



Welcome...

**VALAJI PHARMA
CHEM**

Brief Overview:

VALAJI PHARMA CHEM

Promoted By : Mr. Mahesh S. Patel

Nature Of Business : Bulk drug manufacturing in domestic & export market

Address : Plot No. 475, Post luna,
Taluka : Padara, Vadodara -391440

Established : Year 2010

Corporation year : Year 2012



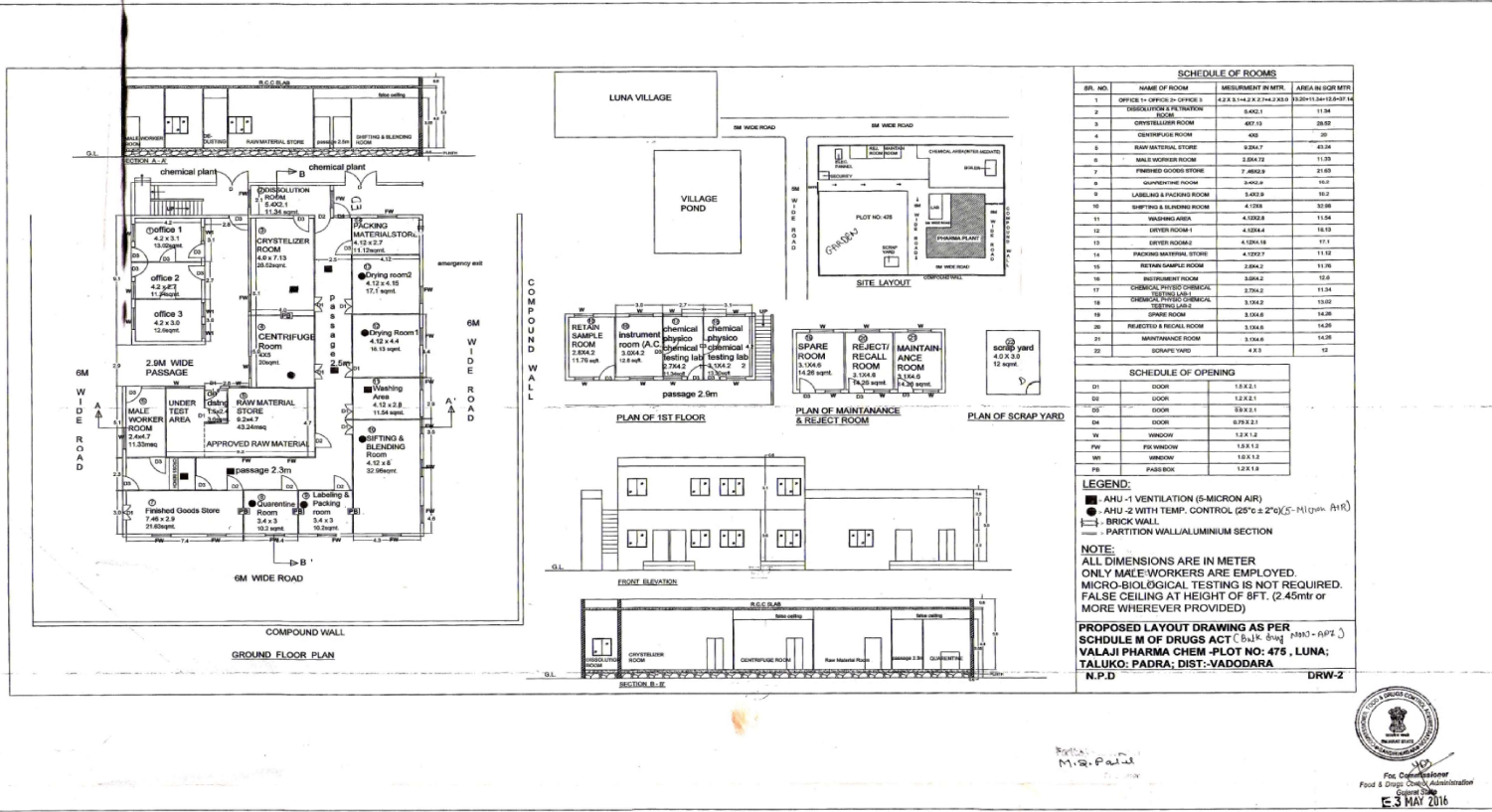
About Valaji Pharma Chem

- A Pharmaceutical bulk drug unit situated at Luna, Padra in Gujarat State.
- Located at Industrial zone in pollution free surrounding.
- Vadodara is large & ever growing commercial hub in western India well known for Banyan Trees, Cultural Activities.
- Nine pharmacy colleges are present in vicinity of 10 miles area and the prominent center for education

Plant LayOut

34

06/4



Total site area : 40000 sq. ft
Built up area : 15000 sq. ft.



Plant Premises :



Quality Policy

We at VALAJI PHARMA CHEM are committed to -

- ② To ensure that every product manufactures and Distribution with consistent Quality, efficacy & safety with present standards.
- ② Excellence in products, process and systems is to be achieved through the team effort of trained personnel of the Company.
- ② Implementation of the quality policy is done through quality system based on current good Manufacturing practices in conformity with national and international Standards.
- ② To provide best quality service to our customers.
- ② Quality is a collective responsibility.

Our Vision:

- To be a leading pharmaceutical bulk drugs [API] and Intermediates manufacturing company in India. To become a significant global player by innovative technology and providing high quality, cost effective and affordable products.

