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 as per customer requirements. Considering all the design parameters with minute details. We work with 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-compliance 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 CO_2 reduction.
- Orbital welded SS316L tubes.
- State-of –the-art PLC technology.
- 21 CFR part 11 compliance 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 as 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.
- Komal's 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 electropolished and Teflon gaskets.
- All tubes joints are Orbital welded and qualified with videoscopy.
- Fully-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 electropolished < 0.5Ra.
- The piping system is orbital welded and qualified using videoscopy procedure.
- Complete documentation to meet and exceed international audit requirements.

For lower investment & smaller footprint, Komal's combo WFI-PSG system optimizes the configuration into a single unit instead of the investment in 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 be made of 316L stainless steel tubes, which are orbitally welded together with a surface quality from Ra <0.4 - 0.8µm.

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

Features

- Storage tank – SS 316L, internally electro-polished 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.
- 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 (stationery 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. 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.

BIOPHARMA VESSELS

Komal manufactures stainless steel pilot scale to production scale Fermentor/Bioreactors which are customized as per the process needs. Biopharma vessels takes into accounts various critical parameters & control devices to make the process effective and efficient. Vessels are suitable for the cultivation of microbial/ animal culture–utilizing robust, industry-standard components of reputed makes for easy integration into any production facility.

Our process range is designed as per ASME/BPE/PED guidelines and with capacities ranging from 5 L to 50 KL and includes process vessels for Media Preparation, Buffer Preparation, Harvest, Chromotography Loading, Refolding, Elution, CIP, & Stability Study vessels.

During the process, the below-mentioned parameters are maintained based on set parameters-

(a) **Temperature :** Sterilization and Temperature control to be maintained at set point.

(b) **Pressure :** pressure sensor at vessel top and back pressure control valve at vent line to control the vessel pressure and back pressure respectively.

(c) **Agitation** Motor with variable frequency drive controls the agitation speed.

(d) **pH :** pH is controlled by acid and alkali solution using peristaltic pumps that works based on feedback from the pH sensor.

(e) **Foam :** Foam is controlled by antifoam solution using peristaltic pumps that work based on feedback from the pH sensor.

(f) **DO :** Cascade mode DO control is agitation and aeration (1.5VVM) by enable/disable options.

(g) **Level :** Level is controlled by pulsing WFI valve that works based on feedback from the level sensor.

After harvesting the batch, CIP is carried out through spray balls.

Features

- Leading industry components for automation, electronics, sensors, valves and gas mixing, among others, offer quality without compromise.
- SCADA software to simultaneously manage multiple bioreactors.
- Fully automatic in-situ sterilisation with integrated steam generator.
- Modular design and interconnectivity with external devices give the possibility of individual solutions.

CIP/SIP SYSTEMS

INTEGRATED OR EXTERNAL CIP SYSTEM

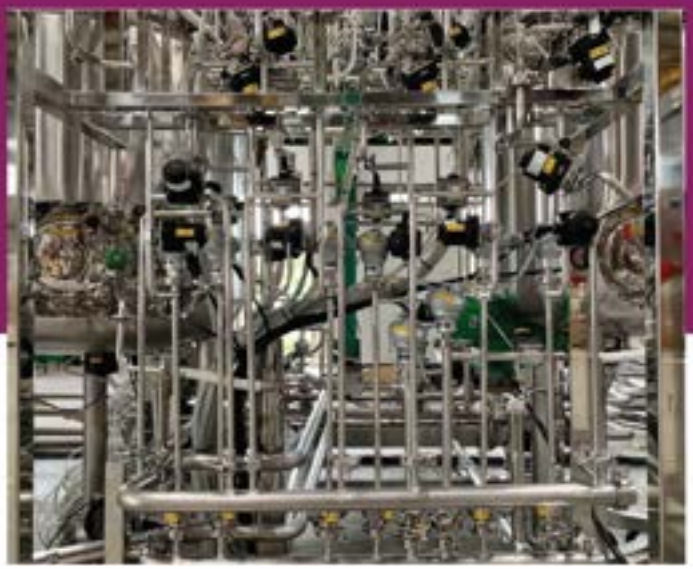
CIP is commonly used for cleaning bioreactors, fermenters, mixing vessels & other equipment used in biotech manufacturing, pharmaceutical manufacturing and food and beverage manufacturing. CIP is performed to remove or obliterate previous cell culture batch components. It is used to remove in-process 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



EASY TO INTEGRATE WITH OTHER EQUIPMENT

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

VALUE ADDED SERVICES

1. Membrane based " Cold" WFI Generation System :

In 2017, European Pharmacopeia (EP) revised its guidelines to allow for an alternative choice in production of WFI. The guidelines state that water for injection can be produced using alternative technologies, as long as the quality is equivalent to distillation.

"Cold WFI" is a descriptor for a purification process to produce WFI by means other than distillation. The key difference between the two types of WFI systems is that Cold WFI systems utilize a second membrane barrier, such as low-pressure ultrafiltration (UF), to ensure microbiological quality in place of energy-intensive distillation processes.

Advantages :
- Significantly Lower CAPEX and OPEX costs for Cold WFI
- Reduced carbon Footprint and Increased Sustainability
- More compact in size

2. Ozonation Systems :

KOMAL manufactures a Corona Discharge Ozone Generator and Ozone application Engineering including dissolution column, air preparation unit and Ozone destruction. 'OZ1 series of Ozonator Generator operate exclusively on oxygen feed gas, Eliminating the need of Air preparation unit. For the smaller requirement of ozone 'OZ' Series Ozone Generator is very efficient, reliable and very cost -effective.

Komal audits, designs and delivers complete ozone solutions for pre-treatment as well as the purified water system. These solutions can be integrated into existing systems or can be supplied as a standalone system depending upon the challenges/expectation from clients.

Auxiliary items for Oznoation systems like Dissolved Ozone Meters, Ozone Destruction unit and Ozone Monitoring Meters can also be provided and integrated with the controlling software.

3. Point of Use (POU) Heat Exchangers :

A compact module developed for point of use cooling in pharmaceutical water systems. Komal's POU module for the pharmaceutical industry is designed as a subloop in hot water systems keeping it sanitized when not in use.

The HMI on the panel can be used to start / stop the water flow and the chilled water flow. It also shows the temperature of water and the dispense times. When not in use, the continuous flow is maintained thus avoiding the bacterial growth.

The heat exchanger has low pressure drop , hence low energy consumption. The HMI shows all the important parameters and can be accesses remotely or can be integrated into any building management system (BMS).

The heat exchanger operates in counter current manner which increases the heat transfer. All contact parts are SS316L, with <0.5 um RA value and ASME BPE compliant. The entire storage and distribution system is fully tested and validated before shipment and all the necessary documents like the DQ,IQ, OQ & manuals are provided with the system.

WE MAKE INNOVATION HAPPEN

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