



Kerala State Homoeopathic Co-Operative Pharmacy Ltd.

(sponsored by government of Kerala & aided by govt. of India)

Office: Pathirappally, Alappuzha, India Pin-688 521

Phone : 477 2258012

:477 2258665

Fax : 0477 2258012

Website : www.homcokerala.com

Email : homcokerala@gmail.com

Supplier's Copy

USER REQUIREMENT SPECIFICATION

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	Utility (On service Floor)
Equipment and Code No.	:	1) WFI –Multi column distillation plant, Capacity 150 liter/Hr. 2) WFI storage tank 300 liters.& accessories 3) SS 316 L Pipe & pipe fitting for WFI supply and return loop system 4) Process & Instrumentation SKID for recirculation system
Name of work	:	Supply, installation, commissioning & validation of cGMP model, Water for Injection (WFI) generation, storage and distribution system, at M/s. Homco –Kerala
Ref. No.	:	
Date	:	
Enclosures	:	



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WATER FOR INJECTION (WFI)

GENERATION, STORAGE & DISTRIBUTION SYSTEM

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION	
(To be specified by the supplier, if any variation)	
Scope	: Supply, Installation, Commissioning and Validation of Water for Injection (WFI) generation, storage & Distribution system including following : 1) Water for Injection (WFI) Generation system 2) SS 316 L, Storage system 3) Distribution system including instrumentation Along with all inter-connecting pipes, valves, instrumentation, electrical cables, Skid, support and all accessories required for successful working of this system at site of M/s. Homco -Kerala
Standard	: cGMP and IP, BP and USP guidelines
Working Principle	: Falling film evaporation principle* Multi effect Distillation Still (MEDS)
Design	: FIN AQUA TYPE*
Output (Flow rate)	: 150 LPH *
Number of columns	: 4 nos. *
Distillate Temp	: 80 to 85° C *
Conductivity	: < 1.0 µ Siemens/cm *
Endotoxin	: < 0.25 Eu. /ml *
TOC	: <500 PPB *
Feed Water	: Purified water*
Conductivity	: <5.0µ Siemens/cm * (Feed water)

* To be specified and confirm by the supplier as per their equipment design



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DESCRIPTION		
(To be specified by the supplier, if any variation)		
Temp	:	20 TO 25°C*
Feed water Consumption	:	200-250 LPH *
Cooling Water	:	Portable tap Water
Hardness	:	<90 ppm CaCo3 *
Feed water Consumption	:	250-400 LPH *
Temp	:	25°C*
Plant (Boiler) Steam	:	Dry Saturated Plant Steam
Steam Consumption	:	70 -150 Kg/hr *
Plant Steam Pressure	:	3 -6 Kg/cm ² *
Compressed Air	:	6-8 bar cfm dry and oil free*

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DESCRIPTION

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SYSTEM DESCRIPTION

Multiple Effect Distillation Still should produces Pyrogen free, sterile, Water for Injection (WFI). It should operate on the Distillation principle and Sterile water should be produced by phase change to provide very high purity water. WFI should produce at sterile temperature without using any filtration medium.

This MEDS should be based on Falling Film Evaporator principle without any moving parts.

1) Generation System:

The 1st column should heat internally with plant steam, after heat exchange and condensing should return to the boiler via the condensate return pipe.

The feed water should pass through all preheater before entering the 1st column to reduce the steam consumption once the WFI generation process is started.

The pure steam generated in column 1 should leave its heat energy to column 2 and 2nd pre heater, condensing into overheated distilled water.

The "Flash – Energy" of the overheated distillate should stepwise re- used backward in the system.

This procedure should repeat in the subsequent columns and pre heaters, except for the last, with gradually falling pressure and temperature.

The steam generated in the last column should be condensed in the cooler, which should be equipped with a degassing device.

The total amount of distillate should be cooled by means additional cooling water in cooling condenser.

The distillate should leave the still with nominal over- pressure at a temperature of approx. 95 to 97 deg C.

Feed water overcharge of approx. 15% should continuously led to the drain from the last column. The still should operate without any moving parts, which gives a low sound level, safe operation and very less maintenance.

The distillate should be normally required as hot as possible to maintain sterility. It should led on to the distillate sterile tank where it should kept and circulated into a closed loop to the various uses at a temperature of minimum 80 to 85 °C.

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DESCRIPTION

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SYSTEM DESCRIPTION

WFI storage & Distribution System:

- WFI storage and Distribution System should be designed for 80°C+5°C temperature during normal working.
- System should be sterilized by pure steam at 121°C. Sterilization procedures & and Pump .Sterilization procedure should be well defined in the control logic.
- The pressure in the loop should always be maintained at 1.5 bar g.
- The flow in the loop should be maintained such that the minimum velocity of water in the loop should be >1.2m/s.
- Slope of 1:100 should be maintained in the loop to prevent any stagnant zones.
- There should not be any dead legs or stagnant zones in the system, so as to facilitate the prevention of microbial growth in the system. No dead leg should be more than 2.0 D of the internal diameter.
- All fittings in clean room area should have tri-clamp connections of sanitary design and all joints on the service floor should be orbitally welded.
- All equipment's and instruments except the tank assembly should be mounted on a skid. Skid should be mounted on ball feet arrangement for easy re-location.
- Sanitary type diaphragm valves with SS-304 bonnet and internal Ra value of <0.5µm should be used. The MOC of diaphragm must be EPDM backed with PTFE

Storage System:

- WFI Storage and Distribution System should be in compliance with the current USP and cGMP regulations. Should be consists of a tank, which has a ball feet arrangement and other accessories for storing water, centrifugal pumps (1working+1standby) with single VFD with recirculation system.
- Storage tank should be hygienically constructed in SS316L, vertical, cylindrical and should be leg mounted with top and bottom dish ends.
- It should be internally electro polished to <0.5 Ra and externally to <0.8Ra.

