following drugs being drugs specified in schedules C & C (1) (Excluding those specified in schedule X) to the Drugs and Cosmetics Rules 1945.

Names of Drugs : As Per List Approved & Annexed

2. Names of approved competent technical staff : As Per List Approved & Annexed
3. The licence authorizes the sale by way of wholesale dealing by the licensee and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.
4. The licence shall be in force from 26-Jul-2022 To 25-Jul-2027
5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

(This Document is Digitally Signed.)

Signature : Dr. H. G. KOSHIA
Designation : Commissioner
Food & Drugs Control Administration
Gujarat State.

Date:- 26-Jul-2022

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedule C and C(1) (excluding those specified in Schedule X) not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 75(3). This licence will be deemed to extend to the items so endorsed.
3. Any change in the (competent technical staff) shall be forthwith reported to the Licensing Authority.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed Constitution.

Doc ID: LI352100001882
ASENCE PHARMA PVT.LTD.
Print Date : 08/08/2022 05:44 PM

Signature valid
Digitally signed by
Date: 2022.08.08 17:47:46 +05:30
Reason: Sign
Location: AHD

Manufacturing License From National FDA For General APIs Other Than Oncology Products

Fresh License

FORM 25

(See Rule 70)

Licence to manufacture for sale (or for distribution) of drugs other than those specified in Schedules C,C(1) and X

Number of licence and date of issue No: G/25/2607 Date: 23-Dec-2022

1. Directors

of M/s. ASENCE PHARMA PVT.LTD. is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in [Schedules C, C(1), and X] to the Drugs & Cosmetics Rules, 1945, on the premises situated at SURVEY NO. 543 & 603, SARABHAI CAMPUS, OPP. RANOLI RAILWAY STATION, VILLAGE. RANOLI, VADODARA - 391 350, GUJARAT under the direction and supervision of the following (competent technical staff):-

(a) Competent technical staff (Names): As Per List Approved & Annexed

(b) Names of Drugs (each item to be separately specified) As Per List Approved & Annexed

2. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.

3. The licence shall be in force From : 23-Dec-2022 To 22-Dec-2027

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Signature : (This Document is Digitally Signed.)
Designation : Dr. H. G. KOSHIA
Commissioner
Food & Drugs Control Administration
Gujarat State.

Date:- 23-Dec-2022

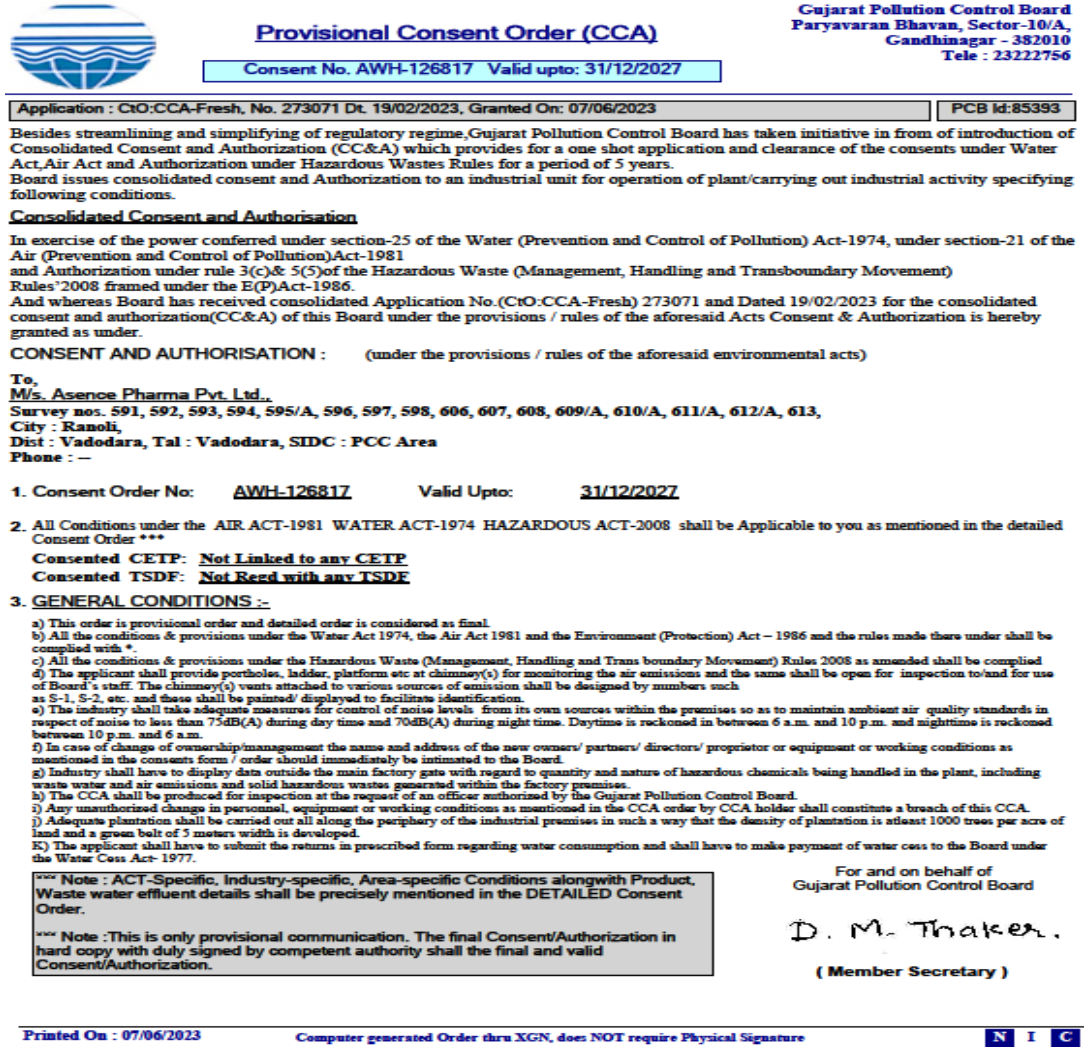
Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the [competent technical staff] named in the licence shall be forthwith reported to the Licensing Authority.
3. If the licensee wants to manufacture for sale additional items of drugs not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 69(5). This licence will be deemed to extend to the categories so endorsed.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

