



PHARMA VALIDTM

AN ISO 9001:2015 & ISO 13485:2016 COMPANY

Mobile : +91 9029061512 Email :- info@pharmavalid.in, devendrak@pharmavalid.in

Ref. No.: - PV/22/0336/R0

Date : - 16.11.2022

To,
M/s GNE Lifesciences Pvt. Ltd.
Khasra No 398, Nanheda,
Bhagwanpur, Roorkee,
Uttarakhand.

Kind Attn. :- Mr. Banmeet Singh Makkar (Director)
Mobile :- +91 8178563879
Email :- banmeet.sm@gmail.com

Subject :- Offer for Supper Heated Water Spray Sterilizer 6 meter.

Dear Sir,

Many thanks for your valuable enquiry, With reference to your enquiry; we are pleased to enclosing herewith our offer for **Supper Heated Water Spray Sterilizer as per your requirement.**

If you require any further clarifications or assistance, please feel free to get in touch with us.

We hope our proposal is in line with your requirement and look forward to the pleasure of receiving your valued order soon.

Thanking you, we remain

Yours faithfully,
For **Pharma Valid**

+91 9029061512
Suryakant Mane



DESCRIPTION OF PHARMA VALID S H W S S

This sterilizer is an automatic sterilizer with cooling and overpressure systems.

This system is most suitable for sterilizing parenteral solutions in PP & glass bottles & pouches. It makes use of streams of super heated water instead of steam.

It consists of

1. Main body with Sliding door on both side
2. Heat exchanger where heat of steam from boiler is transferred to the circulating Sterile water, which circulates in a closed circuit.
3. Water circulation pump suitable for high pressures and temperatures.

During the heating and sterilizing stages of the cycle, water stored in the sump at the bottom of the sterilizer, is sucked up by the pump and moves through the heat exchanger where it reaches the desired temperature. Then it flows through the closed circuit at high speeds around the items placed on shelves.

Pressure is regulated separately from the temperature by letting compressed air in and out of the sterilizer, according to command given by a program.

During the cooling stage, the cooling water is circulated in the heat exchanger to cool the sterile circulating water. These rules out the risk of recontamination.

The heat exchange system also eliminates the danger of any heat shock or breakage of fragile items occurring.

When the end of the cycle is reached, the circulation pump stops automatically.

The sterilized water is stored in the bottom of the tank, while the chamber returns to normal air pressure.

The articles in the unit can now be removed.

The PLC based auto cycle controls all the sterilization parameters.