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DESCRIPTION

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- Should be designed as per ASME, Section-VIII, Div-1.
- The working volume of the tank should be 300 liters. Tank should be cylindrical, Limpet coiled & insulated.
- The temperature of WFI should be $80^{\circ}\text{C}+5^{\circ}\text{C}$.
- WFI loop should be maintained at $80^{\circ}\text{C}+5^{\circ}\text{C}$ by plant steam.
- Tank Insulation (personal protection) for the tank should be mineral wool and must be clad with SS-304.

WFI Tank should Consist of :

- Sight glass, light glass & manhole
- Rupture disc
- Capacitance type of level transmitter, Compound pressure Gauge, temperature
- Element and transmitter with thermo well provision at the bottom dish end.
- 0.2micron-code-7 electrically traced hydrophobic filter. It has an on/off isolation valve above the filter which is normally in open safe condition and is closed down during steam sterilization.
- Shadow free spray balls (1 nos) capable of 360 degree rotation, that rinses the tank completely with water that is returned back from the re-circulation.

WFI Recirculation Pumps:

The pumps should be of sanitary grade centrifugal type (1 working + 1 stand by).
MOC should be SS316L and should be pure steam sterilizable and with a single mechanical seal.

The pump housing should be completely drainable and equipped with drain valves.

All the connections of the pump including mechanical seal, drains vents and process connections should be of hygienic design.

It shall be possible to isolate the circulation pump from the system with isolation valves before and after the pump.

Pump should be equipped with a single VFD.

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DESCRIPTION

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Distribution Loop Piping:

The loop should be SS316L ERW bead removed electro-polished with internal finish of $Ra < 0.5\mu m$ and external finish of $Ra < 0.8\mu m$.

The piping should confirm to design code of ASTM-270.

Insulation:

All pipes and fittings of the distribution loop and the technical area should be insulated (for personal protection) with Nitrile rubber or mineral wool and must be clad with SS304 sheets.

In clean room area all the pipes and fittings should be insulated using the pipe in pipe arrangement.

Entry and exit of the pipe in clean room area must be provided with entry sleeve.

3.3 General Points:

- All POU valves should be block type/Zero Dead Leg diaphragm valves.
- Sampling and drain funnel and pipes from funnels to drain should be included in scope of supply.
- All POU's should have sampling points.
- Sampling points should be provided before and after every
- All sanitary and non-sanitary piping should have no threaded connection.
- All joints to be orbital welded and other non-welded joints to be provide with sanitary tri-clover fittings.
- Boro-scopy test should be 10% and above

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ANNEXURE - II : cGMP FEATURES



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DESCRIPTION		
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MOC		
All welding, Welders Qualifications and Weld inspection techniques should be performed in accordance with ASME boiler and pressure vessel specifications (WPS)		
<ul style="list-style-type: none">Each pressure column should be hydrostatic pressure tested and independently inspected.MOC for all contact parts should be AISI 316L and non-contact parts SS 304Heat transfer by falling film principal should ensure the higher sterility assurance.Each column design should utilize sanitary spiral entrainment separation technology that forces centrifugal action to remove impurities and PyrogenA sight glass assembly should be provided on each column to view the water level.Each column should be provided with a sampling Valve.All columns should be insulated with a minimum of 50 to 75 mm of non-corrosive resin Bonded Glass wool insulation and are covered with riveted AISI 304 stainless steels with mirror surface finish.All gaskets should be of pharmaceutical grade PTFE, silicon, or Viton.A safety relief valve and vacuum breaker should be installed within the piping to protect the pressure vessels.The cooler should be designed for efficiently removal of volatile impurities and non-condensable gases, while condensing pure steam, cooling distillate and preheating of the feed water.		
Working Area Environment	:	Temperature : $26 \pm 2^{\circ} \text{C}$ Relative Humidity : NMT 75%
Finish		$Ra \leq 0.3 \mu\text{m}$ with EP for contact parts. Matt finish for non-contact parts
The equipment should be smooth finished without any sharp edges and crevices		

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ANNEXURE - III : OPERATIONAL FEATURES

