



KOMAL
WHEN QUALITY MATTERS

www.komalwater.com

INTEGRATED HIGH PURITY WATER SYSTEMS AND PROCESS VESSELS



KOMAL AS YOUR PARTNER

Komal water, India, is a research oriented process engineering company . Komal water, with its experience of over 40 years and manufacturing facility of over 75000 sq.ft, specializes in High-Purity Water and Process Systems.

Komal delivers industry leading bespoke turnkey systems – uniquely providing clients with a single source solution for their high purity systems requirements. Komal , with its in-house fabrication and automation capability is able to provide complete validation and documentation services to its clients.

INDUSTRY FOCUS

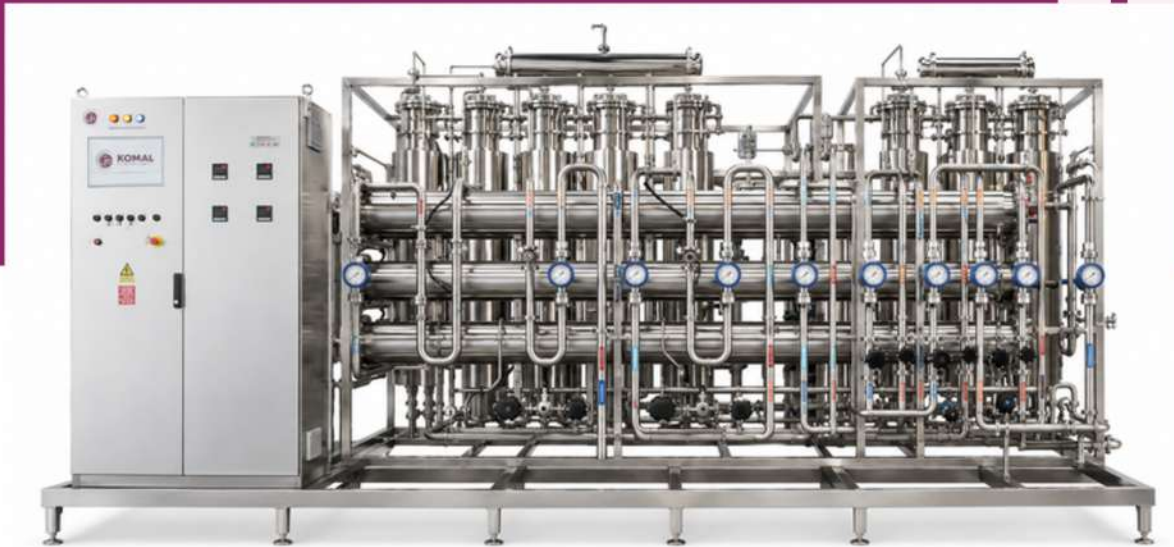


Komal, with its rapid growth due to focus on technological innovation through the continuous R&D has over 4000 installations in over 40 countries world wide.



Komal aims to strengthen its position as an international leader for pharmaceutical engineering processes, pioneering new approaches to our products with a continued commitment to improvement and innovation in High-Purity water and Process Systems.

PURIFIED WATER GENERATION SYSTEMS



Each plant for the production of purified water is custom made, whether its capacity is 100 l/h or over 25 m³/h. Every plant is designed with the customer and all the design parameters in minute details and with the same passion and dedication towards building an effective, safe and reliable system. After all each customer has a different system requirement: An SME engaging in contact manufacture has need which differs from an international conglomerate. Thus no plant is entirely like any other. ALL KOMAL PW basic systems meet EP, USP & guidelines and ensure the production process, product quality and profitability. The GMP-compliant confirms to FDA and ISPE requirements.

The compact, package unit design on a stainless steel skid, are specifically adapted to the high TDS water and offers all purification technologies, such as :

- Automatic Sand and Activated carbon filters.
- Duplex softening units, serially connected and quality-controlled with optional HOT water sanitization.
- Demineralization systems.
- Ultrafiltration units with 6000 Daltons cutoff.
- HOT water sanitisable electrodeionisation units.
- UV Disinfectant.
- Single or two-pass reverse osmosis.
- Membrane degassing for CO₂ reduction.
- ORBITAL welded SS316L tubes.
- State-of -the-art PLC technology.
- 21 CFR part 11 compliant control panels.