Doc ID: LI993700002607
ASENCE PHARMA PVT.LTD.
Print Date : 23/12/2022 05:06 PM

Signature valid
Digitally signed by
Date: 2022.12.23
17:09:[illegible]5:30
Reason: Sign
Location: AHD

Environmental Clearance from Gujarat pollution control Board



Provisional Consent Order (CCA)

Consent No. AWH-126817 Valid upto: 31/12/2027

Gujarat Pollution Control Board
Paryavaran Bhavan, Sector-10/A,
Gandhinagar - 382010
Tele : 23222756

Application : CtO:CCA-Fresh, No. 273071 Dt. 19/02/2023, Granted On: 07/06/2023 | PCB Id:85393

Besides streamlining and simplifying of regulatory regime,Gujarat Pollution Control Board has taken initiative in from of introduction of Consolidated Consent and Authorization (CC&A) which provides for a one shot application and clearance of the consents under Water Act,Air Act and Authorization under Hazardous Wastes Rules for a period of 5 years.
Board issues consolidated consent and Authorization to an industrial unit for operation of plant/carrying out industrial activity specifying following conditions.

Consolidated Consent and Authorisation

In exercise of the power conferred under section-25 of the Water (Prevention and Control of Pollution) Act-1974, under section-21 of the Air (Prevention and Control of Pollution)Act-1981
and Authorization under rule 3(c)& 5(5)of the Hazardous Waste (Management, Handling and Transboundary Movement) Rules'2008 framed under the E(P)Act-1986.
And whereas Board has received consolidated Application No.(CtO:CCA-Fresh) 273071 and Dated 19/02/2023 for the consolidated consent and authorization(CC&A) of this Board under the provisions / rules of the aforesaid Acts Consent & Authorization is hereby granted as under.

CONSENT AND AUTHORISATION : (under the provisions / rules of the aforesaid environmental acts)

To,
M/s. Asence Pharma Pvt. Ltd.,
Survey nos. 591, 592, 593, 594, 595/A, 596, 597, 598, 606, 607, 608, 609/A, 610/A, 611/A, 612/A, 613,
City : Ranoli,
Dist : Vadodara, Tal : Vadodara, SIDC : PCC Area
Phone : —

1. Consent Order No: AWH-126817 Valid Upto: 31/12/2027

2. All Conditions under the AIR ACT-1981 WATER ACT-1974 HAZARDOUS ACT-2008 shall be Applicable to you as mentioned in the detailed Consent Order ***
   Consented CETP: Not Linked to any CETP
   Consented TSDF: Not Reed with any TSDF