DESCRIPTION		
(To be specified by the supplier, if any variation)		
1) WFI Generation plant – Capacity: <u>150 liters/hr.</u>		
MCDP Column		
Tube & Shell Type	:	Single Shell & Seamless Tube*
Material Of Construction	:	Contact Parts -SS 316L *
Insulation	:	SS 304*
Finish	:	Tube-Internally Electro Polished <0.38 Ra*
Shell	:	Inside Mirror Finished Manual Buff*
Position	:	Vertical*
Accessories	:	Sight Glass*
Quantity	:	4 No. *
Make	:	WSPL*
MCDP Preheater		
Material of Construction	:	Contact Parts -SS 316L*
Tube & Shell Type	:	Single Shell & Seamless Tube*
Insulation	:	SS 304*
Position	:	Vertical*
Quantity	:	1 No. *
Make	:	WSPL*
Feed Water Cooler Condenser		
Material Of Construction	:	SS 316L*
Quantity	:	1 No. *
Make	:	WSPL*

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DESCRIPTION		
(To be specified by the supplier, if any variation)		
Cooling Water Cooler Condenser		
Material Of Construction	:	SS 316L*
Quantity	:	1 No. *
Make	:	WSPL*
Insulation		
Material of Insulation	:	Resin Bonded Rock Wool Asbestos Free*
Insulation Cover Material	:	SS 304*
Quantity	:	1 Lot*
Make	:	WSPL*
Sight glass/View glass		
Type	:	Toughened*
Material of Construction	:	SS 316L *
Function	:	To View The Water Level In Each Columns & Distillate Outlet*
Quantity	:	5 No. *
Make	:	WSPL*
PUMPS		
Purified Water Feed Pump		
Capacity	:	0.175 m3/hr*
Head	:	6 Kg/cm2*
Type	:	Multistage Centrifugal Pump*
Application	:	Purified Water*
MOC	:	SS 316*

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DESCRIPTION		
(To be specified by the supplier, if any variation)		
End Connection	:	TC End/Flange End*
Supply	:	415V/3 Phase/50Hz*
Quantity	:	1 No. *
Make	:	Grundfos/Xylem/Equivalent*
Cooling Water Pump		
Type:	:	Multistage Centrifugal Pump*
Application	:	Water*
MOC	:	CI Casing, Impeller- SS 304*
Capacity	:	0.345 m3/hr*
Head	:	3 Bar*
End Connection	:	TC End/Flange End*
Supply	:	415V/3 Phase/50Hz*
Quantity	:	1 No. *
Make	:	Grundfos/Xylem/Equivalent*
Instruments		
Pressure Gauge		
Type	:	Bourdon type*
Range	:	0 to 10 Kg/cm2*
Contact Parts	:	SS 316L*
Non-contact parts	:	SS 304*
Dial Size	:	100 mm*
Dampening Liquid	:	Glycerin Filled*

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DESCRIPTION		
(To be specified by the supplier, if any variation)		
Dampening Liquid	:	Glycerine Filled*
Marking	:	White Backround With Black Marking*
Sensing Elements	:	Bourdon Gauge*
End Connection	:	TC End*
Location	:	Plant Steam Inlet, Purified & Cooling Water Pump Outlet*
Quantity	:	3 No. *
Make	:	Baumer/Equivalent*
Level Switch		
MOC	:	Wetted Parts SS 316L*
Type	:	Top Mounted Magnetic Level Switch*
End Connection	:	TC End*
Location	:	For Column (1st & Last Column) *
Quantity	:	2 No. *
Make	:	Pune Techtrol/Equivalent*
Flow Indicator		
MOC:	:	SS 316L*
Range	:	100 – 1000 LPH*
Installation:	:	Upward Flow Vertical Installation*
Fluid:	:	Water*
Max Operating Temperature	:	150 °C*
Output	:	Digital type 4 -20mA*
Location	:	Cooling & Purified Water Pump Discharge*
End connection	:	TC End*

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DESCRIPTION		
(To be specified by the supplier, if any variation)		
Quantity	:	2 No. *
Make	:	Krohne Marshall/Equivalent*
Temperature Sensor Cum Transmitter		
Type	:	Pt 100/Simplex/3 Wire/Fixed*
MOC	:	SS 316L*
Range	:	0 To 200°C*
Length	:	50 mm*
Accuracy	:	Class A, 4 – 20 mA*
End connection	:	TC End*
Quantity	:	3 No. *
Make	:	Radix / Equivalent*
Conductivity Sensor & transmitter		
Range	:	0 to 10 µS/cm*
MOC	:	SS 316L*
Size	:	DN 20*
Output	:	4-20 mA*
Location	:	WFI outlet*
End Connection	:	TC End*
Quantity	:	1 No. *
Make	:	Forbes marshal/ Mettler/ Jumo*

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DESCRIPTION		
(To be specified by the supplier, if any variation)		
Pressure Switch		
MOC	:	SS*
Range	:	0.2 to 7.5 bar*
Contact System	:	Single Pole Changeover Switch (SPDT) *
Power Supply	:	24 VDC*
Enclosure	:	IP 66*
Location	:	Purified & Cooling Water Outlet*
End Connection	:	TC End*
Quantity	:	2 No. *
Make	:	Danfoss/Indfos*
Valves		
Pneumatic Actuated Angle Seat Piston Type Valve		
MOC	:	SS 316*
Size / Quantity	:	DN 20-1 No.; DN 25-1 No. *
Actuator	:	Single Acting (Air to Spring) *
Operation	:	Pneumatic Operated*
Operating Temperature	:	Upto 180°C*
Operating Pressure	:	Upto 16 bar*
End Connection	:	TC End/Flange End*
Make	:	Mascon/Avcon/Equivalent*
Actuated Diaphragm Type Valve		
Size / Quantity	:	DN 20-2 No. *
Type	:	Two Way Actuated Diaphragm valve*