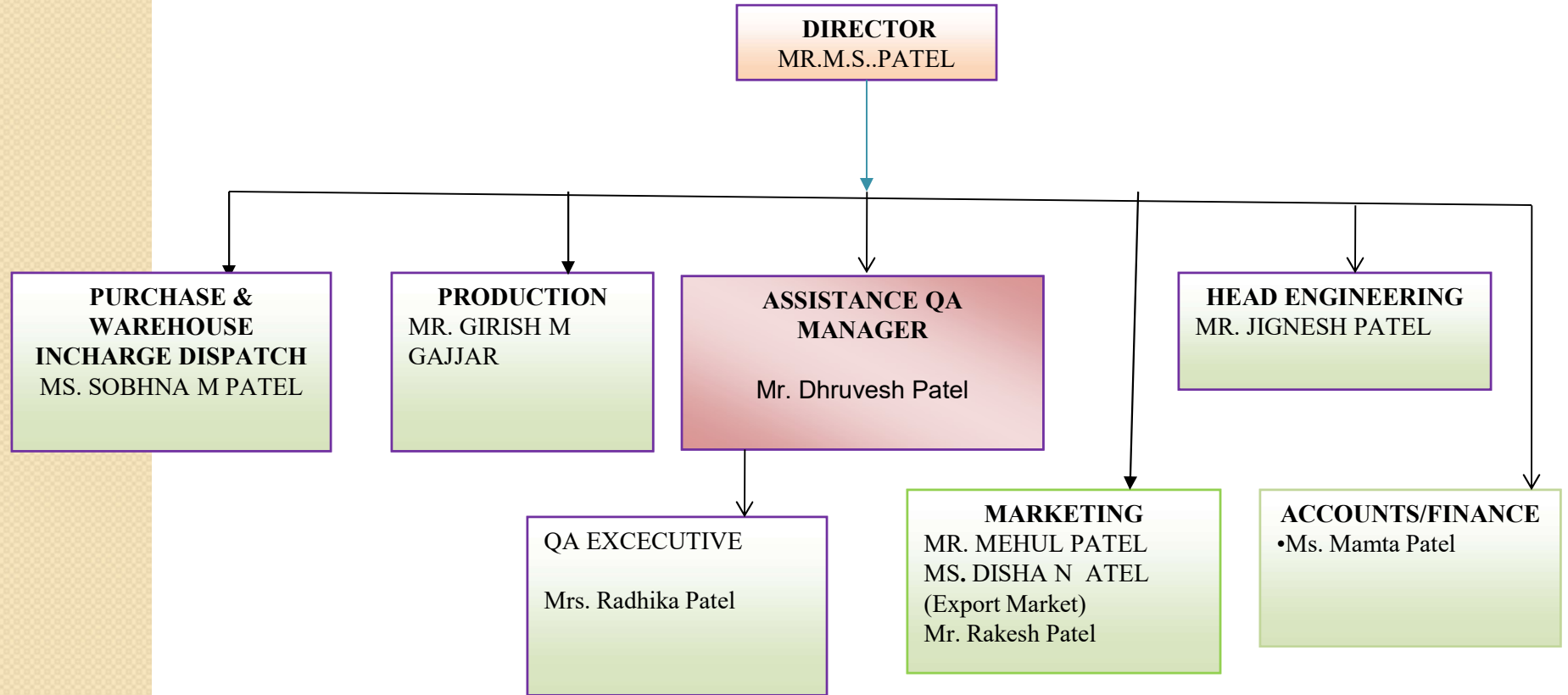


Our Mission

- To Be the leading manufacturer of API's & intermediate inputs through adoption of State of the Art and Innovative process technology.
- To be get sustainable economic growth based on excellence manufacturing technology driven by ethical business practices, professionalism & dynamism
- To develop, manufacture and market of Active Pharmaceutical Ingredients following cGMP standards, which will help to improve the health of Human Life.
- To create value and respect for all our customers, Suppliers, partners, and employees while applying environmentally safe and socially responsible business practices.
- To provide Consistent Quality, Timely delivery and competitive price to the customers.

ORGANOGRAM

Organization Chart



ACCRIDATION AND CERTIFICATION

- @ Manufacturing
Lisence Valid up to 09/05/2022
- @ ISO 9001:2008 Valid up to 07/08/2019
- @ FSSAI Valid up to 25/10/2021
- @ GMP(state) Valid up tp 08/10/2019
- @ GLP (state) Valid up to 08/10/2019
- @ FSSC 220000 Valid up to 10/09/2022
- @ HACCP Valid up to 10/09/2022

Certification & Accreditation



FRESH LICENCE


FORM 25

(See Rule 70)

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

Number of licence and date of issue G/25/2197 Date- 10/05/2017

- Mr. MAHESHBHAI SANABHAI PATEL, PROPRIETOR of M/s. VALAJI PHARMA CHEM is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in Scheduled C, C(1), and X to the Drugs & Cosmetics Rules, 1945, on the premises situated at PLOT NO. 475, AT & POST -LUNA, TAL - PADRA, DIST- VADODARA - 391 440.
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 As Per List Approved & Annexed
(each item to be separately specified)
- The licence authorizes 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.
- The licence shall be in force From: 10/05/2017 To 09/05/2022
- 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 : _____
 Designation : Commissioner
Food & Drugs Control Administration
Gujarat State.

Date:- 10/05/2017

Conditions of Licence

- 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.
- Any change in the (competent technical staff) named in the licence shall be forthwith reported to the Licensing Authority.
- 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.
- 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.

FDC/GUJARAT/25/987


Food & Drugs Control Administration
 BLOCK NO. 8, 1ST FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
 GANDHINAGAR, GUJARAT STATE, INDIA. PIN: 382010
 

Certificate No. : S-GMP/1710409

G.M.P. CERTIFICATE


This is to certify that M/s. VALAJI PHARMA CHEM, PLOT NO. 475, AT & POST - LUNA TAL- PADRA, Dist VADODARA - 391 440 is holding valid drug manufacturing licenses in Form No. 25 bearing No. G/25/2197 issued by this administration under the provisions of Drugs & Cosmetics Act 1940 & Rules there under. Under the said licenses the firm is permitted to manufacture & sell drugs covered under the following categories.


