

(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

#### **Supplier's Copy**

# **USER REQUIREMENT SPECIFICATION**

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	Utility (On service Floor)
Equipment and Code No.	:	<ol> <li>Pure Steam Generation Plant         <u>Capacity 100 kgs/hr.</u> </li> <li>Pipe and pipe fittings for pure steam distribution system</li> </ol>
Name of work	:	Supply, Installation, Commissioning & Validation of cGMP model Pure Steam Generation (PSG) & distribution system at M/s. HOMCO -Kerala
Ref. No.	i	
Date	:	
Enclosures	:	



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# PURE STEAM GENERATION PLANT Capacity: 100 kgs/hr.

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION					
(To be specified by the supplier, if any variation)					
		Supply, Installation, Commissioning and Validation of Pure Steam generation system including following:			
		1) Pure steam Generation System			
Scope		Distribution system including instrumentation			
		Along with all interconnecting pipes, valves, instrumentation, electrical cables, Skid , support and all accessories required for successful working of this system at site of M/s. Homco -Kerala			
Design Data	•				
Standard	•	cGMP and IP,BP and USP guidelines			
Working Principle	•	Finn Aqua Type			
Output ( Flow rate )	:	100 kgs/hr			
No. of columns	•	1 No.			
No. of pre heaters	•	2 Nos.			
Pure steam Temp	:	95 to 120 °C			
Outlet pure steam pressure	•	4 to 5 kgs/cm2			
Feed Water		Purified water			
Conductivity		<5.0μ Siemens/cm *			
Temp	-	25°C*			
Feed water Consumption	•	110-120 LPh *			

<sup>\*</sup> To be specified and confirm by the supplier as per their equipment design



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DESCRIPTION						
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Plant steam consumption	•	120 to 150 kgs/hr *				
Steam pressure	-	6 kgs/cm <sup>2</sup> *				
Compressed air Consumption	-	8-9 cfm @6-8 bar ,dry and oil free*				
PSG Output quality						
Endotoxins	:	<0.25 EU/ml				
TOC	-	<500 ppb				
Conductivity	:	<1.3 uS/cm at 20 °C				
Microbial Limit	-	<10 cfu/ml				
Non Condensable Gases	=	<3.5%				
Dryness	-	>90%				
Colour ,Test and odour	-	Clear				
Feed water Input quality						
Endotoxins	•	<250 EU/ml*				
TOC	:	<500 ppm				
Conductivity	:	<1.3 uS/cm at 20 °C *				
Microbial Limit	:	<100 cfu/ml*				
Colour ,Test and odour	:	Clear				
Design parameter						
Shell	:	6 to 9 kgs/cm <sup>2</sup> *				
Tube	•	5 to 7.5 kgs/cm <sup>2</sup> *				
Separator shell	:	5 to 7.5 kgs/cm <sup>2</sup> *				

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#### **DESCRIPTION**

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

#### SYSTEM DISCRIPTION

- The pure steam generation system should consist of two columns Evaporator and Separator.
- The Evaporator should be a shell and tube type of heat exchanger.
- The driving force i.e. plant steam heats the feed water in the tube side of the evaporator to generate vapor.
- The generated vapor should enter the Separator column. The separator column should use a double punch separation technique for particle entrainment and separation of impurities such as droplets and pyrogenic material.
- The first punch should offer by the multi- directional baffle, which should makes, the vapour traverse a torturous path. In the second stage, the steam should passes through a cyclone type centrifugal separator.

#### 1) Generation System:

Evaporator & separator heat exchanger	•	Shell Type: SS 316 L double tube sheet Tube type: SS 316L seamless tube Duly argon welded with purging
Insulation	•	Resin bonded glass wool covered with SS 304
De gasser system		In built
Sampling condenser	•	MOC SS 316L, for condensing generated pure steam for sampling

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ANNEXURE - II : cGMP FEATURES

#### **DESCRIPTION**

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

#### MOC

Evaporator and separator: SS 316 L

Insulation: Resin bond glass wool duly covered with SS 304

Structure : SS 304 pipe

MOC for all contact parts should be AISI 316L and non-contact parts SS 304

• Piping: Contact parts: SS 316 L and non-contact: SS 304 TC end and orbital welding

Sight and light glass : Toughened

 Valve: SS 316 L (Pneumatic piston valve, non return valve, safety valve, diaphragm valve and control valve.

• Steam trap : Float type

• Float switch: SS 316 L

Pressure gauge : Bourdon type SS 316 L

• 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.