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DESCRIPTION		
(To be specified by the supplier, if any variation)		
MOC	:	Body-SS 316L, Bonnet- SS 316, Stem-ASTM A276*
MOC of Diaphragm	:	PTFE Backed EPDM*
Operation	:	Pneumatic Operated*
Operating Temperature	:	Upto 180°C*
Operating Pressure	:	Upto 16 bar*
End Connection	:	TC End*
Make	:	Mascon/Avcon/ Leistung*
Manual Diaphragm Valve		
Size / Quantity	:	DN 15-1 No.; DN 20-1 No.; DN 25-1 No. *
Type	:	Two Way Manual Diaphragm Valve, weir type*
MOC	:	SS 316L*
MOC of Diaphragm	:	PTFE backed EPDM*
Operation	:	Manually Operated*
Operating Temperature	:	Upto 180°C*
Operating Pressure	:	Upto 16 bar*
End Connection	:	TC End*
Make	:	Mascon/Avcon/ Leistung*
Sampling Valve		
Size / Quantity	:	DN 8-1 No.; DN 15-3 No. *
Type	:	Two Way Manual Diaphragm Valve, weir type *
MOC	:	SS 316L*
MOC of Diaphragm	:	PTFE Backed EPDM*

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DESCRIPTION		
(To be specified by the supplier, if any variation)		
End Connection	:	TC End*
Make	:	Mascon/Avcon/ Leistung*
Non-Return Valve		
Size / Quantity	:	DN 20-5 No.; DN 25-1 No. *
MOC	:	SS 316*
Type	:	Spring Loaded/Disc Check Valve*
End Connection	:	TC End*
Make	:	WSPL*
Pressure Safety Valve		
MOC	:	SS 304*
Size / Quantity	:	DN 15-1 No. *
Type	:	Disk Type*
End Connection	:	TC End/Threaded End*
Make	:	TRAX/Forbes Marshall*
Steam Trap For Condensate Drain		
Size / Quantity	:	DN 15-1 No. *
MOC	:	SS 316L*
Type	:	Ball & Float Type*
End Connection	:	BSPT(F) *
Make	:	Pennent/ TRAX*
Y-Type Strainer		
Size / Quantity	:	DN 25-1 No. *
Type	:	Thermodynamic*

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DESCRIPTION		
(To be specified by the supplier, if any variation)		
MOC	:	Carbon Steel*
End Connection	:	DN 25 BSP*
Make	:	Trax / Equivalent*
Manual Ball Valves		
Type	:	3 piece full port*
Size / Quantity	:	DN 15-3 No.; DN 20-3 No.; DN 25-4 No. *
End Connection	:	SS 304*
Application	:	Steam Condensate Removal*
Operating Temperature	:	Upto 180°C*
Pressure Rating	:	Upto 10 bar*
Make	:	Unison/Aira/Racer/Equivalent*
Actuated 3 way Valve For Dumping		
Size / Quantity	:	DN 25-1 No. *
MOC:	:	Body-SS 316L, Bonnet-SS 316, Stem-ASTM A276*
Diaphragm MOC:	:	PTFE Backed EPDM*
Type:	:	Flow diverter valve*
End Connection:	:	TC End*
Operation:	:	Manually Operated /Pneumatic Operated*
Operating Pressure:	:	0-10 bar*
Make	:	IDMC/Leistung*
Piston valve		
MOC	:	SS 304*
Size / Quantity	:	DN 25-1 No. *

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DESCRIPTION		
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Operation	:	Manually Operated*
Operating Temperature	:	Upto 180°C*
Operating Pressure	:	Upto 16 bar*
End Connection	:	TC End*
Make	:	Mascon/Avcon/Equivalent*
Interconnecting piping		
MOC	:	SS 316L for Contact parts Internally Electro polished/SS 304 for Non-Contact parts*
End Connection	:	Sanitary Triclover*
Welding	:	Orbital Welding & 10% Boroscopy of welded joints*
Finish	:	Electro polished to Ra <0.38 Internally*
Make	:	Rensa/Equivalent*
Quantity	:	1 Lot*
Process & Instrumentation For WFI generation Plant		
<ul style="list-style-type: none"> ➤ PLC – RS 232 port and in built real time clock and 21 CFR part 11 compatible. * ➤ HMI : Colour display with resistive type touch screen* ➤ Online printing by 80 column dot matrix data printer * ➤ SS 304 Skid structure for instrumentation and distribution system. * 		
<i>Any other detail not mentioned above, also to be included.</i>		
<i>Client will provide & connect the required cable in to vendor's panel. From machine panel to machine and its other accessories to be supplied and connected by vendor at site.</i>		