Dosage Form (s)	Category (ies)
Bulk Drug (Non - APIs)	General

The firm has employed competent technical staff to undertake manufacturing & testing of the permitted drugs. They are following GOOD MANUFACTURING PRACTICES in manufacturing and testing as laid down under the REVISED SCHEDULE-M of Drugs & Cosmetics Act 1940 & Rules There under.

The manufacturing plant is subjected to inspection at suitable intervals by competent authority.

This certificate is valid from Dt : 09/10/2017 to 08/10/2019.



(R. L. VAISHYA)
 Commissioner
 Food & Drugs Control Administration
 Gandhinagar, Gujarat State
 

Email : comfdca@gujarat.gov.in
 Phone : 91-79-23253417, Fax : 91-79-232-53400



Certificate of Registration

This is to certify that

Valaji Pharma Chem

Factory & Office: Plot No. 475, P.O. Luna, Ta. Padra, District Vadodara - 391440 (Gujarat), India.

has been assessed by RICL and found to comply with the requirements of

ISO 9001 : 2008 Quality Management System

For the following activities:
Manufacturer & Exporter of Fine Chemicals

This Certificate is Valid from 08/08/2016 Until 07/8/2017

Date of Initial Certification: 08/8/2016
1st Surveillance on or before: 07/07/2017
1nd Surveillance on or before: 07/07/2018
Certification Valid Until: 07/08/2019

Certificate No.:
16RQ08AP



Director
Royal Impact Certification Ltd.
Certificate details entered into JAS-ANZ register on 08/08/2016
203, II Floor, R - 19, Aruna Park, Shakarpur, New Delhi - 110092, India.
www.isointernational.org, info@isointernational.org
Phone : + 91 - 11 - 42418770

This Certificate can be verified at: www.isointernational.org and www.jas-anz.org

MS4009131N

This Certificate remains the property of Royal Impact Certification Limited. Must be returned on request or if certificate is withdrawn. Validity of this certificate is subject to successful surveillance audits. RICL is accredited by JAS-ANZ, URL of Joint Accreditation System of Australia & New Zealand- www.jas-anz.org/register

भारत सरकार
Government of India
भारतीय खाद्य संरक्षा एवं मानक प्राधिकरण
Food Safety and Standards Authority of India



खाद्य संरक्षा और मानक अधिनियम, 2006 के अधीन अनुज्ञप्ति
License under Food Safety and Standards Act, 2006

अनुज्ञप्ति संख्या / License Number : **10016021002354**

- | | |
|---|--|
| 1. अनुज्ञप्तिधारी के पंजीकृत कार्यालय का नाम और पता
Name & Registered Office Address of Licensee | VALAJI PHARMA CHEM
Plot.No. 475, P.O. Luna, Taluka-Padra, Dist. Vadodara -
391440,Vadodara(Gujarat), -391440 |
| 2. प्राधिकृत परिसरो का पता
Address of Authorized Premises | Plot.No. 475, P.O. Luna, Taluka-Padra, Dist. Vadodara -
391440,Vadodara(Gujarat), -391440 |
| 3. कारोबार का प्रकार / Kind of Business | Manufacturer |
| 4. डेयरी कारोबार विवरण हेतु / Dairy Business Details | N.A. |
| 5. अनुज्ञप्ति का वर्ग / Category of License : | Central |

यह अनुज्ञप्ति खाद्य संरक्षा और मानक अधिनियम, 2006 के अधीन अनुदत्त की गई और वह अधिनियम के उपबंधों के अन्वये ही मिनका अनुज्ञप्तिधारी द्वारा अवश्य पालन किया जाना चाहिए / This license is granted under and is subject to the provisions of FSS Act, 2006 all of which must be complied with by the licensee.



