

KOMAL INDUSTRIES

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COMPANY PROFILE

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1. INTRODUCTION

Formed in 1975, Komal has steadily grown to become one of the leaders in the field of water purification. The company consists of interdisciplinary teams consisting of chemical, electrical, electronics, mechanical engineers and chemists. Our office is located at Lower Parel, which is in the heart of the city of Mumbai, India. Our plants are manufactured at Kandivali and Dombivali, which are situated in the suburb of Mumbai. We have total working force of around 50 people that include engineers, service technicians and workers. The total working area of around 5000 sq. ft is available in both our factories.

Komal's rapid growth has been a result of focus on technological innovation through continuous R&D and through affiliations through some of the best water treatment companies in the world. Through a round-the-year training program for the employees aimed at acquainting the employees with the latest technological breakthroughs. An above all, with an "outside-in philosophy" which allows us to stay close to the customer to satisfy his needs and anticipate his wants.

Komal delivers customer value by improving quality and the performance of the product and by reducing operating costs and extending equipment life in a broad range of products and services. These products and services are used to optimize total water/process system performance, safeguard customer assets from corrosion, fouling and scaling, and protect the environment through water and energy conservation.

Expertise:

Komal with more than 25 years of experience behind it is equipped to help Industrial customers meet their operational, environmental and profitability goals.

We understand the following needs of the industry:

- * Assurance of on-time supply
- * Quality and regulatory compliance
- * Prompt service
- * Competitive cost
- * Innovation for continuous process improvement

2. CLIENTELE

Komal is equipped with a strong team of design specialists, chemists and service technicians to meet and exceed these needs within the pharmaceutical industry. We understand the strict standards required, and we pride ourselves in helping our customers succeed.

Some of our customers in the pharmaceutical industry are as follows:

* M/S. Associated Capsules Ltd.	Mumbai
* M/s. Aristo Pharmaceuticals Ltd.	Daman
* M/s. Aristo Laboratories Ltd.	Daman
* M/s. Ajanta Pharma Ltd	Aurangabad / Paithan
* M/s. Arti Lab Chem Pvt. Ltd.	Thane
* M/s. Bharat Serum & Vaccines Ltd.	Mumbai
* M/s. Bengal Chemicals & Pharma. Ltd.	Kanpur
* M/s. Blue Cross Lab Ltd.	Nashik
* M/s. Benzo Chemical Ind. P. Ltd.	Boisar
* M/s. Blue Cross Lab Ltd.	Goa
* M/s. Cadila Lab Ltd.	Ahmedabad
* M/s. Camlin Ltd. (Pharma Div.)	Mumbai/Nashik
* M/s. Charak Pharma Ltd.	Umargaon
* M/s. Colour Con Asia P. Ltd.	Mumbai
* M/s. Cheryl Lab Ltd.	Goa
* M/s. Elder Pharma Ltd.	Mumbai
* M/s. Elder Healthcare Ltd.	Mumbai
* M/s. Elder Projects Ltd.	Mumbai
* M/s. Eastern Medikit Pvt. Ltd.	Delhi
* M/s. Glenmark Pharma Ltd.,	Goa/Nashik
* M/s. Gujarat Lyka Ltd	Ankleshwar
* M/s. Geno Pharmaceuticals	Goa
* M/s. Group Pharma P. Ltd.	Mumbai
* M/s. IPCA Lab Ltd	Ratlam
* M/s. Khandelwal Lab Ltd.	Daman/Mumbai
* M/s. Konarak Textile Ind. P. Ltd.	Tarapur
* M/s. Lyka Lab Ltd	Tarapur/ Ankleshwar
* M/s. Makjai Laboratories Ltd.	Kolhapur
* M/s. Maneesh Pharma Ltd	Mumbai
* M/s. Mark Medicines Pvt. Ltd.	Gurgaon
* M/s. Mepro Pharmaceuticals Ltd.	Suredranagar
* M/s. Mehta Pharmaceuticals P. Ltd	Vasai
* M/s. Mangalam Drugs & Organics Ltd.	Vapi
* M/s. Norrish Medicines Ltd.	Ankleshwar
* M/s. Nandu Chemical Ltd.	Hubli
* M/s. Nicholas Piramal India Ltd.	Mahad
* M/s. Rhone Poulence I Ltd	Mumbai
* M/s. Sevak Pharma Ltd.	Palghar/Vapi/Tarapur