Working Area Environment	:	Temperature : $26 \pm 2^{\circ} C$
	:	Relative Humidity : NMT 75%
Finish		Ra ≤ 0.4 µm 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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**OPERATIONAL FEATURES** 

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### DESCRIPTION

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#### 1) Pure steam generation plant - 100 kgs/hr.

#### **Process & Instrumentation**

- SS316 horizontal centrifugal feed pump
- > SS316L pressure switch with TC end

ANNEXURE - III

- > FRL: Filter regulator and lubricator for incoming compressed air.
- > PLC : RS 232 port for data communication, In built real time clock with data and time function , battery backup and 21 CFR part 11 compatible
- ➤ HMI: 5.7" screen size, with color display and resistive type touch screen.
- Printer: 80 column dot matrix data printer.
- > SS316 conductivity sensor to measure the conductivity of feed water
- > Rota Flow meter: SS 316 L to monitor flow of inkling feed water.
- > Temperature sensors : Type PT100 duplex type class A
- > Temperature indicator cum controller: To control the temperature.
- > Skid structure for instrumentation and distribution system.

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#### **DESCRIPTION**

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

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	:	1 No.*
Make	:	WSPL*
PSG Preheater		
Material Of Construction	:	Contact Parts -SS 316L*
Tube & Shell Type	:	Single Shell & Seamless Tube*
Insulation	:	SS 304*
Position		Vertical*
Quantity		2 No.*
Make		WSPL*
Non Condensable gases Rem	over (NCG	R)
Material Of Construction	:	Contact Parts -SS 316L*
Quantity	:	1 No.*
Make	•	WSPL*
PSG Column		



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Sampling Condenser			
Material Of Construction	:	Contact Parts -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	:	1 No.*	
Make		WSPL*	
Vent Filter			
Туре	:	Plain*	
Material of Construction	:	SS 316L*	
Size	:	10" Long*	
End Connection	•	TC End*	
Location		On top of the NCGR*	
	i		

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vvepsite . www.nome	okci ala.com	Linaii . <u>Horricokerala(wymaii.com</u>	
Vent Filter Cartridge		4	
Туре	:	Hydrophobic*	
Material of Construction	•	PTFE*	
Size		10" Long, 0.2 Micron*	
End Connection		Code-7*	
Location		Over The Tank Inside The Vent Filter*	
Temperature		Ambient to 125°C*	
Quantity		1 No.*	
Make		WSPL*	
Feed Water Pump			
Capacity	•	0.115 m3/hr*	
Head	•	3 Kg/cm2*	
Type	•	Centrifugal Pump*	
Application	•	Purified Water*	
MOC	•	SS 316*	
End Connection	•	TC End/Flange End*	
Supply	•	415V/3 Phase/50Hz*	
Quantity	:	1 No.*	
Make		Grundfos/Xylem/Equivalent*	
Instruments			
Pressure Gauge	r		
Туре	•	Bourdon type*	

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Range	:	0 to 10 Kg/cm2*
Contact Parts	•	SS 316L*
Non-contact parts		SS 304*
Dial Size	•	100 mm*
Dampening Liquid	:	Glycerin Filled*
Marking	•	White Background With Black Marking*
Sensing Elements		Bourdon Gauge*
End Connection		TC End*
Location	•	Feed Water Pump Outlet, Plant Steam Inlet & Plant Steam Line To Preheater*
Quantity		3 No.*
Make		Baumer/Equivalent*
Level Switch		
MOC	:	Wetted Parts SS 316L*
Туре		Top Mounted Magnetic Level Switch*
End Connection		TC End*
Location		For Column & NCGR*
Quantity		2 No.*
Make	:	Pune Techtrol/Equivalent*
Flow Indicator Switch		
MOC:	:	SS 316L*
Installation:	:	Upward Flow Vertical Installation*
Fluid:		Water*

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End connection:	:	TC End*	
Quantity		1 No.*	
Make	i	Danfoss / Indfos*	
Temperature Sensor Cum Transmi	tter		
Туре	:	Pt 100/Simplex/3 Wire/Fixed*	
MOC	i	SS 316L*	
Range		0 To 200°C*	
Length		50mm*	
Accuracy		Class A, 4 – 20 mA*	
End connection		TC End*	
Quantity		4 No.*	
Make		Radix / Equivalent*	
Conductivity Sensor & transmitter			
Range	•	0 to 10 μS/cm*	
MOC	i	SS 316L*	
Size		DN 20*	
Output	i	4-20 mA*	
Location		Sampling Condenser Outlet*	
End Connection		TC End*	
Quantity		1 No.*	
Make	i	Forbes marshal/ Mettler/ Jumo*	
<b>DESCRIPTION</b> ( To be specified by the supplier, if any variation)			