Sheetal Gupta
(Dr. Sheetal Gupta)
(Designated Officer)

Stamp and signature of Designated Officer

स्थान / Place : Mumbai
दिनांक / Date : 26/10/2016

डॉ. सं. और मा. अति., 2006 के अधीन केंद्रीय अनुज्ञापन अधिकारी
Central Licensing Authority under FSSA, 2006

सिध्दमान्यता और नवीनीकरण / Validation And Renewal

License Issue / Renewal Date	Period of validity	License Fee Paid	Items of Food products with capacities authorized to Manufacture/ Re-pack/ Re-label	Installed handling Capacity	Signature Of Designated Officer
26/10/2016	25/10/2021	Rs. 37500	Please refer to annexure.	Please refer to annexure.	<i>Sheetal Gupta</i>

Disclaimer-This License is only to commence or carry on food businesses and not for any other purposes.

Sheetal Gupta
DESIGNATED OFFICER
Food Safety & Standards Authority of India
Ministry of Health & Family Welfare,
Western Region, Mumbai - 51.



Certificate of Registration

This is to Certify that

Valaji PharmaChem

Plot. No. 475, P. O. Luna, Tal: Padara, District Vadodara, (Gujarat), India.

has been assessed by RSBV and found to comply with the requirements of

FSSC 22000

(Certification scheme for Food Safety System Including ISO 22000:5000, ISO/TS 22000-1:2009 as well as additional FSSC 22000 requirements)

For The Following Scope:

Manufacture and Supply of Mineral Fortifiers, Nutritional Supplements & FCC Grade Minerals for Food Industries.

Datum Van Publicatie / Date of Issue : 11/09/2019
Vervaldatum / Date of Expiry : 10/09/2022
1st Annual surveillance audit due on : 10/08/2020
1Ind Annual surveillance audit due on : 10/08/2021

Director (Certification)

Royal Stancert B.V.

Factelijke Beoordelingen - Wereldwijde Beoordelingen

Certificaat Nummer / Certificate No. : F-BV-1909-1876

Regd. Office - Joop Geesinkweg 701, 1114 AB Amsterdam, The Netherlands.
(KvK-Nummer 71431802 / RSN 858713159 - Rechtsvorm - Besloten Vennootschap).

This certificate remains the property of Royal Stancert B.V. and must be returned whenever demanded. The validity of this certificate can be verified at <http://www.royalstancert.nl>. Royal Stancert B.V. is an independent system, product and personal assessment body accredited by Global Euro Accreditation Centre, Georgia. (GCIN - 654). Email: info@royalstancert.nl



PAC-GEAC-1506-299



Certificate of Registration

This is to Certify that

Valaji PharmaChem

Plot. No. 475, P. O. Luna, Tal: Padara, District Vadodara, (Gujarat), India.

has been assessed by RSBV and found to comply with the requirements of

HACCP

(Hazard Analysis & Critical Control Points)

For The Following Scope:

Manufacture and Supply of Mineral Fortifiers, Nutritional Supplements & FCC Grade Minerals for Food Industries.

Datum Van Publicatie / Date of Issue : 11/09/2019
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PAC-GEAC-1506-299

PRODUCTION CAPACITY

- ✓ **Single Product Based : 100-125 Mt. Ton Per Month**
- ✓ **Production Capacity Varies as per the Product Portfolio Requirement For Multiple Products**