3. GENERAL CONDITIONS :-

a) This order is provisional order and detailed order is considered as final.
b) All the conditions & provisions under the Water Act 1974, the Air Act 1981 and the Environment (Protection) Act – 1986 and the rules made there under shall be complied with *.
c) All the conditions & provisions under the Hazardous Waste (Management, Handling and Trans boundary Movement) Rules 2008 as amended shall be complied
d) The applicant shall provide portholes, ladder, platform etc at chimney(s) for monitoring the air emissions and the same shall be open for inspection to/and for use of Board's staff. The chimney(s) vents attached to various sources of emission shall be designed by numbers such as S-1, S-2, etc. and these shall be painted/ displayed to facilitate identification.
e) The industry shall take adequate measures for control of noise levels from its own sources within the premises so as to maintain ambient air quality standards in respect of noise to less than 75dB(A) during day time and 70dB(A) during night time. Daytime is reckoned in between 6 a.m. and 10 p.m. and nighttime is reckoned between 10 p.m. and 6 a.m.
f) In case of change of ownership/management the name and address of the new owners/ partners/ directors/ proprietor or equipment or working conditions as mentioned in the consents form / order should immediately be intimated to the Board.
g) Industry shall have to display data outside the main factory gate with regard to quantity and nature of hazardous chemicals being handled in the plant, including waste water and air emissions and solid hazardous wastes generated within the factory premises.
h) The CCA shall be produced for inspection at the request of an officer authorized by the Gujarat Pollution Control Board.
i) Any unauthorized change in personnel, equipment or working conditions as mentioned in the CCA order by CCA holder shall constitute a breach of this CCA.
j) Adequate plantation shall be carried out all along the periphery of the industrial premises in such a way that the density of plantation is atleast 1000 trees per acre of land and a green belt of 5 meters width is developed.
K) The applicant shall have to submit the returns in prescribed form regarding water consumption and shall have to make payment of water cess to the Board under the Water Cess Act- 1977.

*** Note : ACT-Specific, Industry-specific, Area-specific Conditions alongwith Product, Waste water effluent details shall be precisely mentioned in the DETAILED Consent Order.

*** Note :This is only provisional communication. The final Consent/Authorization in hard copy with duly signed by competent authority shall the final and valid Consent/Authorization.

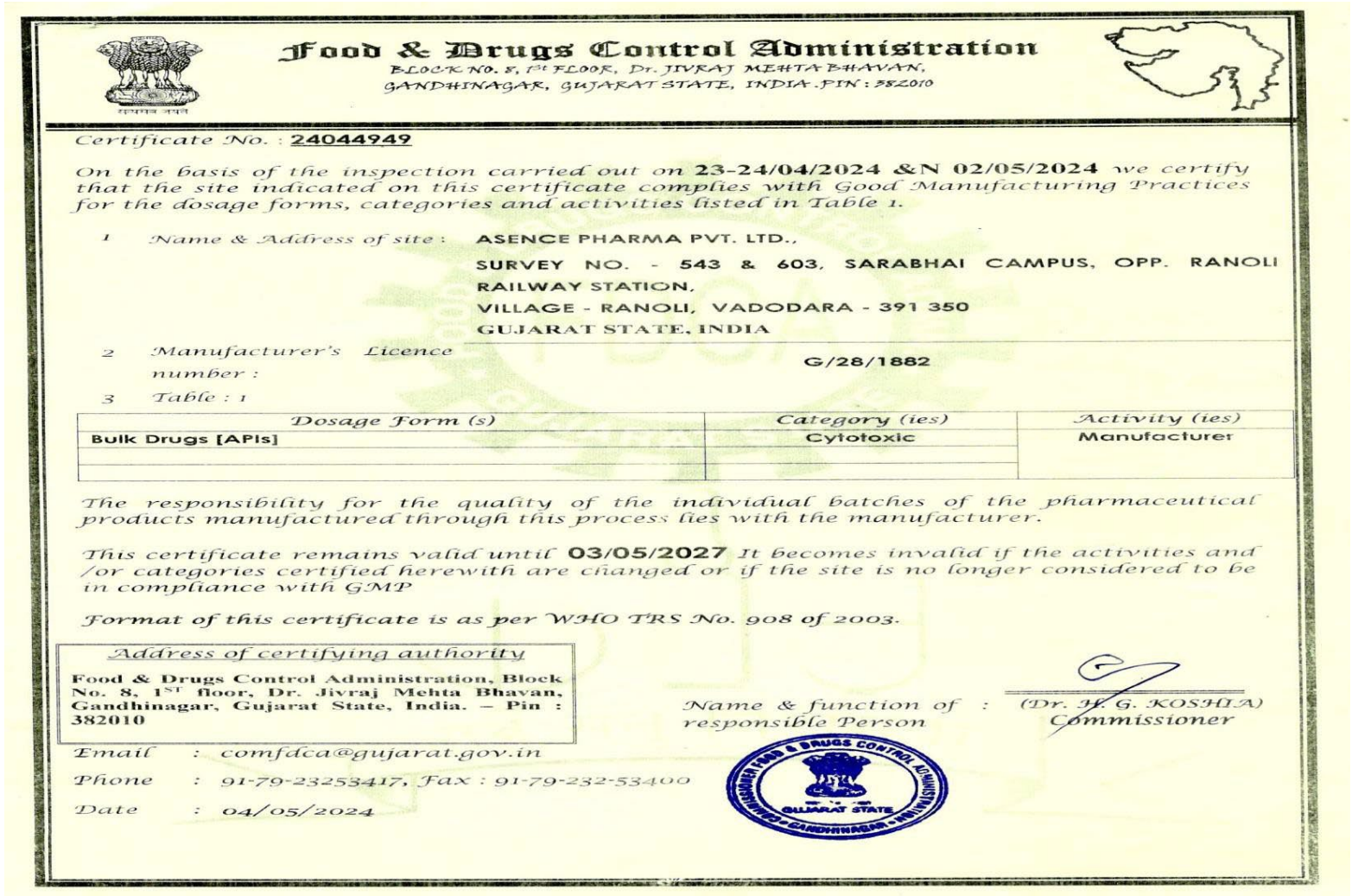
For and on behalf of
Gujarat Pollution Control Board