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Pressure Transmitter		
MOC	:	SS*
Rang	:	0 to 10 bar*
Location	:	Pure Steam Outlet*
End Connection	:	TC End*
Quantity	:	1 No.*
Make	:	Keller/Equivalent*
Valves		
Pneumatic Actuated Angle So	eat Piston 1	Гуре Valve
MOC	:	SS 316*
Size / Quantity	:	DN 20-2 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 Va	ılve	
Size / Quantity	:	DN 20-4 No.; DN 25-1 No.*
Туре	:	Two Way Actuated Diaphragm valve*
MOC	:	Body-SS 316L, Bonnet- SS 316, Stem-ASTM A276*

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Website: www.homcokerala.com Email: homcokerala@gmail.com PTFE Backed EPDM\* MOC of Diaphragm Operation : Pneumatic Operated\* Operating Temperature : Upto 180°C\* Operating Pressure : Upto 16 bar\* **End Connection** : TC End\* Make Mascon/Avcon/ Leistung\* **Manual Diaphragm Valve** : DN 15-1 No.; DN 20-2 No.; DN 25-1 No.\* Size / Quantity : Two Way Manual Diaphragm Valve\* Type SS 316L\* MOC MOC of Diaphragm : PTFE backed EPDM\* Operation : Manually Operated\* : Upto 180°C\* Operating Temperature Operating Pressure : Upto 16 bar\* **End Connection** : TC End\* Make Mascon/Avcon/ Leistung\* **Sampling Valve** Size / Quantity : DN 15-1 No.\* : Two Way Manual Diaphragm Valve\* Type MOC : SS 316L\* PTFE Backed EPDM\* MOC of Diaphragm

*	Tο	he	specified	and	confirm	hv	the	sunnlier	as no	er their	equipment	desian
		$\mathbf{p}$	<b>Specified</b>	allu	COIIIII	υv	uie :	Suppilei	as p	ei tileii	equipilien	Lucsigii

DESCRIPTION	
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Website: www.homcokerala.com Email: homcokerala@gmail.com TC End\* **End Connection** Mascon/Avcon/ Leistung\* Make : **Non-Return Valve** Size / Quantity : DN 20-4 No.\* MOC : SS 316\* Type : Disc Check Valve\* **End Connection** TC End\* : : WSPL\* Make **Pressure Safety Valve** MOC SS 304\* DN 15-1 No.; DN 20-1 No.\* Size / Quantity : : Disk Type\* Type Location : Plant steam Inlet & Pure Steam Outlet\* **End Connection** TC End/Threaded End\* Make : TRAX/Forbes Marshall\* **Steam Trap For Condensate Drain** Size / Quantity : DN 15-1 No.; DN 20-2 No.\* MOC SS 316L\* Type : Ball & Float Type\* **End Connection** BSPT(F)\* : Make Pennent/ TRAX\*

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

#### **DESCRIPTION**

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Website: www.homcokerala.com Email: homcokerala@gmail.com Y-Type Strainer Size / Quantity : DN 25-1 No.\* Type : Thermodynamic\* MOC : Carbon Steel\* Location Plant Steam Inlet\* : **End Connection** : DN 25 BSP\* Make : Trax/Equivalent\* **Manual Ball Valves** Type : 3 piece full port\* Size / Quantity DN 20-8 No.; DN 25-5 No.\* : SS 304\* **End Connection** : : Steam Condensate Removal\* **Application Operating Temperature** : Upto 180°C\* Pressure Rating : Upto 10 bar\* Make : Unison/Aira/Racer/Equivalent\* Globe valve SS 304\* MOC : Size / Quantity DN 25-1 No.\* Operation Manually Operated\* : **Operating Temperature** : Upto 180°C\* Operating Pressure Upto 16 bar\* Plant Steam Inlet\* Location :

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		<u></u>					
End Connection	:	TC End*					
Make	:	Avcon/Airmax/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					
Any other detail not mentioned al	bove, also	to be included.					
	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.						
	DES	CRIPTION					
( To be spe	cified by th	ne supplier, if any variation)					