**ALL KOMAL PW
SYSTEMS ARE
PRE-TESTED,
VALIDATED,
COMPACT AND
READY-TO-USE.**

MULTI COLUMN DISTILLATION PLANT (W.F.I GENERATION SYSTEM)



- Distillation is the primary process used for the production of USP Water for Injection for pharmaceutical applications.
- As the name suggests, MCDP consists of individual pressure vessels (single columns) assembled in series.
- Komal's Multi-Column Distillation Plants (MCDP) are designed to produce pyrogen/endotoxin free water conforming to IP/BP/EP/USP standard.
- These individual columns are designed , constructed and tested per the American Society of Mechanical Engineers (ASME, Section VIII, Division 1- Unfired Pressure Vessels) since they operate at pressures as high as 6 to 10 bar.
- Plants are available from 50 Liters/hour to 10000 Liters/hour.
- Komals WFI-Combo design optimizes the Control Panel by combining the panel for WFI Generation and Distribution system.

Special Features

- All Evaporator (columns) sheets and tubes as well as all surfaces in contact with Pure Steam or distillate are constructed of 316L stainless steel with inside electropolish and Teflon gaskets.
- All tubes joints are Orbital welded and qualified with videoscapy.
- Full-Automatic PLC based Control Panel System with auto sanitization and printing facility.
- First column equipped with Double tube sheet as a provision to avoid boiler steam mixing with Purified water.
- Pure steam generation port.
- Complete documentation to meet and exceed international audit requirements.

PURE STEAM GENERATOR (P.S.G.)



INBUILT NON- CONDENSABLE GASES REMOVAL (NCGR) SYSTEM

- Komals Pure Steam Generator is a packaged skid mounted unit incorporating all necessary controls and functions to produce Pure steam as per latest IP/BP/USP standards. Plants are available from 50 kgs/hr to 2000 Kgs/hr.
- These generators are basically used for Sterilization of vessels, Sterilisation of Distribution systems, Autoclave, reactors and also humidification of sterile area.

Special Features

- Full-Automatic PLC based Control Panel System with auto sanitization and printing facility.
- First column equipped with Double tube sheet as a provision to avoid boiler steam mixing with purified water.
- All Contacts parts are SS316L with internally electropolishing < 0.5Ra.
- The piping system is orbital welded and qualified using videoscapy procedure.
- Complete documentation to meet and exceed international audit requirements.



For lower investment & smaller footprint, Komals combo WFI-PSU system optimizes the configuration into a single unit instead of the requiring investment two separate units. Production of WFI & Pure steam can be in series or in parallel. Guaranteed product quality due to strict separation of liquid & steam phases.

STORAGE & DISTRIBUTION SYSTEM



After the purification of PW or HPW, engineering of the customer -specific storage and distribution system takes place, so product water can be delivered to each point of use in the sterile distribution system without recontamination. The entire distribution system is made of 316L stainless steel tubes, which are orbitally welded together with a surface quality from $Ra < 0.4 - 0.8 \mu m$.

The designing of the distribution system requires detailed engineering towards achieving a sterile environment.



Features

- Storage tank – SS 316L, internally electropolished and externally matt finish.
- Jacketed hydrophobic 0.2 micron Vent Filter.
- Level transmitters.
- Spray ball
- Frequency controlled sanitary distribution pump.
- Optional dual pump station
- High efficiency UV disinfection/ozone reduction.
- Temperature compensated conductivity measurement.
- Flow management through a vortex flow meter.
- Ozonation
- On-line TOC measurement.