D. M. Thaker.

(Member Secretary)

Printed On : 07/06/2023 Computer generated Order thru XGN, does NOT require Physical Signature N I C

WHO GMP Certificate For Hydroxyurea



Food & Drugs Control Administration

BLOCK NO. 8, 1ST FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA .PIN : 382010

Certificate No. : 24044949

On the basis of the inspection carried out on **23-24/04/2024 &N 02/05/2024** 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.

1 Name & Address of site : **ASENCE PHARMA PVT. LTD.,**
SURVEY NO. - 543 & 603, SARABHAI CAMPUS, OPP. RANOLI RAILWAY STATION,
VILLAGE - RANOLI, VADODARA - 391 350
GUJARAT STATE, INDIA

2 Manufacturer's Licence number : **G/28/1882**

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Bulk Drugs [APIs]	Cytotoxic	Manufacturer

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 **03/05/2027** 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

Format of this certificate is as per WHO TRS No. 908 of 2003.

Address of certifying authority

Food & Drugs Control Administration, Block No. 8, 1ST floor, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujarat State, India. – Pin : 382010

Email : comfdca@gujarat.gov.in

Phone : 91-79-23253417, Fax : 91-79-232-53400

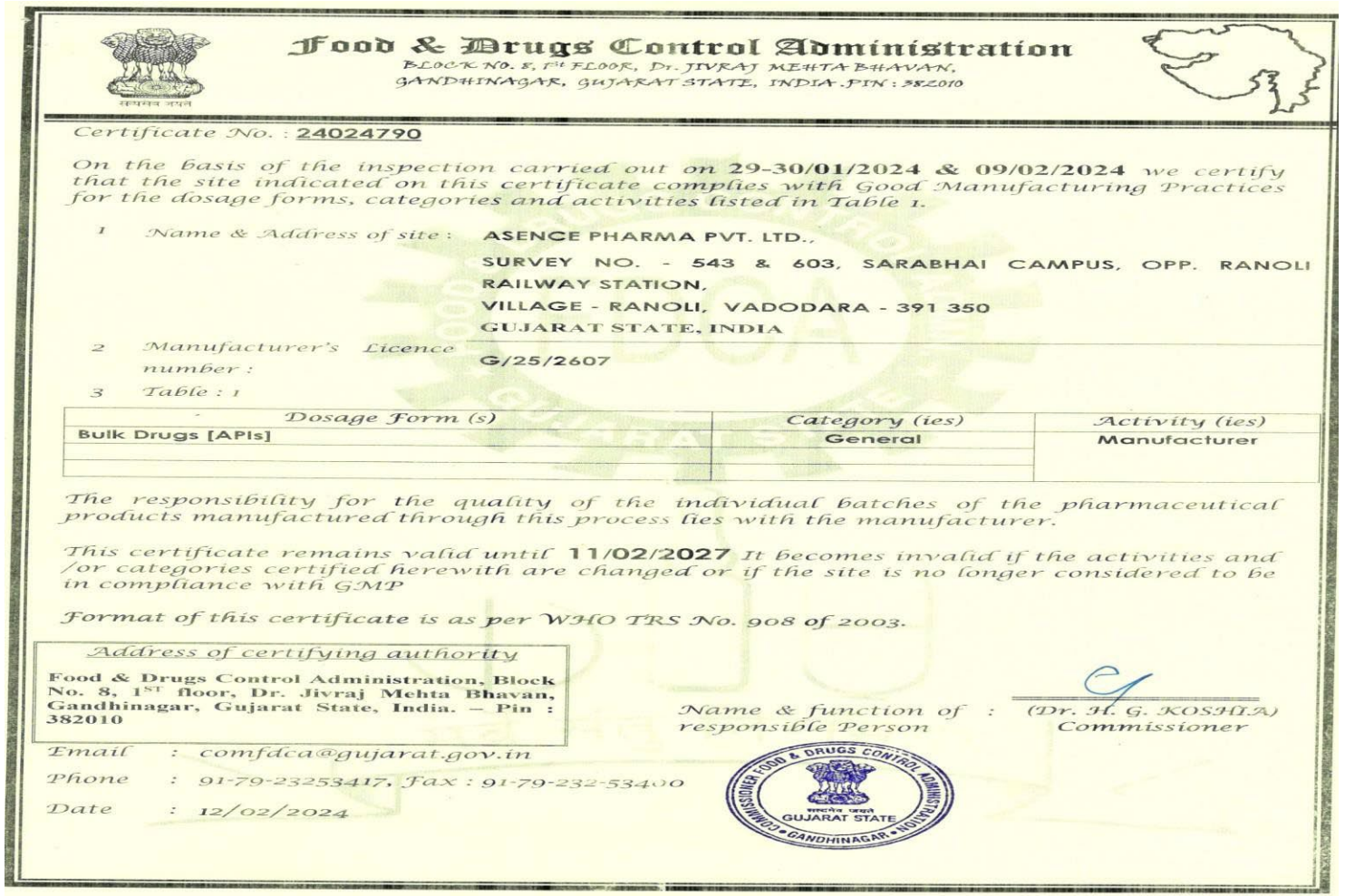
Date : 04/05/2024

Name & function of responsible Person : (Dr. H. G. KOSHIA) Commissioner

FOOD & DRUGS CONTROL ADMINISTRATION GUJARAT STATE GANDHINAGAR

Applied For Written Confirmation for EU GMP Certificate For Hydroxyurea/ Hydroxycarbamide

WHO GMP Certificate For General APIs



Food & Drugs Control Administration

BLOCK NO. 8, 1ST FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA. PIN : 382010