*M/s. Swift Chemical P. Ltd.	Mumbai
*M/s. Sapphire Capsule	Mumbai
*M/s. Sun Pharma Ltd.	Vapi/Baroda
*M/s. Sandu Pharma Ltd.	Goa
*M/s. Sigma Laboratories Ltd.	Goa
*M/s. Sterling Geletin Ltd.	Baroda
*M/s. Sidmak Laboratories Ltd.	Valsad
*M/s. Suyog Pharmaceuticals P. Ltd.	Tarapur
*M/s. S. Kant Healthcare Ltd.	Daman
*M/s. Syntho Pharmaceuticals Pvt. Ltd.	Lucknow
*M/s. Techno Drugs & Intermediates P. Ltd.	Bharuch
*M/s. Unichem Lab Ltd.	Mumbai/Ghaziabad
*M/s. US Vitamin Ltd.	Mumbai
*M/s. Zandu Pharma Ltd.	Vapi
*M/s. Ally Pharma Options P. Ltd.	Tarapur
*M/s. Corel Lab. Ltd.	Daman
*M/s. Fresenius Kabi Ltd.	Ranjangaon
*M/s. Sparsh Biotech Ltd.	Rajkot
*M/s. Supriya Pharma Ltd.	New Delhi
*M/s. Ozone Pharmaceuticals P. Ltd.	Baddi
*M/s. Centaur Pharmaceuticals Ltd.	Goa
*M/s. Brasica Pharma & Chemicals Ltd.	Goa
*M/s. Shreya Life Sciences Ltd.	Aurangabad

GOVT./SEMI GOVT.

- *M/s. Airport Authority Of India
- *M/s. Gail India Ltd.
- *M/s. Ammunition Factory
- *M/s. Isro
- *M/s. Bharat Heavy Electric Co.
- *M/s. Currency Note Press
- *M/s. Shar Centre
- *M/s. Atomic Energy - (indore)
- *M/s. Isro - Shriharikota
- *M/s. Gas Authority Of India - Surat
- *M/s. Hindustan Petroleum Co. Ltd.
- *M/s. Indian Airlines
- *M/s. Haffkin Bio Pharma
- *M/s. Msrtc

INDUSTRY

- *M/s. Hindustan Lever Ltd.
- *M/s. Godrej & Boyce Mfg. Co. LTD.

COLLEGES / INSTITUTES

- * M/s. Manipal Inst. Of Technology
- * M/s. Bhavans College
- * M/s. Bombay College Of Pharmacy
- * M/s. College Of Pharmacy (delhi)
- * M/s. Tata Institute Of Fundamental Research
- * M/s. Dbj College Chiplun
- * M/s. Dwarkadas Sanghavi College
- * M/s. K. C. College - Mumbai
- * M/s. Indian Institute Of Technology
- * M/s. Udct
- * M/s. Indian Telephone Co.
- * M/s. Institute Of Pharmacy Wardha
- * M/s. Institute Of Preventive Medicines

Laboratories

- * M/s. Analytical Solution
- * M/s. Metropolis Health Care Ltd.
- * M/s. Ura Lab.
- * M/s. Colgate Plamolive (i) Ltd.
- * M/s. Rubicon Research Pvt. Ltd.
- * M/s. Offshore Testing & Inspection Services

Dairy

- * M/s. Apna Bazar Dudha Dairy
- * M/s. Dairyfield Ltd.
- * M/s. Dairy Dev. Corporation
- * M/s. Govt. Milk Scheme - Amravati
- * M/s. Govt. Milk Scheme - Parbhani
- * M/s. Govt. Milk Scheme - Khopoli
- * M/s. Kerala Co-op Milk Marketing
- * M/s. Milk Speciality Ltd.