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DESCRIPTION	
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2) WFI storage Tank and accessories – 300 liters SS 316L	
Storage tank	
Capacity	: Working: 300 liters *
MOC of all contact parts	: SS 316 L *
MOC of non-contact parts	: SS 304 *
Type of tank	: Vertical Cylindrical, Jacketed & insulated, Dish end *
Design Criteria	: ASME SECTION VIII DIV-I*
Operating Temperature	: Normally 80 to 85 and during sterilization 121 to 150 deg C*
Shell/Dish thickness	: (3 mm for shell, bottom dish & Top dish), (Jacket shell & bottom dish- 4 mm)*
Insulation	: 50 mm thick Rockwool and SS304 2mm cladde *
Internal finish	: Electro-polished with finish ,0.8 Ra *
External finish	: Matt
Accessories	
Level Transmitter	: Capacitance type, SS316 L, 0-300 ltrs, as per height of tank with TC end (1.5") Make - E & H*
Compound pressure gauge	: Sanitary Type, Diaphragm Sealed Glycerin Filled 4" dia with diaphragm (1 to 10 bar) , SS 316L,TC end (1.5") (over the tank)
SS 316L Vent filter with accessories	: Size 4"x10" , Type Electrically heated Insulated & cladde – 1.5" TC end ,PT -100 sensor with wire*
PP/PTFE Vent Cartridge	: Hydrophobic Type, 0.2 micronx10" with code 7 cartridge electrical heat traced – Make: Sartorius /Parker*

*** To be specified and confirm by the supplier as per their equipment design**



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:477 2258665
Fax : 0477 2258012

Website : www.homcokerala.com

Email : homcokerala@gmail.com

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Spray ball with assembly	:	3/4" OD screwed/Pin connection, 360-degree rotary, SS 316L, with adapter, and operating pressure 1 bar
Tank outlet pipe and fittings	:	SS 316 L, 1.5" ASME BPE,
Temperate sensor cum transmitter	:	SS 304, PT 100 3 wire, 1/2" BSP, 150 mm long, with thermo well*
SS 316 L sampling valve	:	8 mm ,manual diaphragm valve TC end
Two way manual diaphragm valve	:	DN40 ,SS 316L with TC connection at tank bottom suction line
Two way manual diaphragm valve	:	DN25 SS 316L with TC end at tank drain valve
Auto Diaphragm valve	:	DN40 & DN25 SS 316L, TC end at Vent filter In & Exhaust
TC clamp and Gasket	:	As required*
Accessories at Jacket Side		
Actuated Angle seat valve	:	3/4" SS 304 , ON/OFF non IBR type, Single acting TC end at inlet of jacket
Ball valve for steam inlet	:	3/4" SS 304 ,3-piece full port TC end for steam inlet
Ball valve for condensate line & Air jacket vent	:	15 NB SS 304 3-piece full port ,TC end up to 10 bar
Pressure safety valve with blow down piping	:	1/2" Brass/MS powder coated, Spring loaded non IBR, screwed end at steam inlet,

* To be specified and confirm by the supplier as per their equipment design



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DESCRIPTION		
(To be specified by the supplier, if any variation)		
Accessories at Jacket Side		
Steam trap	: 15 NB CS, Thermodynamic TC end at jacket drain pressure up to 10 bar	
Pressure Indicator with syphon	: 1/2" BSPT dia 4" at jacket SS 304 ,Bourdon type, range 0 to 10 bar	
Accessories	: 1 lot	
Distribution SKID with accessories		
SS 316L Centrifugal mono block type Sanitary Pump TC End	1.1 m3/hr @ 7.5 bar *	2 nos.
Pump discharge valve , SS 316 L Base ,TC end at pump discharge with PTFE backed EPDM rubber diaphragm	20 NB	1 No.
SS 316L Return line Isolation Valve , TC end , manual diaphragm valve	20 NB	2 nos.
SS 316L pure steam inlet & MCDP inlet on the tank, TC end, pneumatic actuated diaphragm valve, Weir type	20 NB	1 nos.
SS 316L valve for condensate removal TC end,, at Suction and return line , Weir Type	15 NB	3 Nos.
SS 316 L clean steam trap for condensate removal,	15 NB	3 Nos.
SS316L pressure gauge for supply and return line, 0 to 10 bar, TC end at distribution pump discharge	1.5"TC	2 nos.
SS 316L sampling valve , TC end at supply and return line	8 mm	2 nos.
SS 316L Conductivity sensors & Transmitter in the return line , compensated type, range 0 to 10 us/cm TC end	40 NB	1 no.
SS 316 L temperature sensors and transmitter in the return line 0 to 150 deg C 50 mm probe length TC end	50 mm	2 nos.
SS 316L Vortex Flow Meter 0-1500 lph Transmitter TC end	DN 20	1 no.
SS 316L three way flow diverted valve TC end 0 to 10 bar	DN20	1 no.
SS 316L pressure transmitter TC end 0 to 10 bar	DN 20	1 No.
SS 316 L sanitary pressure safety valve ,TC end 0 to 10 bar	DN20	1 no.
TOC analyser	DN15	1 no.