PHARMA VALIDTM

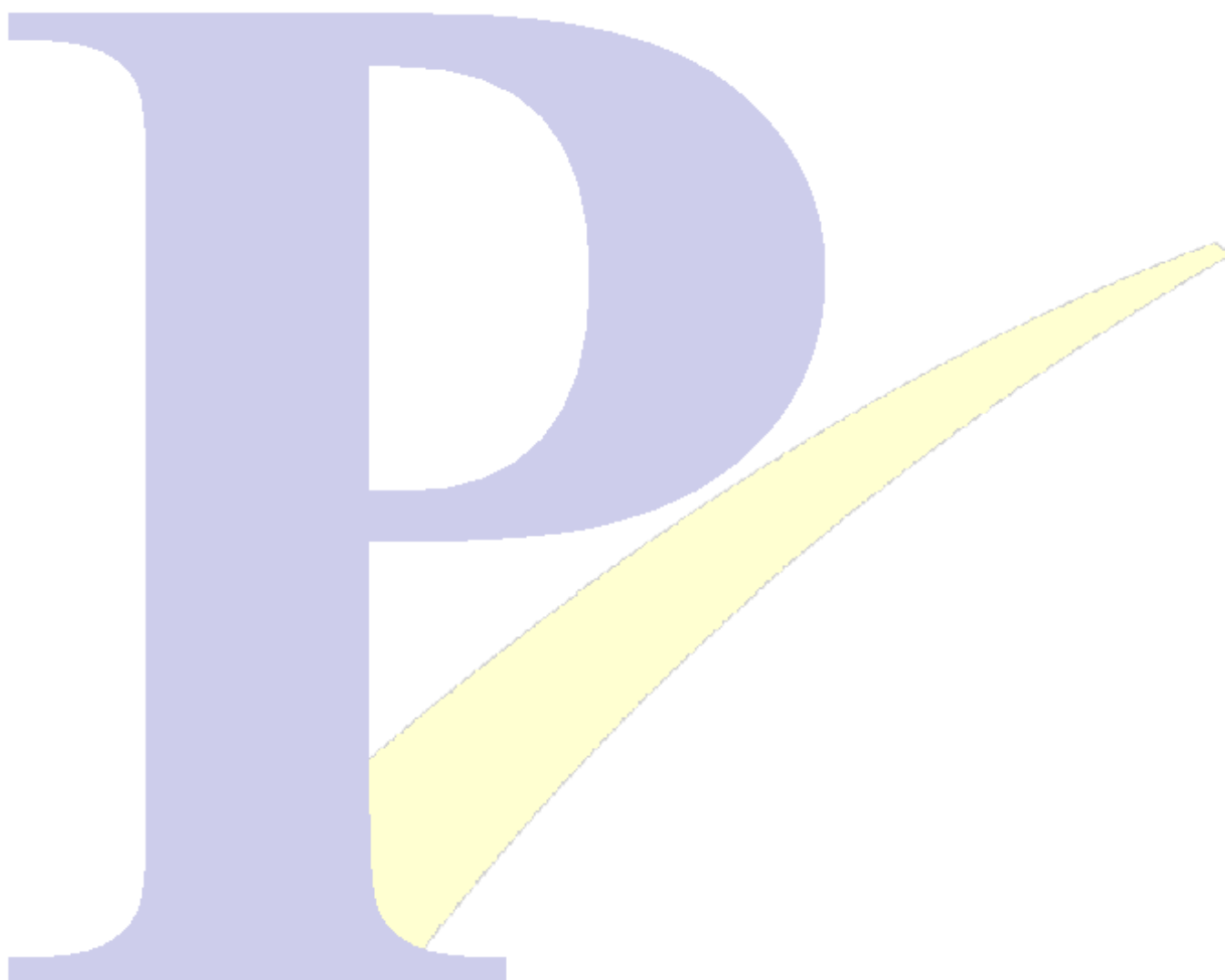
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This includes the regulation of the temperature and pressure, monitoring functions and alarm.

The advantage of this system is that the temperature is kept even and uniform throughout the system, regardless of the number of shelves in use.

The flow of water is also identical throughout the machine. Its design rules out the danger of contamination because all the water coming into contact with the products placed in it has been sterilized.





CYCLE DETAILS FOR S H W S S

When door closed condition fulfilled then on the command from the control panel to start the cycle, the following sequences occur.

- a. Recirculation pump starts.
- b. Steam inlet for heat exchanger will start.
- c. The outlet water temperature of heat exchanger shall be maintained at preset value (as required) as programmed on PLC for the duration of sterilization cycle.
- d. Precision pressure sensor will sense pressure accordingly regulate the sterile air over-pressure.
- e. The sterilization cycle will be terminated on the basis of on line F_0 values calculated by the PLC (optional) or as per set time. However, the minimum F_0 values desired will be programmable.
We recommend a minimum of four temperature sensors for calculating F_0 values on line optionally.
- f. During the cooling cycle, the steam in the heat exchanger will be cut-off and cooling water will be circulated to reduce the temperature rapidly.
- g. At a predetermined cooling temperature (programmable) the cycle will be deemed complete.
- h. Safety interlocks.
- i. Door will not open during cycle time.
- j. Recalculating pump will not start unless there is enough water in the sump.
- k. Steam supply to the heat exchanger will not start until the recirculation pump is on.
- l. In case of drop in pressure of instrument air supply or support air supply or steam pressure while the equipment is in operation, audio alarm and display on HMI will indicate the fault condition.

The same will also be documented on a 80 column Dot matrix printer .
- m. We recommend use of UPS for the control systems, so that in case of power failure, the control status is not disturbed.
- n. All other standard safety features will also be provided.
e.g. safety valves on all pressurized lines.