Hospitals

- * M/s. Shri Ambadevi Sansthan
- * M/s. Bses Mg Hopital
- * M/s. Sir Harkishandas Hospital
- * M/s. Grace Intensive Cardiac Care
- * M/s. Bombay Hospital
- * M/s. K.e.m. Hospital
- * M/s. Baccha Hospital
- * M/s. Bakubhai Nanavati Hospital
- * M/s. Nddb
- * M/s. Ashapura Chinaclay Ltd.
- * Karuna Hospital
- * Mr. Damani (Single Bed Unit)
- * Prince Aly Khan Hospital

- *Swami Sarvanand Hospital
- *Gabani Urosurgical Hospital
- *J V Parekh Charitable Trust
- *Dr. Rajendra Mahajan Memorial Hospital
- *Dr. Chowdhry Hospital
- *Sai Vilaytrai & Sai Jiwatrai Hospital
- *Sushrut Hospital
- *Shri Kandivli Hitwardhak Hospital
- *Shri Sardar Smarak Hospital , Bardoli
- *Muslim Ambulance Hospital
- *Hitech Hospital Kolhapur - (dm)
- *Lancelot Medical Centre - (dm)
- *Saraswati Hospital & Advance Medical Centre - (dm)
- *Cardinal Grasis Hospital - (dm)
- *Sri Shanmukhanand Fine Arts & Sangeetha Sabha
- *Sarvanand Hospital - Ulhasnagar
- *Dr. Basarge's Hospital
- *St. Elizabeth's Hospital
- *Dr. Joshi - Kolhapur
- *Ohm Critical Care Centre - Dhule
- *Fauziya Maternity Nursing Home
- *Dr. Dedia (parakh Hospital)
- *Nulife Hospital - Ghatkopar
- *Shraddha Hospital - Lonavla

Pharmaceutical production demands reliable, consistent performance. As a vertically-integrated company in the water purification industry, Komal is uniquely qualified to design and manufacture complete, cost-effective systems that offer "single-source" assurance. Since we manufacture most of the major components, you can count on the highest quality system available.

Pharmaceutical Water Systems are designed to work together to provide reliable and worry-free operation. Our experienced engineers and project managers oversee the design of the system, material procurement, component assembly, and validation documentation. The end result is a completely valid table system that meets USP/ IP / EP / BP criteria.

3. VALIDATION

Buying from a sole source also simplifies validation. Komal supplies pharmaceutical equipment with a comprehensive validation support package including documentation that may be used for your equipment qualification (EQ), installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ). The recommended operating ranges for each component are provided to establish alert and action limits. These recommended operating limits should be an integral part of the action plans in the OQ. Komal supports the customer during the PQ phase of validation by scheduling periodic visits or teleconferences to review the validation process.

VALIDATION SUPPORT

To support your validation process Komal can supply:

- * Operation and maintenance manuals
- * Instrumentation calibration certificates
- * NIST certification
- * Surface finish certificates
- * Material certifications
- * Certified electronic and paper copies of drawings
- * Inspections to verify the accuracy of the as built drawings
- * Functional test reports
- * Process parameters monitoring

4. TECHNICAL SUPPORT AND SERVICE

Once the system is in operation, Komal is available to service your equipment and provide "hands-on" training, both on-site and at our training facility. Because we manufacture all of the major system components, we understand what it takes to keep the system running efficiently. Our personnel are available for on-site inspection and start-up of the equipment. During the start-up process we provide complete classroom and hands-on training sessions. System operation and preventative maintenance requirements are discussed in detail. A start-up is not complete until you are satisfied with the training we provide to your personnel.

Komal provides the level of after-sale service you expect from an industry leader:

- * Experienced field sales engineers
- * Comprehensive, custom training programs
- * Expert field service
- * Spare parts inventory
- * History of all service

5. EQUIPMENTS

KOMAL uses the latest technology in water pretreatment Reverse Osmosis, Electro Deionisation UV Disinfectant and Pyrogen removing Ultrafiltration produce highest Resistivity low TOC USP Purified water. KOMAL can offer Hot Water Sanitisation FDA accepted R.O. membrane for consistent quality and a perfect solution to prevent micro organisation growth and biofilms development in the RO System without utilizing expensive or unacceptable chemical biocides.

5.1 PRESSURE SAND FILTER

One of the most widely used filtration method is a sand filter, which utilizes sand as a filtration medium. Sand filtration filters particles down to the size of around 15 microns. The filter sand must be cleaned regularly to remove debris. Sand filter is mainly used as a pre-filter for the reverse osmosis membrane. The filtrate is normally clear with turbidity less than 1 NTU.