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#### **DESCRIPTION**

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2) Pipes & Pipe Fittings For Pure Steam Loop Syst	em	
Description	Size	Quantity
SS 316L Pipe Stainless Steel bead removed tubes of Schedule 40 (Wall thickness around 1.6mm), material shall be as per ASTM A 270 TP 316L ERW, Internal finish shall be electro polished to better than 0.5 Ra & externally mirror polished to 180 grit. Flanges Class ASA150 SORS	1.0"OD ¾″ OD ½″ OD	70 mtrs. 15 mtrs. 15 mtrs.
SS 316L Elbow of Schedule 40 (Wall thickness around 1.6mm), made out of ASTM A270 TP 316L tube bead removed wall thickness to match with respective match with respective pipe wall thickness. Internal finish shall be electro polished to better than 0.5 Ra ASTM A270 TP 316L ERW & externally mirror polished to 180 grit	1.0"OD ¾″ OD ½ ″ OD	30 nos. 07 nos. 07 nos.
SS316L TEE of Schedule 40 (Wall thickness around 1.6mm), made out of ASTM A270 TP 316L tube bead removed wall thickness to match with respective match with respective pipe wall thickness. Internal finish shall be electro polished to better than 0.5 Ra ASTM A270 TP 316L ERW & externally mirror polished to 180 grit	3/4"	3 nos.
SS316L UNEQUAL TEE of Schedule 40 (Wall thickness around 1.6mm), made out of ASTM A270 TP 316L tube bead removed wall thickness to match with respective match with respective pipe wall thickness. Internal finish shall be electro polished to better than 0.5 Ra ASTM A270 TP 316L ERW & externally mirror polished to 180 grit	1" × ¾" 1" × ½"	3 nos. 6 Nos.
SS316L Reducer of Schedule 40 (Wall thickness around 1.6mm), made out of ASTM A270 TP 316L tube bead removed wall thickness to match with respective match with respective pipe wall thickness. Internal finish shall be electro polished to better than 0.5 Ra ASTM A270 TP 316L ERW & externally mirror polished to 180 grit	¾" to ½"	3 nos.
TC Gasket , MOC PTFE	1" ¾" ½"	20 nos. 10 nos. 10 nos.
TC Clamp, MOC: SS304, Standard: ASTM A270	1" ¾" ½"	20 nos. 10 nos. 10 nos.



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DESCRIPTION									
( To be specified by the supplier, if any variation)									
Description	Size	Quantity							
TC Liner, MOC : SS316L	1" ¾" ½"	20 nos. 10 nos. 10 nos.							
Insulation of PSD Line, Nitrile rubber with Aluminum Cladding	1" 3¼" ½"	70 mtrs. 10.5 mtrs. 15 mtrs.							
Pipe in pipe , MOC - SS 304	3/4" x 2.5" OD	03 nos.							
SS 304 Pipe Holding Clamp	1" ¾" ½"	20 nos. 10 nos. 10 nos.							
Standard Support (SS)	100mm	15 nos.							
SS Studs	100/50MM	30 nos.							
SS Anchor Bolt / panel bolt	M10×75mm	40 nos.							
MS Square Plate	100×100×5mm	30 nos.							
MS Anchor Bolt	M10×75mm	20 nos.							
MS Angle	40 × 40× 6 mm	20 mtrs.							
Insulation Tap	3/4" x 3.0" OD	2 Roles							
Manual Diaphragm Valve  Type: Two Way Manual Diaphragm Valve , MOC: SS 316L (Base), MOC of Diaphragm: PTFE backed With EPDM, Operation: Manually Operated, Operating Pressure: Up to 16 bar, End Connection: TC End, Location: Inlet & At Condensate Drain Line Of Header & POU	DN 15 DN 20 DN 25	5 Nos. 3 Nos. 1 No.							
Actuated Diaphragm Valve For Vent Filter Isolation: Type: Two Way Actuated Diaphgram Valve, MOC: SS 316L (Base), MOC of Diaphragm: PTFE backed With EPDM, Operation: Pneumatically Operated, Operating Pressure: Upto 16 bar, End Connection: TC End, Location: For Vent Filter Isolation	DN 15	1 No.							