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- o. Any fault condition occurring during the sterilizer operation, will be indicated on the MMI along with audio indication.
- p. Fault conditions concerning inputs, e.g.
- Low instrument air pressure
 - Failure of water circulation pump (Over Load)
 - Unlocked door condition
 - Low sump water level
 - Power failure and resumption times etc. will be displayed on HMI and documented on printer.

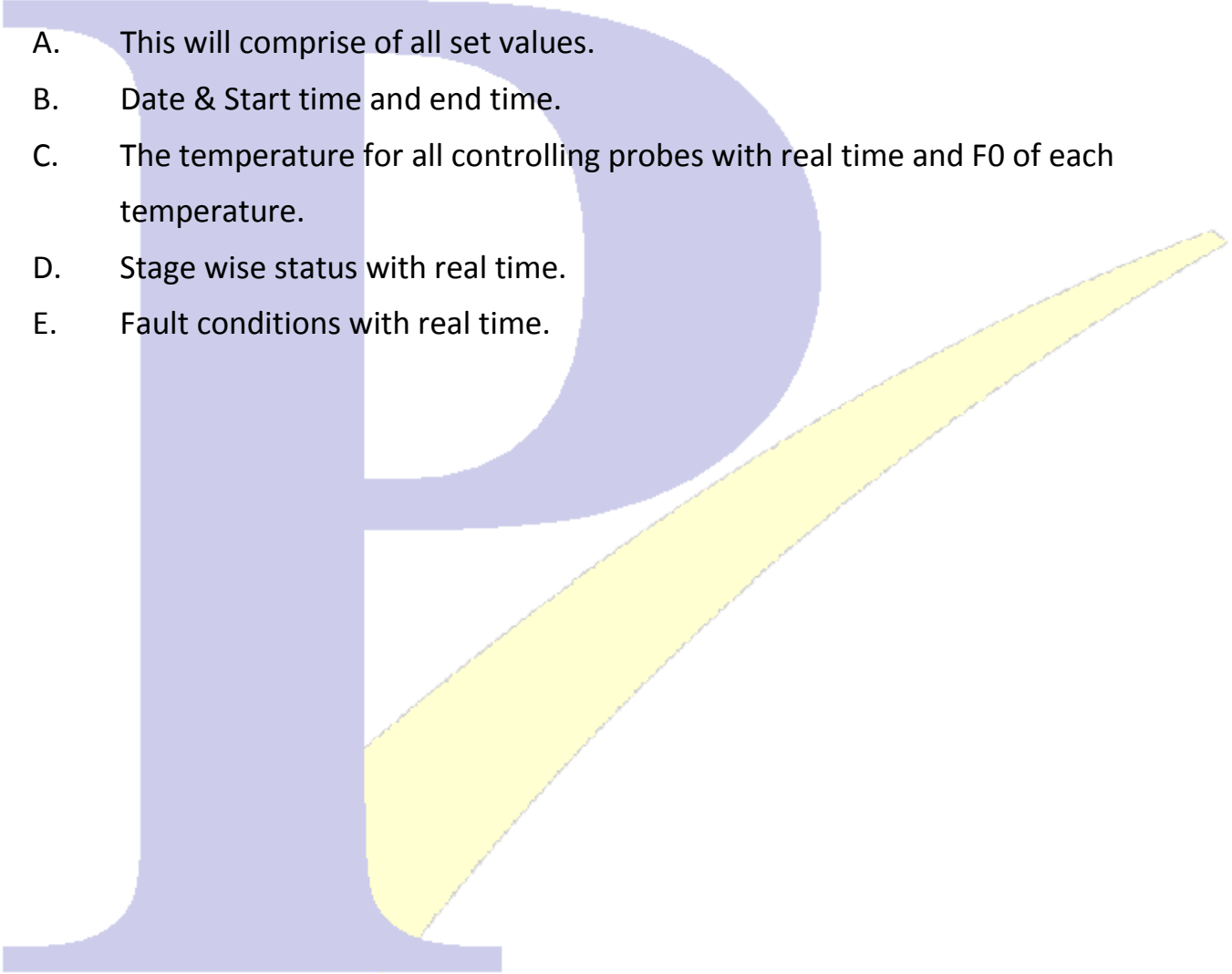


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PRINT OUT

- 
- A. This will comprise of all set values.
 - B. Date & Start time and end time.
 - C. The temperature for all controlling probes with real time and F0 of each temperature.
 - D. Stage wise status with real time.
 - E. Fault conditions with real time.