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DESCRIPTION (To be specified by the supplier, if any variation)		
Distribution Pipe and accessories		
Pipe & Pipe fittings		
Description	Dimension	Qty.
Pipe		
MOC :SS316L (1.6mm thickness)	3/4"OD	260 mtrs.
Type: ERW		
Finish: Internal Electro polish (ra<.5µm), External Matt finish		
standard : ASTM A 270		
Elbow		
MOC :SS316L	3/4"OD	78 No.
Type: ERW		
Finish: Internal Electro polish (ra<.4µm), External Matt finish		
standard : ASTM A 270		
Radius: 1.5D		
TC Ferrule		
MOC :SS316L	3/4"OD	50 Nos.
Type : Rod Machined		
Finish: Internal Electro polish (ra<.4µm), External Matt finish		
standard : ASTM A 270		
TC Clamp		
MOC :SS304	3/4"OD	65 Nos.
standard : ASTM A 270		
TC Gasket		
MOC :Silicon	3/4"OD	65 Nos.
standard Compliance : FDA Complied		
PH Clamp	3/4"OD	130 Nos.
MOC :SS304		
Stud	1/2"x50mm	115 Nos.
MOC :SS304		
Standard Support	1/2"x100mmx80mm dia round plate with stud	15 Nos.
MOC :SS304		

Note: Mentioned quantity may vary as per site condition and actual requirement.

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DESCRIPTION (To be specified by the supplier, if any variation)		
Description	Dimension	Qty.
Anchor Bolt/ Panel Bolt	M10x75mm	30 Nos.
MOC :SS304		
Anchor Bolt	M10x75mm	200 Nos.
MOC :MS		
Square Plate	100x100x6mm	60 Nos.
MOC :MS.		
MS Angle	40x40x6mm	30 Nos.
HT class Nitrile rubber insulation	1"	250 meter.
Pipe in and pipe out insulation at user point	3/4"x2.5"	6 nos.
Zero dead leg Valve for POU	3/4"OD	3 Nos.
MOC : ASTM A351 CF3M (SS316L)		
Diaphragm: EPDM Backed PTFE		
Make : Mascon/Avcon/ Leistung		
Type: Weir Type		
Size: Equal Inlet Outlet		
Handle: ABS Plastic		
End Connection : TC , Location : User point		
Temperature: Normal Operation 85 Degree Upto 150 Degree Celcius		
Actuated Zero Dead leg Valve for Userpoint	3/4"OD	1 No.
Hose Nipple for User points	1"x1/2"/3/4"/1"	3Nos.
MOC :SS316L		
End Connection : TC		
Location: User point		
4.1)Process & Instrumentation with Skid for recirculation system		
Pipes, Fittings, Union, Bends, Tees, Skid Inter-connecting	3/4"	1 lot
PLC Based Control Panel for Online process Instruments sensors, VFD for Pumps, flow diversion valves with appropriate synchronised in SS304 Enclosure panel with printer Dot-Matrix Epson Make	-	1 no.
Skid Structure for Instrumentation and distribution System	STD.	1 no.
Closed Head Orbital Welding Joints	STD	1 lot.
Internal Borescope of the Orbital Weld joint (10%)	STD	1 lot.

Note: Mentioned quantity may vary as per site condition and actual requirement



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ANNEXURE - IV : ELECTRICAL DETAILS

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Standard Operating Frequency	:	50 Hz
Standard Operating Voltage	:	230 /415 V*
Total power consumption	:	Vendor to specify
Motor Details with rpm	:	Vendor to specify
Gear Box Details (If any)	:	Vendor to specify
PLC and HMI details	:	Vendor to specify
VFD details (If any)	:	Vendor to specify
Tower lamp	:	Vendor to specify
Starter	:	*
Major Cabling details		
For Main supply (In client's scope)	:	*
For Main drive motor	:	*
End connection details	:	MCB or Socket should be with equipment
Earthing requirement	:	Arrangement should be with system
An Isolator Circuit breaker	:	To be supplied with machine at power supply in point of appropriate capacity by vendor. *
Cable length with equipment	:	*
<i>Any other detail not mentioned above, also to be included.</i>		
<i>Client will provide & connect the required cable in to vendor's panel. From machine panel to machine and its other accessories to be supplied and connected by vendor at site.</i>		

*** To be specified and confirm by the supplier as per their equipment design**

- ❖ Wiring between Panel and the Machine is in the Scope of Vendor. The exact measurements shall be taken by visiting the site.



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- ❖ The Incomer to the Operating Panel shall be provided by HOMCO, however any Cable Trays or SS 304 Conduits required for the same shall be provided by the Vendor.
- ❖ Cable routing from Operating Panel to the Machine shall be done as per cGMP i.e. routing through Cable Trays outside Clean Room Areas and SS 304 Conduits inside Clean Room Areas.
- ❖ All the Component Makes should match the Approved Makes list provided. Any deviation from this should be documented and communicated to HOMCO.
- ❖ All Calibration Certificates are to be produced during Installation of Machine, without which the Installation is deemed incomplete. All the Certificates should be Traceable to National / International Standards.
- ❖ The Validity of Calibration shall be minimum 9 months and maximum 12 months from the date of Installation.
- ❖ All the Signal Cables should be shielded to avoid interference.
- ❖ Complete Earthing should be provided to Equipment.
- ❖ Complete covering of Electrical Cables and Other Connections.