5.2 ACTIVATED CARBON FILTER

Activated carbon is normally used to remove organic carbon and residual disinfectants from the water supply. It not only improves taste and minimizes health hazards; it also protects the other water treatment units like reverse osmosis membranes and ion exchange resins from possible damage due to oxidation or organic fouling. Activated carbon is a favored water treatment technique because of its multifunctional nature and the fact that it adds nothing detrimental to the water.

Depending on the desired results, activated carbon may be used in powdered or granular form. Granular activated carbon is commonly used in water treatment facilities where the water is passed through a granular carbon bed to remove tastes, colors, odors, and dissolved organics. Powdered carbon also is used in treatment facilities at various points for its quicker rate in removing various contaminants.

5.3 WATER DM PLANT

Komal is one of the leader in manufacturing DM Water System. Komal can supply complete System including Prefiltration DM Plant including Mixed Bed, Microfiltration and UV Disinfectant. KOMAL has supplied more than 3500 DM Plants of various capacities for wide range of applications right from 10 lit./hr. of Ultrapure Water System to 40 m³/hr. All the plants are provided with on line Conductivity Meter.

5.4 RO-EDI

RO-EDI series of KOMAL's Reverse Osmosis Electro deionisation system are self continued FDA accepted meeting all accurate guidelines for the preparation of USP Purified water. RO-EDI units are manufactured using eGMP techniques including inspection and documentation of each

manufacturing.

5.5 UV DISINFECTANT

For the purposes of disinfection, there is no other process as effective, safe, cost efficient and sensible as ultraviolet light purification. It results in 99.9% bacteria-free water and it does so without tradeoffs. It eliminates the handling and storage of harsh and hazardous chemicals (and thus reduces costs associated with liability insurance and emergency planning). It purifies without changing water temperature or physical makeup. It assures ongoing protection of your product. Essentially, ultraviolet light energy prevents micro organisms from replicating by disrupting their DNA strands. When they can't reproduce, they die out, leaving safe, germ-free water. Within the ultraviolet band of the energy spectrum between 200 and 300 nanometers (nm) wavelength, the 250 to 260 nm range is most effective for germicidal processes, especially for destroying microorganisms, mold spores, protozoa, viruses, and yeast. Most water-borne, disease-causing microorganisms are destroyed at 254 nm using low pressure germicidal UV lamps.

KOMAL is one of the leading manufacturers of UV Disinfectant standard features of Germicidal UV for Pharma Industries

- * More than 99.8% Bacterial reduction
- * More than 9000 hr. lamp life.
- * More than 40,000 mw sec/cm UV dosage.
- * S.S. 316 UV Chamber.
- * UV Lamp Display.
- * Viton 'O' ring.
- * UV Intensity Meter
- * Sanitary fittings.
- * MCCB Protector.

5.6 UV - TOC REDUCTION

Sanitary Ultraviolet Disinfectant unit having dual wavelength lamp to destroy microorganism and TOC reduction. All the units are internally Electropolished and made from S.S. 316L quality steel. Only reliable disinfection with TOC reduction that meets strict purify criteria of high purity water.

5.7 MICROFILTRATION

Microfiltration is a process of removing impurities in the 0.1 to 10 m range from water, by passing it through a micro porous media. Before the water enters the membrane water should be free from

all the particulate matters down to 10 micron. If the water is contaminated with dirt particles pretreatment like sand filter with alum/Floculant doser is needed. Contamination with dirt particles, increases the chances of clogging of micron filters.

5.8 ULTRAFILTRATION

Ultrafiltration is a form of filtration that uses membranes to preferentially separate different fluids or ions. The primary basis for separation is molecular size although some secondary factors such as molecular shape and charge can play a role. Ultrafiltration is not as fine a filtration process as reverse osmosis, but it also does not require the same energy to perform the separation. Ultrafiltration is capable of concentrating bacteria, some proteins, some dyes, and constituents that have a larger molecular weight of greater than 10,000 Daltons. Ultrafiltration is only somewhat dependent upon the charge of the particle and is much more concerned with the size of the particle. Ultrafiltration is typically not effective at separating organic streams.