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TECHNICAL SPECIFICATIONS (MACHINE COMPONENTS)

No.	COMPONENTS	MANUFACTURER'S SPECIFICATIONS
1.	Chamber	
	Type	Horizontal Sliding doors type Super heated Water Spray Sterilizer with auto operation, double door Cylindrical
	Overall Chamber dimensions in mm (Dia x length)	1. 2200 Dia. x 7600 Lg
	Overall dimensions (W x H x D in mm)	Drawing will be approved
	Chamber Door opening and useable Chamber size	1. 1200(w) mm x 1650 (h)mm x 6300 (d) mm
	Corners of chamber opening	R 75 mm
	Inner chamber (MOC)	SS 316L
	Thickness of chamber	6 mm
	Operating temperature	Up to 121°C
	Working Pressure	2.1 kg/cm ²
	Design Pressure	2.31 kg/cm ²
	Hydraulic test pressure	3.15 kg/cm ²
	Surface finish	0.6 µm
2.	Shell Insulation	
	MOC of outer cover	SS 304
	Thickness of outer cover	1.2 mm
	Insulation material	Resin Bonded Glass wool
	Thickness of insulation material	75 mm
	Skin Temperature	Approx. 35° above ambient temperature.
3.	Doors	
	Type	Horizontal sliding double doors
	Doors contact parts (MOC)	SS 316L
	Thickness of contact parts	6 mm
	Doors noncontact parts (MOC)	Mild Steel



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No.	COMPONENTS		MANUFACTURER'S SPECIFICATIONS
	Thickness of noncontact parts		22 mm
	Door gasket (MOC)		Hollow circular silicon door gasket
	Rails of sliding door		No Lubrication required
	Door interlocking (description)		Electro Pneumatic door Interlocking System with following features Any Door cannot be opened during process 'ON' or When chamber is under pressure Both doors cannot be opened at a time after "Cycle Complete"
4.	Door Cylinder		
	Operation		Pneumatic
	Make		N Flow / Janatics
	Mounting		Horizontally
	Size		80 Bore x 1350 Stroke
5.	Saddle Support Details		
	Material		Mild Steel
	Mounting		Pit Mounted
6.	Carriage (Optional)		
			Designed as per load description
7.	Carriage Railing		
	C channel		SS 316
8.	Chamber Internal Walking Plate		
	MOC		SS 316
	Thickness		4 mm
9.	Sprinkling Tray		
	Upper Tray	MOC	SS 316



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No.	COMPONENTS		MANUFACTURER'S SPECIFICATIONS
	Lower Tray	Perforated	8 mm Dia. holes
		MOC	SS 316
		Perforated	3 mm Dia. holes
10.	Interconnection Piping		
	Piping material of Chamber		SS 316
	Piping material of Heat Exchanger		SS 316
	Connections		No flexible
	End connections		Process Piping – Triclover & Flange Instrument Tube – Compression fittings.
11.	Heat Exchanger		
	Make		Pharmavalid Make
	Type		Shell & Tube type
	Shell MOC		SS316
	Tube MOC		SS316L
	Working Pressure Shell/Tube		2.5 kg/cm ² / 4 to 6 kg/cm ²
	Design Pressure Shell/Tube		3.0 kg/cm ² / 6.6 kg/cm ²
	Hydraulic Test Pressure Shell/Tube		3.75 kg/cm ² / 9.0 kg/cm ²
12.	Pressure Switch		
	Make		Indfos
	Model		B3/B2
	Location		For Doors & Chamber
	Function		To Maintain the pressure level for the Gasket. & Chamber
13.	Vacuum Switch		
	Make		Indfos
	Model		V2