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ANNEXURE - V : SAFETY FEATURES

DESCRIPTION (To be specified by the supplier, if any variation)	
Safety of system operation is of utmost importance.	
All guards to be with interlock switches. *	
Equipment to be provided with overload safety relay. *	
In the event of malfunction or stoppage of utilities, the unit must contain all necessary protection devices to ensure that equipment and product remain in safe condition. *	
Equipment settings should not get disturbed due to power failure and should not Re-start without human intervention. *	
Equipment should indicate fault through audio / visual signal with details on Control panel/PLC (Failure mode detection). *	
An easily accessible emergency stop to be provided on main control panel door. *	
Lubricant should not come in product contact. *	
Wherever possible, warning symbols should be provided. *	

ANNEXURE - VI : CLEANING TECHNIQUE

DESCRIPTION (To be specified by the supplier, if any variation)	
Mode of machine cleaning	: *
Use of Lubricants	: *
All contact parts should be easily dismantled and cleanable.	
If CIP is required , please provide the details of CIP and water consumption*	
Drain points: Vendor should specify the pipe size and location of drain points required as per system requirement *	

*** To be specified and confirm by the supplier as per their equipment design**



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ANNEXURE - VII : SAFETY interlock

DESCRIPTION					
(To be specified by the supplier, if any variation)					
Safety Features & Alarms					
Sr. No.	Condition	Display on HMI	Alarm	Print	Action
1.	Feed water conductivity High	Y	Y	Y	Feed Pump OFF
2.	Main steam inlet temp., low	Y	Y	Y	Feed Pump OFF
3.	Insufficient Vaporization In the First Column	Y	Y	Y	Feed Pump OFF
4.	Insufficient Vaporization In the Last Column	--	--	--	Purging Valve ON
5.	Absence of Feed Water	Y	Y	Y	Feed Pump OFF
6.	WFI Temperature Out Of Range	Y	Y	Y	-----
7.	Air Pressure Low	Y	Y	Y	Full System Down (After Delay Time)
8.	WFI Conductivity Out Of Range	Y	Y	Y	Dumping Valve ON
9.	WFI Storage Level High	Y	Y	Y	Full System Down
10.	Emergency OFF	Y	Y	Y	Full System Down
11.	Cooling Water Temperature High	Y	Y	Y	-----
12.	WFI Temperature Low	--	--	--	Dumping Valve ON + Cooling Pump OFF
13.	Feed Pump Trip	Y	Y	Y	Feed Pump OFF
14.	Cooling Pump Trip	Y	Y	Y	Cooling Pump OFF



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Sr. No.	Condition	Display on HMI	Alarm	Print	Action
	Additional alarm in sanitization mode				
	Overshoot Temperature	Y	Y	Y	Boiler Steam Inlet Valve off
	Mid Shoot Temperature	Y	Y	Y	Sterile counting Stop and when set temperature reaches counting will start from where it stopped
	Undershoot Temperature	Y	Y	Y	Sterile counting Reset and when set temperature reaches counting will start from beginning.

Alarms should be generated if:

1. Emergency stop is pressed.
2. Feed Water Conductivity high.
3. WFI Conductivity High.
4. WFI temperature low.
5. Boiler steam Temp low.
6. Cooling water temperature high.
7. Feed water Pump Trips.
8. Cooling water Pump Trips.
9. Feed Water level Low.
10. Compressed Air Pressure Low.
11. Storage Tank Water Level Full

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ANNEXURE - VIII : UTILITY REQUIREMENT

DESCRIPTION (To be specified by the supplier, if any variation)		
Steam	:	*
Vacuum	:	*
Compressed Air	:	*
Purified Water	:	*
Cooling water	:	*
Power	:	*
Any other (Which is required but not mention)	:	*

ANNEXURE - IX : PHYSICAL DETAILS

DESCRIPTION (To be specified by the supplier, if any variation)		
Dimension (In mm)	:	*
Net Weight (In Kgs.)	:	*
Type of Packing	:	*
Case Dimension (In mm)	:	*
Gross Weight (In Kgs.)	:	*
Foundation details (if required)	:	*

*** To be specified and confirm by the supplier as per their equipment design**



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ANNEXURE - X : LIST OF ANCILLARY / ACCESSORIES / OPTIONAL ITEMS

DESCRIPTION

(To be specified by the supplier, if any variation)

- Optional Items (If any , Vendor should provide the list with rate) *
- Recommended Spares along with list & quantity (Vendors should submit with tender) *
- If any items required but not included in URS , to be mentioned and submitted with unit rate and quantity * **(And it can be indicate during pre-bid meeting)**

Details of Bought out components to be specified.

Any other ancillary or accessories or optional items not mentioned above also to be quoted.

ANNEXURE - XI : TRAINING REQUIREMENT

- Training to all concern of HOMCO, Kerala for Installation, Operation, Maintenance and Cleaning of Blister Packing Machine should be provided by vendor and training record will be documented.
- Vendor shall support client in execution of all the Qualification Phases.