Ultrafiltration also uses a membrane that is partially permeable to perform the separation, but the membrane's pores are typically much larger than the membrane pores that are used in reverse osmosis. Consequently, it requires a lower driving force to push the fluid through the membrane.

5.9 REVERSE OSMOSIS

Reverse osmosis occurs when water is pushed through a semi-permeable membrane using external pressure. Most reverse osmosis units use a cross flow technology to allow the membrane to continually clean itself. As some of the fluid passes through the membrane the rest continues downstream, sweeping the rejected species away from the membrane. The process of reverse osmosis requires a driving force to push the fluid through the membrane, which is attained using a pump. As the concentration of the fluid being rejected increases, the driving force required to continue concentrating the fluid increases.

Reverse osmosis is capable of rejecting bacteria, salts, sugars, proteins, particles, dyes, and other constituents that have a molecular weight of greater than 150-250 Daltons. The separation of ions with reverse osmosis is aided by charged particles. This means that dissolved ions that carry a charge, such as salts, are more likely to be rejected by the membrane than those that are not charged, such as organics. The larger the charge and the larger the particle, the more likely it will be rejected.

5.10 ELECTRODEIONIZATION

The need to satisfy the increasing demand for high purity water can be achieved using Electrodeionization (EDI) equipment EDI process systems replace conventional DI mixed resin beds to produce deionized water. Unlike DI resin, EDI does not require shutdowns for replacing resin beds or for resin regeneration using chemicals. Because of this, EDI minimizes water quality upsets and operating and capital cost. EDI removes ions from aqueous streams, typically in

conjunction with reverse osmosis (RO) and other purification devices. Our high-quality modules continually produce ultrapure water continuously or intermittently.

Advantages over Conventional EDI

- *EDI does not require chemicals for regeneration
- *EDI does not require shutdown for regeneration
- *EDI skids are compact
- *Provides water of consistent quality
- *Requires little energy
- *Economic use of capitalsaves operating expense
- *Process of Electrodeionization

EDI design combines two well-established water purification technologies electro dialysis and ion-exchange resin deionization. Through this revolutionary technique, dissolved salts can be removed with low energy cost and without the need for chemical regeneration; the result is high-quality water of multi-Mohm. cm Resistivity which can be produced continuously at substantial flow rates. EDI removes ions from water by forcing them out of the feed stream into an adjacent stream via an electric potential. The resins operate in steady state; they act not as an ion reservoir but as an ion conduit.

The Electrodeionisation process uses a combination of ion-selective membranes and ion-exchange resins sandwiched between two electrodes (anode (+) and cathode (-)) under a DC voltage potential to remove ions from RO pretreated water. Ion-selective membranes operate using the same principle and materials as ion-exchange resins, and they are used to transport specific ions away from their counter ions. Anion-selective membranes are permeable to anions but not to cations; cation-selective membranes are permeable to cations but not to anions. The membranes are not water-permeable. By spacing alternating layers of anion- and cation-selective membranes within a plate-and- frame module, parallel purifying and concentrating compartments are created. Under the influence of an applied DC potential, ions in the purifying chambers are transported across the membranes into the concentrating chambers. Thus, as water moves through the purifying compartment, it becomes free of ions. This stream is the product stream. The RO feed to the EDI module is channeled into three separate streams:

1. Product stream (up to 99% water recovery)
2. Concentrate stream (typically recycled to RO feed)
3. Electrolyte stream (1%, Anolyte + Catholyte to drain)

5.11 SOFTENER

These days softening of water is almost exclusively effected by ion exchangers. In this process the calcium and magnesium ions are replaced by sodium ions, so that the hardness forming components are converted into soluble sodium salts. Softening is carried out by simple filtration through the exchange material.

When the exchange material is exhausted, it requires regeneration using sodium chloride. The calcium and the magnesium ions, which were taken up before, are replaced by sodium ions and flow out together with the regeneration water. The capacities of regeneration will however, vary according to the raw water.

KOMAL's complete line means there is a model to fit your exact requirements.

Performance Data :

Raw water should be free of colour, oil. Turbidity and at the service rates specified.