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No.	COMPONENTS	MANUFACTURER'S SPECIFICATIONS
	Location	For Doors
	Function	To reached the Vacuum level for the Gasket.
14.	Compound Gauge	
	Make	Radix
	Size	4" Dial Size
	Mounting	Panel
	Range	-1 to 5.0 kg/cm ²
	Connection	Back Connection 3/8" bsp
	Location	Door 1 Pressure on ST Door 1 Pressure on NST Door 2 Pressure on NST
	Function	Indicating the Door Gasket Pressure
15.	Pressure Gauge	
	Make	Radix
	Size	4" Dial Size
	Mounting	Panel
	Range	0 to 4 kg/cm ²
	Connection	Back Connection 3/8" bsp
	Location	Chamber Pressure on ST Chamber Pressure on NST
	Function	Indicating the Chamber Pressure
16.	Pressure Gauge	
	Make	Radix
	Type	Bourdon Tube, panel Mounting, Back conn, ss Body
	Size	4" Dial.
	Range	0 – 6 kg/cm ²
	Connection	Back Connection 3/8" BSP



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No.	COMPONENTS	MANUFACTURER'S SPECIFICATIONS
	Location	HE Pressure gauge
	Function	Indicating the HE tube side Pressure
17.	Pressure Gauges	
	Make	Radix
	Type	Bourdon Tube, panel Mounting, Back conn, ss Body
	Size	4" Dial.
	Range	0 – 7 kg/cm ²
	Connection	Back Connection 3/8" bsp
	Location	Instrument Air Pressure gauge
	Function	Indicating the Air Pressure
18.	Safety Valve	
	Make	Frobes Marshal
	Type	Spring loaded
	Size	1 ½"
	Range	0 To 6 kg/cm ²
	Location	On Chamber
	Function	For Chamber over Pressure Safety
	Size	1 ½"
	Range	0 To 9 kg/cm ²
	Location	On Heat Exchanger
	Function	For HE tube side over Pressure Safety
19.	Steam Trap for Condensate Removal	
	Make	Forbes Marshal
	Type	Float Type
	Size	1" BSP



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No.	COMPONENTS	MANUFACTURER'S SPECIFICATIONS
	Location	On H.E. Condensate Line
	Function	To Prevent Loss of steam along the condensate removal line
20.	FRL	
	Make	Phoniex
	Size	¼" BSP
	Function	To Filter, Regulate & Lubricate the incoming Air Pressure used for solenoid valves
	Size	½" BSP
	Function	To Filter, Regulate & Lubricate the incoming Air Pressure used for door gasket pressure
21.	Limit Switch	Jai Balaji
	Model	1 NO 1 NC
	Location	On Door
	Function	To Give the signal to plc door is close & open
	Quantity	04 nos.
22.	Circulating Pump	
	Make	Supper flow pumps pvt. Ltd.
	Type	PPF
	Discharge	1. 325 M ³ /Hr (6 meter)
	RPM	960
	Suction & discharge	1. 200 X 150 (6 meter)
	Material	SS 316
	Head	5 Mtrs
	Quantity	01 nos.
23.	Motor for Circulating pump	
	Make	Hawells /Siemens



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No.	COMPONENTS		MANUFACTURER'S SPECIFICATIONS
	HP		1. 10 (6 meter)
	Type		Foot mounted
	RPM		960
	Qty.		01 Nos.
24.	Pneumatic Angle Valve		
	Make		Rotex
	MOC		SS316
	Model		Single Acting
1.	Size		2"
	Location		Plant Steam in H.E. for fast heating
2.	Size		1"
	Location		Plant Steam in H.E. for slow heating
3.	Size		2"
	Location		Cooling water in H.E.
4.	Size		2"
	Location		Cooling water out to cooling tower
5.	Size		1½"
	Location		H.E. Condensate outlet
6.	Size		1½"
	Location		PW inlet
7.	Size		1½"
	Location		Chamber drain
8.	Size		1½"
	Location		Air inlet
9.	Size		1½"
	Location		Air outlet