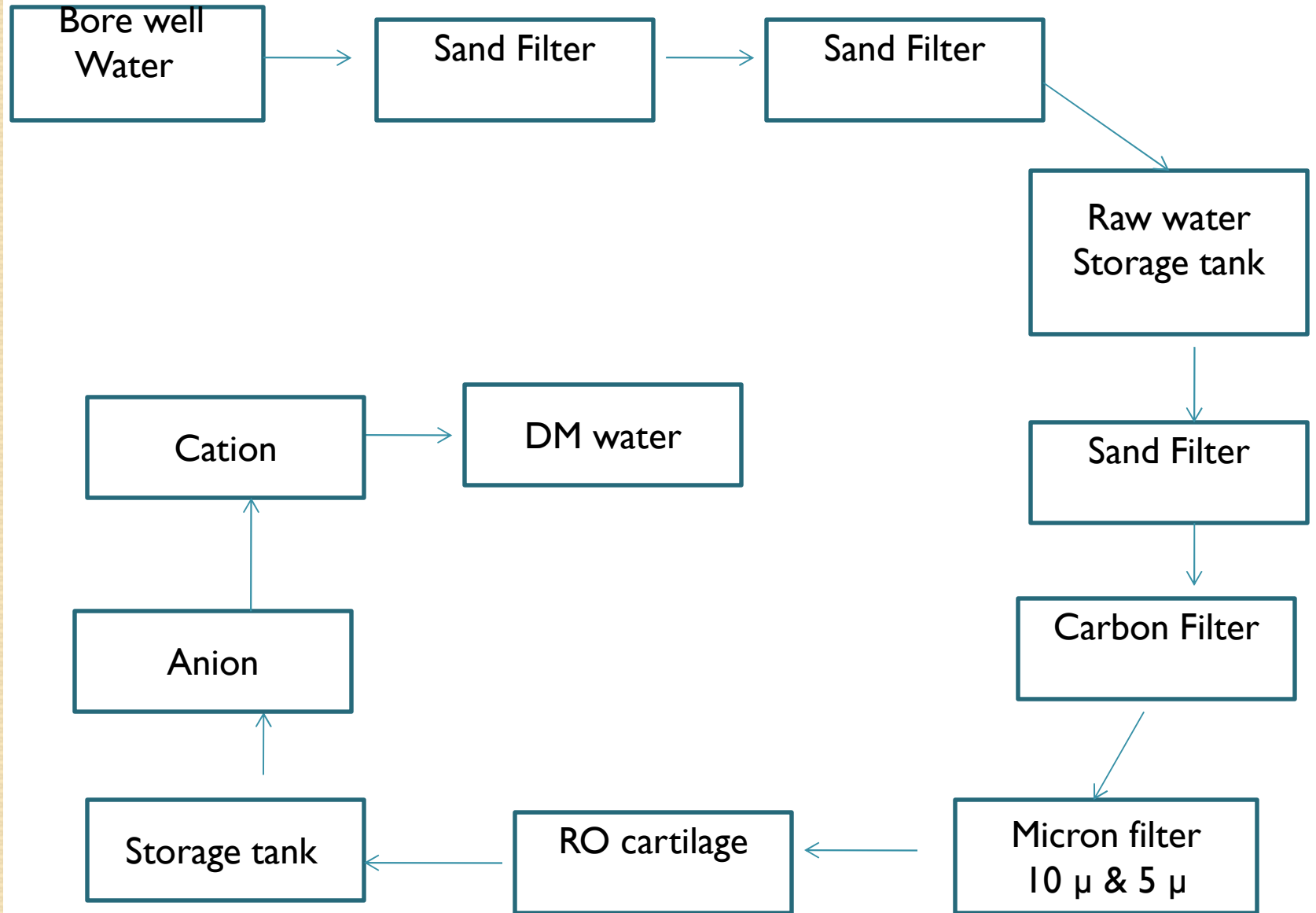
Facility Tour

- Valaji phartilation sma Chem is facilitated with ventilated system to provide clean environment to valuable products
- The system consists of 05 Air Handling Units housed at service floor.
- A typical AHU is comprised of a Mixing Chamber, Filter section (pre filters 10 μ , Intermediate filter 5 μ), cooling section, & fan section. The air from the fan section is distributed to room through closed circuit in Galvanised sheet steel ducts, which are insulated with cross-linked closed cell polyethylene insulation laminated with metalized pre – laminated foil. All duct joints have RTV silicon sealant