STERILE/ASEPTIC MANUFACTURING VESSELS



INTEGRITY,
LONG LIFE,
RELIABILITY

We build customized process vessels to meet the process requirements of our customers that ensure the integrity, long life and reliability. The process vessel is designed for easy maintenance and accessibility. Process vessels are designed for various functions such as media preparation, Inactivation, or any other as per process requirement.

Instrumentation and automation are provided as per requirement of the process chain. All vessels can be supplied as stand-alone equipment (stationary or mobile) or as automated process units delivered as fully-functional modules installed on-site that include: agitators; homogenizers; metering and regulating technology; control units; valves and pipe connections. Options for hazardous environments are also available. Precise instrumentation measures all the key parameters of pH, Dissolved Oxygen, temperature, agitator speed and weight, throughout the processing.

Features

- Bottom mounted magnetic mixer with variable speed control. Automatic speed control to prevent dry run of magnetic agitators.
- Designed for sterile application in clean environment.
- Can be supplied with different types of filtration skids depth or membrane filtration.
- Accurate level control for preparation vessel with staged.
- WFI addition through pilot valve.
- High repeatability with temperature control & low mixing variance to achieve the highest growth & product formulation rates.

Functional Specifications

- Volume: 2 to 20,000 liters nominal capacity.
- Material: stainless steel 316L, 316Ti.
- Surface finish: < 0.38 μm .
- Surface polishing: mechanical and/or electro-chemical.
- Pressure: Vacuum/-1/10 bar (g).
- Temperature: -20 °C to 200 °C.
- Cleaning options: CIP/SIP.
- Design: Single, double and triple wall design, heatable, insulated.



CIP/SIP SYSTEMS



EASY TO INTEGRATE WITH OTHER EQUIPMENT

CIP is commonly used for cleaning bioreactors, fermenters, mixing vessels & other equipment used in biotech manufacturing, pharmaceutical manufacturing and food and beverage manufacturing. CIP is performed to remove or obliterate previous cell culture batch components. It is used to remove in-process residues, control bioburden, and reduce endotoxin levels within processing equipment and systems. Residue removal is accomplished during CIP with a combination of heat, chemical action & turbulent flow.

Repeatable, reliable, and effective cleaning is of the utmost importance in a manufacturing facility. Cleaning procedures are validated to demonstrate that they are effective, reproducible, and under control. In order to adequately clean processing equipment, the equipment must be designed with smooth stainless steel surfaces and interconnecting piping that has cleanable joints. The chemical properties of the cleaning agents must properly interact with the chemical and physical properties of the residues being removed.

Features

- Designed for meeting the cleaning requirements of various equipment.
- Optional return or remote pump.
- Accurate dosing of cleaning agents and temperature control.
- Variable speed control of pump to ensure cleaning fluid velocity.
- Easy to integrate with other equipment.
- Available with integrated SIP stations for mobile vessels.
- SIP station fully automated for hands-free SIP of mobile vessels.



PROCESS PIPING



Process Piping design is an integral part of pharmaceutical facility design. Since piping systems are frequently in contact with product materials, the design needs to be efficient and meet the stringent rules and standards set by the industry.

Due to multiple bends in the piping route and the different size of pipes, cleaning, sterilizing and drying pose a challenge. Process piping is designed and fabricated to avoid any cross-contamination from cell debris, media, residue from prior batches and cleaning agents.

During the designing phase, various aspects like pressure hold test, cleaning-in-place, sterilization-in-place and drying are taken into consideration based on individual customer needs. All instruments, valves and steam traps are hence considered adequately. Lastly, Boroscopy and videoscropy reports accompanies process piping documents.

Komal Team consisting of highly qualified welding engineers are large fleet of orbital welding machines are equipped to serve any process piping requirements.

PROCESS AUTOMATION

Manufacturing of any Pharma or Biopharma products may involve complex processes. To control each of these processes manually becomes a risk on the quality and efficiency of the product. Only by having control processes through automation, the performance parameters can be monitored. It is not physically possible for the machine operators to physically monitor performance values and the quality of output to determine the best settings on which to run the production equipment.