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No.	COMPONENTS		MANUFACTURER'S SPECIFICATIONS
	10.	Size	¾"
		Location	Loading Door Gasket Pressure
	11.	Size	¾"
		Location	Unloading Door Gasket Pressure
	12.	Size	¾"
		Location	Loading Door Gasket Vacuum
	13.	Size	¾"
		Location	Unloading Door Gasket Vacuum
	14.	Size	¾"
		Location	HE Tube side Vent
	15.	Size	¾"
		Location	HE Tube side Drain
25.	Electrical Control Panel		
	Material		SS 304
	Type		Front Panel mounted
26.	Manual Ball Valves		
	MOC		SS316
	Make		Gamu
	Size		1" TC End
	Application		Steam Trap Bypass
	Size		¾" TC End
	Application		Level Switch
	Quantity		2 nos.
27.	Switch Gear		
	Contactor		Siemens



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No.	COMPONENTS	MANUFACTURER'S SPECIFICATIONS
	MCB	Siemens
	Over load relay	Siemens
	Control Relay	Omron
	Indication Lamp	Technik / Siemens / Schneider / Mkey / Sumo
	Emergency	Technik / Siemens / Schneider / Mkey / Sumo
	Push Button	Technik / Siemens / Schneider / Mkey / Sumo
	Rocker Switch	Technik / Siemens / Schneider / Mkey / Sumo
	Terminal	Connect well
28.	Float Switch	
	Make	Mahalaxmi
	Material	SS 316
	Model	Horizontal Float Type
	Location	On Chamber
	Function	Chamber water level high Chamber water level low
29.	Automation	
	PLC	
	Make	Allen Bradley
	Model	ML1400 L32BWAA
	Inbuilt DI/DO	20/12 (24VDC/Relay)
	Inbuilt AI/AO	4/2 (0 to 10 volts)
	Ports	1. Ethernet for communication 2. RS232 3. RS232/RS485 configurable
	Temperature Input Card	
	Make	Allen Bradley
	Model	1762 IR4
	AI	04 channel RTD input



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No.	COMPONENTS	MANUFACTURER'S SPECIFICATIONS
	Power	Bus Power
	Quantity	02 nos. for 6 meter
	Printer	
	Make	TVS
	Model	MSP270
	Type	Dotmatrix
	HMI loading side	
	Make	Proface / Schneider
	Configuration	7" colour capacitive touch screen
	Ports	1. USB 2.0 - 02 nos. 2. Ethernet – 01 no. 3. RS232 – 01 no. 4. RS485 – 01 nos.
	Application	To monitor and control status of machine and also operating and controlling with high level password in case.
30.	Temperature Sensor	
	Make	Radix
	Accuracy	0.1%
	Type	Pt100 RTD Three Wire Class A Duplex type
	MOC	SS316 Tip
	Range	0 to 200 °C
	Connection	½" BSP
	Size	6 mm Dia X 100 mm tip length fix sensor
	Application	1. HE Temperature 2. Drain Temperature
	Size	6 mm Dia X 100 mm tip length flexible sensor
	Application	Chamber Temperature 06 nos.
	Quantity	8 nos.
31.	Pressure Transmitter	



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No.	COMPONENTS	MANUFACTURER'S SPECIFICATIONS
	Make	Jumo
	MOC	SS316L
	Connection	½" BSP
	Input	24 VDC
	Output	4 to 20 mA
	Range	0 to 4 bar
	Application	Chamber Pressure
32.	Number of Programmed Cycles	1. Process-1 2. Process-2 3. Process-3 4. Process-4 5. User can Edit Process in recipe management 6. Additional memory for extra cycles
33.	Temperature Uniformity	± 0.5 °C as per HTM 2010
34.	Validation Port	
	MOC	SS316L
	Size	2" TC End
	Application	To insert 24 temperature sensors in chamber for mapping
	Quantity	02 nos.
35.	Vacuum Ejector	
	Make	Festo
	Application	Retraction of Door Gasket Pressure
36.	Door safety sensor	
	Make	Schneider / Omron
	Type	Retro reflective



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No.	COMPONENTS	MANUFACTURER'S SPECIFICATIONS
	Function	Human Safety
37.	Solenoid Valve	
	Type	3/2 single acting
	Coil Voltage	24 VDC
	Make	Festo
38.	QUALIFICATION DOCUMENTATION	<ol style="list-style-type: none">1. Maintenance & Service manual,2. Design Qualification Documents3. Installation Qualification Protocols4. Operational Qualification Protocols5. Test & Calibration reports for instruments used6. MOC certificates.7. All Electrical and Mechanical Drawings
39.	EQUIPMENT DESIGN GUIDELINES AND STANDARDS FOLLOWED FOR MANUFACTURING THE MACHINES	<ol style="list-style-type: none">1. EN2852. ASME3. cGMP4. HTM 20105. ASTM for material testing6. ISO 9001:20157. ISO 13485:2016