Operating Data :

Pressure Range : 2 kg / cm² - 3.5 kg / cm²

Temperature Range : 40oF - 120oF

Quality : The water Produced from the above plant will have the "Commercial Zero" hardness

5.12 OZONE

Ozone (O₃) is one of the strongest oxidizing agents that is readily available. It is used to reduce color, eliminate organic waste, reduce odor and reduce total organic carbon in water.

Ozone is created in a number of different ways, including ultra violet (UV) light, corona discharge of electricity through an oxygen stream (including air), and several others. In treating small quantities of waste, the UV ozonators are the most common, while large-scale systems use either corona discharge or other bulk ozone-producing methods.

Ozone is formed as oxygen (O₂) is struck by a source of energy. The bonds that hold the O₂ together are broken and three O₂ molecules are combined to form two O₃ molecules. The ozone begins to break down fairly quickly, and as it does so, it reverts back into O₂. The bonds that hold the O atoms together are very weak, which is why ozone acts as a strong oxidant as readily as it does.

6. TYPICAL PURIFIED WATER SYSTEM

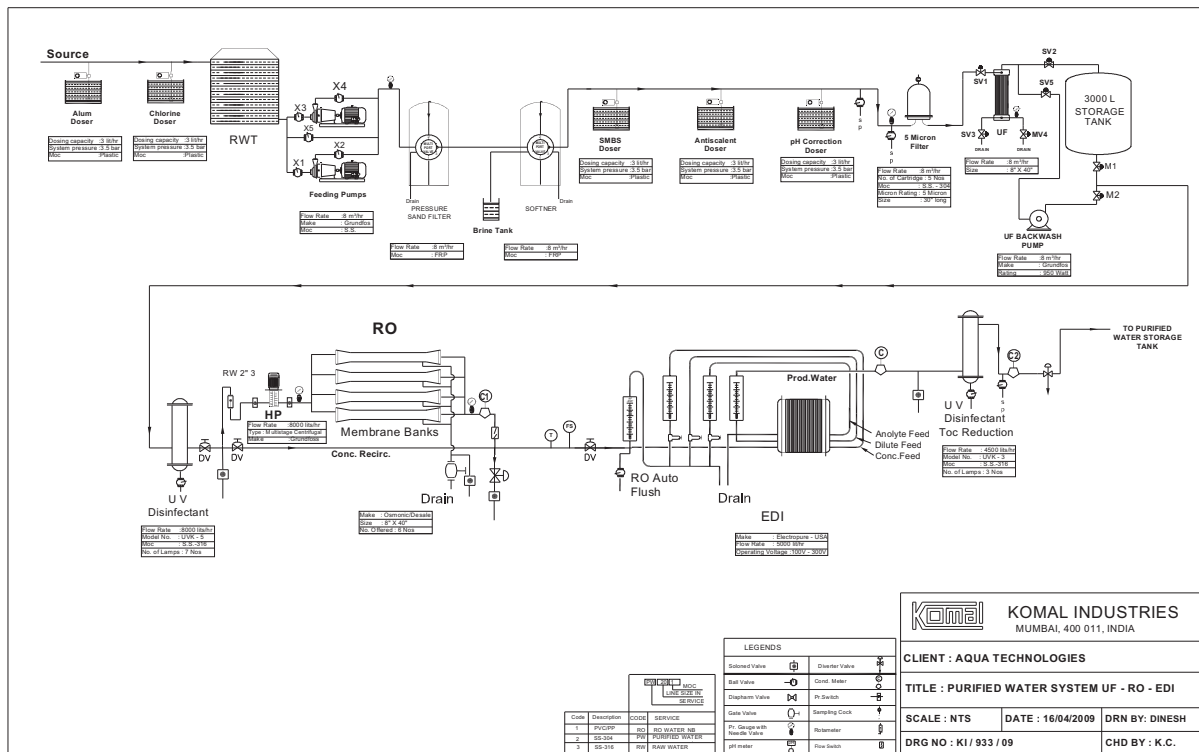


figure 1 : Typical system for USP Grade Purified water system

7. WATER SPECIFICATION FOR VARIOUS PHARMACOPOEIAS

Specifications	I.P.	E.P.	U.S.P
Conductivity ($\mu\text{S/cm}$)	8	-	1.2
TOC (ppb)	-	-	500
Bacterial Count (cfu/ml)	100	100	100