Komals automation systems are designed to increase operational efficiency and safe operating conditions. They connect, streamline and sequence processes seamlessly, ensuring all equipment works in harmony.

Komal, with its in-house automation team, can provide 24 hour support to its client with any process automation customisation or qualification.

Features

- 21 CFR part 11 complaint.
- ISA88 programming.
- DCS compliance & controls.
- PLC-SCADA open solution.
- HMI/IPC for localized control.
- Server-based control & operation.
- GAMP 5 guidelines.
- Electronic Batch Records (EBR).



- » Komal **Bio-engineering** provides bioreactor for whole gamut of needs from pilot plant to full-fledged production.
- » We have rich experience in anaerobic, facultative anaerobic and aerobic fermentation of various microorganisms in the Biopharmaceutical industry. Our solutions also include process design, automation control and verification of suspension cell bioreactors.
- » We are known for our robust, reliable and high quality equipment's, from cell bioreactors to microbial fermenter systems.

FEATURES :

- **Feeding Pipelines** : Multiple aseptic feeding pipelines required for all kinds of nutrients.
- **Surface/Deep Aeration Device** : Control of agitation and ventilation of various gases, to reduce the impact of bubble rupture on cells.
- **Exhaust Device** : Multistage exhaust as per company requirements.
- **Temperature Control** : Precise temperature control during fermentation process with an accuracy of $\pm 0.1^{\circ}\text{C}$.
- **Aseptic Sampling** : Special sampling bottle & sampling valve for aseptic sampling.
- **Fully Automatic CIP and SIP** : For the cleaning and sterilization of tanks, pipelines inlet and exhaust devices;
- **Accurate pH Control** : Automatic adjustment of pH using peristaltic pumps and pH transmitters.
- **Accurate Foam Control** : Control of foam sensor and defoaming pump for automatic detection and defoaming;
- **Multi-function Touch Screen Operation**: Intuitive display of process and running status, real-time data recording of pH, DO, liquid level, auto valve, curve drawing and alarm functions;
- **Multi-level Password Protection**: Electronic signature and data audit trail in compliance with **FDA 21CFR** part 11, implemented in accordance with the requirements of **GAMP5**.

BIOPHARMACEUTICAL MODULAR SYSTEM SOLUTIONS



Our bioprocess modular solutions include solutions for applications like human vaccine process, animal vaccine process, **genetic recombinant DNA** & monoclonal antibodies process.

All the above applications mainly include vessels like media preparation, buffer preparation, harvesting, inactivation, purification, emulsification system, etc.

BLOOD PRODUCTS	HUMAN VACCINE	ANIMAL VACCINE	GENETIC COMBINATION / MONOCLONAL ANTIBODY
Plasma Thawing System	Fermentation System	Fermentation System	Fermentation System
Cold Perception System	Bioreactor	Bioreactor	Bioreactor
PCC adsorption System	Harvesting system	Homogenization System	Centrifugal System
PCC pre-production system	Salting out system	Centrifugal System	Homogenization System
PCC post-production system	Detoxification system	Filtration System	Chromatography System
Fibrous pre-Production system	Combined System	Chromatography System	Ultrafiltration System
Combined System	Seedling System	Combined System	Combined System
Fibre post-Production system	Preparation System	Ultrafiltration System	Inactivation System
FVIII pre-Production system	Ultrafiltration System	Inactivation System	
FVIII post-Production system	Chromatography System	Emulsification System	
Albumin reaction system		Preparation System	
Globulin reaction system			
Protein crude system			
Protein refining system			
Pap inactivation			
Hatch System			
Ultra filtration system			
Chromatography system			
Sterilization system			



OUR CERTIFICATION

Komal Industries is proud to be CE-certified and ISO 9001:2015 certified, demonstrating our commitment to quality, safety, and compliance with global standards.

These certifications reinforce the trust in our bioreactors, fermenters, purified water systems, and sterile manufacturing vessels, ensuring they meet stringent industry regulations and deliver exceptional quality and reliability worldwide.



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