Water System

- Water for manufacturing purpose uses DM water, it is provided by a Shree ram water supply, Luna, Padra. (approved vendor)
- The vendor has facilitated with bore water supply .Also providing on-site underground water storage tank. Before use of this water for manufacturing purpose, pass the water through De-mineralized water system to produced purified water.
(Capacity 4000 liters per hour)
- De-mineralized water plant is equipped with ion exchange resin bed like, cation exchange resin bed, anion exchange resin bed; mixed bed and cartridge filter to ensure freedom from Dissolved solids. Finally pass the DM Water through UV light chamber to ensure free from microbial contamination

- **Water system schemetic diagram**



UTILITY:

- * Power supply 250 HP connection from GEB grid. Continues Process industry licence to supply continuous power from Gujarat State.
- * Boiler Capacity : 2000 Kgs
- * Air Compressor : 100 CFM
(Oil Free) Pressure 12 kg./cm²
Terminal Filters of 5 micron

Quality Control Tour

- ✧ Independent Quality Control Section
- ✧ Separate From Production Area
- ✧ Segregated Sections For
 - ✧ Instrumentation
 - ✧ Chemical Analysis
- ✧ Qualified And Trained Staff
- ✧ Sophisticated Instruments
 - ✧ Analytical balance (symadzu)
 - ✧ pHmeter (analab)
 - ✧ Conductivity meter
 - ✧ KF content
 - ✧ Stability Chamber
 - ✧ Calibration And Qualification Activities Under
- ✧ Written Procedures For Handling
 - ✧ Solvents, Reagent
 - ✧ Working Standards
 - ✧ Retain Samples
- ✧ Stability Studies Carried For All Process Validation Batches of Product And Thereafter Annually One Batch.



Production department

- Production operations follow clear procedures from Master Formula Cards in accordance with manufacturing and customer requirements, with the objective of obtaining products of requisite quality. Written instructions for operation of various equipments are available to workmen at the place of work
- Production department is facilitate with the following latest technology equipment .
- Access to production premises are restricted to authorized personnel.
- Cross contamination is avoided by appropriate technical and organizational measures,
 - such as:
 - Segregated processing areas such as milling, pulverization etc.
 - Provisions of air exhaust
 - Use of cleaning and decontamination procedures of known effectiveness
 - Use of cleanliness status labels on equipment
 - Allocation of workforce to specific area

Equipment detail

Sr no.	Name of equipment	specification	Make	Nos.
1	Fluid bed dryer (FBD)	150 KG GMP MODEL	Kothari ENG	VFBD-1
2	Centrifuge	ss-316 GMP MODEL	Kothari ENG	VCF-1
3	Sparkler filter	ss-316 GMP MODEL	Kothari ENG	VSF-1
4	Blender	ss-316 GMP MODEL 1200 KG	Kothari ENG	VBLR-1
5	MULTI MILL	ss-316 3 HP MOTER	Kothari ENG	VMM-1
6	VIBRO SHIFTER	ss-316	Kothari ENG	1VVSF-1
7	REACTOR	---	Amar eng.	VR-1

List of Testing Contractor (Govt. FDA Approved):

1) Baroda Analytical services

Lic. No.: GTL/37/32
78/2/3 GIDC, Makarpura,
Vadodara- 390 010

2) Aum research lab

Lic. No.: GTL/37/27
Block No.: 843/P/3, Opp. Amardeep Plastics
Rakanpur Village Road, Rakanpur-382721
Ta : Kalol, Dist : Gandhinagar (Gujarat)

SALIENT FEATURES OF THE PLANT

- ✚ Plant located in pollution free surrounding
- ✚ Facility for Bulk Drugs manufacturing
- ✚ Air Handling Units for effective segregation of processes and products
- ✚ Serving multinational & big Indian companies
- ✚ Practicing GMP – way of working
- ✚ Plant inspection is carried out by International and National Health Agencies
- ✚ Approval of GMP, FSSC 22000, ISO certification