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UTILITY REQUIRED FOR SHWSS 6 METER

SR NO	TYPE OF UTILITY	LINE SIZE (inches)	PRESSURE (kg/cm ²)	FLOW RATE	CONSUMPTION
1	RAW STEAM	2½	6 to 8	1500 kg/hr	750 kg/cycle
2	COMPRESSED AIR FOR VALVE OPERATION	½	6 to 8	0.2 m ³ /hr	7 cfm, dry air
3	PROCESS AIR	2	4 to 6	6 m ³ /min	16 m ³
4	PURIFIED WATER	2½	2	-	(1800 liter) can be change in 24 hrs
5	COOLING WATER	1½	4 to 6	470 liter/min	14000 liter cycle demand
6	POWER	3 phase, 415VAC with neutral & earthing / 1 phase, 220VAC with neutral & earthing			10 kw
7	DRAIN LINE	2½	Drain line must be 100 mm up from ground level		

LOAD DESCRIPTION FOR SHWSS 6 METER

Ampoule Description	Size of Ampoule			No of Ampoules per tray	No of tray per Layer	No of layers per carriage	No of Ampoules per carriage	No of Carriage per cycle	No of Ampoules per cycle	No of Ampoules per day
	W	D	H							
5 ml	14.11	23	55	821	4	13	42692	6	256152	1793064
10 ml (Aiswarya)	14.5	21	80	910	4	13	47320	6	283920	1987440
10 ml (Gattu)	18	26	55	570	4	13	29640	6	177840	1244880
10 ml (Nirlife)	14.1	25.4	65	741	4	13	38532	6	231192	1618344
30 ml	18.1	30	94	498	4	13	25896	6	155376	1087632



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SUPER HEATED WATER SPRAY STERILIZER

DESCRIPTION	PRICE
<p>Horizontal cylindrical chamber with Sliding type Double door Super Heated Water Spray Sterilizer.</p> <p><u>Overall Chamber Size</u> : 2200 Dia x 7600 Depth <u>Chamber Size</u> : 1200 (W) x 1650 (H) x 6300 (D)</p> <p>Price of Basic unit with following Accessories.</p> <p><u>Scope Of Supply :</u></p> <ol style="list-style-type: none">1. Basic Unit with automatic sliding door.2. Shell and tube type Heat Exchanger with SS316 piping, SS316 Circulation pump & Mechanical Seal with Motor.3. Fully Automatic PLC, HMI based control system including Pneumatic actuated Valves, Solenoid Valves, Pressure Transmitter, Pressure gauge, Temperature sensors etc.4. SS 316 railing assembly 2 nos.5. SS 316 Walking Plate 4 mm thk.6. SS outer cover.7. Ejector system for door vacuum.8. Non occupancy sensors for doors.9. Validation port 02 nos.10. MS mounting stand with epoxy painted.11. HMI 7.0" color touch screen on loading side.12. Online printing for all set parameters, 08 chamber temperatures and pressure with individual F0 valve for each temperature13. Documents for DQ, IQ, OQ, FAT Protocol.14. Installation and commissioning.	<p>₹ 82,60,000.00</p>



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TERMS & CONDITIONS

- Price : Ex-works, Mumbai
- Packing & Forwarding : Extra at actual
- Freight : Extra at actual
- Transit Insurance : To be arranged by Buyer
- GST : 18%
- Delivery : Within 16 weeks after receipt of order & advance
- Payments Terms : 40% advance along with firm order
50% + full tax after inspection before dispatch.
10% after installation & commissioning **or 90 days from date of dispatch whichever is earlier.**
Our Engineers Lodging Boarding and local transportation in your scope at time of installation.
- Warranty : **12** months against any manufacturing defects. It however does not extend to consumables and bought out items. Warranties of manufacturers will be passed on to the customer.
- Validity : 30 days.

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