*** To be specified and confirm by the supplier as per their equipment design**



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ANNEXURE - XII : APPROVED MAKES

Stainless Steel Sheet : Tata / Jindal	:	*
Stainless Steel Pipe: Rensa / Reliant / Vishal	:	*
Pump: Alfa Laval / Fristam / Inoxpa	:	*
PLC: Siemens / Allen Bradely / Delta / ABB / Mitsubishi	:	*
HMI: Siemens / Allen Bradely / Delta / Exor	:	*
Valve/Diaphragm Valve (Weir Type): Mascon/Avcon/ Leistung	:	*
Steam Trap: Unikigler/ Sterflow /FORBSMARSHAL / Pennent/Trax	:	*
VFD: Schnieder / ABB /Siemens / Allen Bradely / Delta	:	*
FRL Unit & Pressure Switch: Festo / Euroswitch / SMC	:	*
Pressure Guage: Baumer / Wika / Cole-Parmer / Bourden	:	*
Level Indicator / Flow Indicator :Spink / Pune Techtrol / Krohne	:	*
Valve/Safety Valve : Mascon / Avcon / Leistung / IDMC / Aira / Racer / Trax / Forbes Marshall	:	*
Spray Ball :Jetspray / Spraytech	:	*
Flow Meter : Krohne Marshal / Emerson / E & C	:	*
Sensors/ Transmitter/ TOC analyser : Forbes / Mettler /Jumo / Radix/ Keller/ GE / Membra Pure	:	*
Cables: Finolex / Polycab	:	*
<p>❖ Any other components, not mentioned above, to be specified by the vendor.</p> <p>❖ All the Component Makes should match with the Approved Makes listed above. Any deviation from this should be documented and communicated to HOMCO and Pharma Consultant.</p> <p>❖ Material Test & Warranty Certificate should be provided for the applicable items.</p>		

*** To be specified and confirm by the supplier as per their equipment design**



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ANNEXURE - XIII : DOCUMENTATION

List of all Documents to be supplied along with equipment [AS APPLICABLE]

Sr. No.	Document to be supplied	Qty	Remarks
1	Design and operational qualification	2 sets	
2	SAT/FAT procedures and format	2 sets	
3	Operation manual	2 sets	
4	Maintenance manual	2 sets	
5	Spare parts manual	2 sets	
6	All engineering drawings (GA drawing)	2 sets	
7	List of instruments	2 sets	
8	Calibration certificates	2 sets	
9	Warranty / Guarantee	2 sets	
10	List of all components with referencing	2 sets	
11	Civil foundation drawings (If required)	2 sets	
12	Pre installation requirements	2 sets	
13	Installation requirements	2 sets	
14	Installation manual	2 sets	
15	Technical literature, data sheets and equipment catalogues	2 sets	
16	DQ, IQ, PQ documents.	2 sets	
17	Calibration Report of all sensors, controllers, PLC, transmitters, indicators etc.	2 sets	
18	Test Certificates of all material of construction	2 sets	
19	Test Certificates of the software used in machine control / monitoring system.	2 sets	



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ANNEXURE - XIV : TERMS AND CONDITIONS

Delivery Period	:	*
Payment Terms	:	AS mentioned in tender.
Packaging and Forwarding	:	*
Un- loading at site	:	By vendor /Supplier (If required, help for the arrangements of unloading can be done by client) Installation in position by the vendor under the client's supervision
GST	:	*
Material for Trial if any	:	* (To be arranged by client)
Installation and Commissioning	:	*
Submission of documents and drawings		
Response to URS and submission of quotation	:	Within 1 week
Submission of detail functional design specification and schematic drawings	:	Within a week after order finalization
Submission of FAT / SAT specification	:	2 weeks before FAT
Submission of DQ, IQ, OQ, PQ documents	:	With equipment delivery
Final drawings / diagrams	:	With one week of receiving PO
The supplier should notify customer 2 weeks in advance of the beginning of FAT.		
Catalogue, Equipment drawing (As built), List of clients and year of establishment to be submitted alongwith quotation.		
<i>Any other terms, not mentioned above, also to be specified.</i>		

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ANNEXURE - XV : ABBREVIATION

1.	URS	:	User Requirement Specification.
2.	HOMCO	:	Kerala State Homeopathic Co-operative Pharmacy Ltd.
3.	DQ	:	Design Qualification
4.	IQ	:	Installation Qualification
5.	OQ	:	Operational Qualification
6.	PQ	:	Performance Qualification
7.	SS	:	Stainless Steel
8.	RHS	:	Right Hand Side
9.	MOC	:	Material of Construction
10.	KW	:	Kilo Watt
11.	HP	:	Horse Power
12.	RPM	:	Rotation Per Minute
13.	FLP	:	Flame Proof
14.	cGMP	:	Current Goods Manufacturing Practices
15.	O&M	:	Operation and Maintenance
16.	GA	:	General Arrangement
17.	SLD	:	Single Line Diagram
18.	HOD	:	Head of Department
19.	QA	:	Quality Analysis
20.	MRP	:	Maximum Retail Price
21.	NMT	:	Not more than
22.	VFD	:	Variable frequency drive

Any other details, not mentioned in Annexure I to XIV, to be specified in the quotation/specification by the vendor.