Certificate No. : 24024790

On the basis of the inspection carried out on **29-30/01/2024 & 09/02/2024** 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.

1 Name & Address of site : ASENCE PHARMA PVT. LTD.,
SURVEY NO. - 543 & 603, SARABHAI CAMPUS, OPP. RANOLI RAILWAY STATION,
VILLAGE - RANOLI, VADODARA - 391 350
GUJARAT STATE, INDIA

2 Manufacturer's Licence number : G/25/2607

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Bulk Drugs [APIs]	General	Manufacturer

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 **11/02/2027** 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

Format of this certificate is as per WHO TRS No. 908 of 2003.

Address of certifying authority

Food & Drugs Control Administration, Block No. 8, 1ST floor, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujarat State, India. – Pin : 382010

Email : comfdca@gujarat.gov.in

Phone : 91-79-23253417, Fax : 91-79-232-53400

Date : 12/02/2024

Name & function of responsible Person : (Dr. H. G. KOSHIA) Commissioner

COMMISSIONER FOOD & DRUGS CONTROL ADMINISTRATION GUJARAT STATE GANDHINAGAR

Applied For Written Confirmation for EU GMP Certificate For Crotamiton

CONTACT DETAIL

- Registered Office : Asence Pharma Pvt.Ltd
  Asence House , Gorwa Road
  Vadodara – 390 023.
  Gujarat (INDIA)
  Phone : +91 265 2283178
- Manufacturing Facility : Survey No 543, 603, Sarabhai Campus,
  Opp. Ranoli Railway Station, Ranoli,
  Vadodara - 391350. , Gujarat (INDIA)

➢ Contact person : Ms. Trupti Shah-----tshah@asence.com (Export Mkt.)
Mr. Sunil Pandya -- spandya@asence.com (Quality)

➢ Web site : www.asence.com

Thank You…