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DESCRIPTION								
( To be specified by the supplier, if any variation)								
Description	Size	Quantity						
Vent Filter with Accessories :								
Type: Electrically heated Insulated & cladded, MOC: SS 316L, Temperature sensor: PT 100, 3 wire, Heater Make: Hot Watt, End Connection: TC End, Accessories: Temperature sesnsor with transmitter, Make: Radix	10" long	1 No.						
Vent Filter Catridge :								
Type: Hydrophobic, MOC: PP/PTFE, Size: 10" Long, End Connection: Code-7, Location: Inside the Vent Filter	0.2 Micron	1 No.						
Pressure Gauge :								
Type: Bourdon Type, MOC: SS 316L, Range: 0 to 10 kg/cm2(g), Sensing Elemen: Bourdon Gauge, End Connection: TC End, Marking: White Background with Black Marking, Location: Pure Steam inlet	4" Dial size	1 No.						
Pressure Switch :								
Range: 0.2 to 3.0 bar, Contact System: Single Pole Changeover Switch (SPDT), MOC: SS 316, Power Supply: 24 VDC, Enclosure: IP 66, End Connection: TC End with Diaphragm Seal	0.2 to 3.0 bar	1 No.						
Temperature Sensor Cum Transmitter :								
MOC: SS 316L, Model: PT100, 3 wire Type, Size: 1/2" BSP, Length: Approx. 50 mm, End Connection: TC End, Location: In pure steam line after vent filter, Temperature Range: 0 to 200 °C	0-200 °C	1 No.						
Clean steam trap for condensate removal :								
MOC: SS 316L, Location: At condensate drain line, End Connection: TC End	DN 15	5 Nos.						
ORBITAL WELDING PER INCH DIA	1",3/4",1/2"	dia						
Hydro testing	1",3/4",1/2"	1 lot						
passivation	1",3/4",1/2"	1 lot						
Boroscope inspection (10% only)	1",3/4",1/2"	1 lot						
Pipe erection /Laying of piping per inch meter	1",3/4",1/2"	mtr						



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ANNEXURE - IV : ELECTRICAL DETAILS

( To be specifie	ad by t	he supplier, if any variation)
( To be specific	Eu by t	The supplier, it arry variations
Standard Operating Frequency	ŧ	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	:	*

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.

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



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**SAFETY interlock** 

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#### DESCRIPTION

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

#### **Safety Features & Alarms**

ANNEXURE - VI

- The Plant Steam supply should not start unless the Feed Water is filled up to the Level Switch.
- AUTO PURGING FACILITY: To prevent build-up of impurities in the evaporator and NCGR columns an auto purging facility should be wherein feed water should purged at pre-defined time interval.

#### Alarms should be generated if:

- Feed Pump Trip.
- Plant Steam Pressure Low.
- Feed Water Pressure Low.
- Compressed Air Pressure Low.
- Pure Steam Pressure High / Low

ANNEXURE - VII : CLEANING TECHNIQUE

	DES	CCRIPTION
( To be specifie	ed by t	the supplier, if any variation)
Mode of machine cleaning	•	*
Use of Lubricants		*
All contact parts should be easily disr	nantle	d and cleanable.
If CIP is required , please provide the	detai	ls of CIP and water consumption*
Drain points: Vendor should specify t system requirement *	he pip	pe size and location of drain points required as per

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



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### ANNEXURE - VIII : UTILITY REQUIREMENT

(To be spe	cifie	<b>DESCRIPTION</b> ad by the supplier, if any variation)
Plant Steam	•	*
Vacuum	•	*
Compressed Air	:	*
Purified Water	:	*
WFI water	•	*
Cooling water	:	*
Power		*
Any other	:	*

ANNEXURE - IX : PHYSICAL DETAILS

(To be specifie		CRIPTION he 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		*

<sup>\*</sup> To be specified and confirm by the supplier as per their equipment design



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LIST OF ANCILLARY / ACCESSORIES / OPTIONAL ITEMS ANNEXURE - X

#### **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.

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

**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.



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#### ANNEXURE - XII : APPROVED MAKES

- \* Any other components, not mentioned above, to be specified by the vendor.
- \* All the Component Makes should match with the Approved Makes listed above. Any deviation from this should be documented and communicated to HOMCO.
- \* Material Test & Warranty Certificate should be provided for the applicable items.

<sup>\*</sup> To be specified and confirm by the supplier as per their equipment design



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ANNEXURE - XIII : DOCUMENTATION

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,	2 sets	
	transmitters, indicators etc.		
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	:	By Vendor
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 <b>supervision</b>
GST	:	*
Material for Trial if any	:	* (To be arranged by client)
Installation and Commissioning	:	By Vendor
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	adv	ance of the beginning of FAT.
Catalogue, Equipment drawing (As built), Lis submitted alongwith quotation.	t of	clients and year of establishment to be
Any other terms, not mentioned above, also to	be s	pecified.

<sup>\*</sup> To be specified and confirm by the supplier as per their equipment design



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### ANNEXURE - XV : ABBREVIATION

1.	URS	:	User Requirement Specification.	
2.	НОМСО	:	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 XV, to be specified in the quotation/specification by the vendor.