



Technical Specification

SVP Manufacturing & Holding Vessels

Client Name: M/s. Rastagene Darou Co.

Location : Iran

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1. Technical Specifications

The technical specifications of the equipment covered in this offering are specified in the following sections: -

SVP Line		
Description	Capacity	Quantity
Manufacturing Vessel with accessories	10 L	01 No.
Manufacturing Vessel with accessories	50 L	01 No.
Holding Vessel with accessories	10 L	01 No.
Holding Vessel with accessories	50 L	01 No.
Tankless CIP Skid	N.A.	02 No.
Filtration Skid between Manufacturing Vessels & Holding Vessels	1Rx 5" Housing X 2Nos.	01 nos.
Filtration Skid between Holding Vessels & Filling Machine	1Rx 5" Housing	01 No.
Common PLC & HMI for Manufacturing area + Common PLC & HMI For Holding area (with Individual RIO panel for each vessel)	N.A.	01 Lot.

SVP Manufacturing & Holding Vessels

1.1 10 L & 50 L Liters Manufacturing Vessel

PARAMETERS		UNIT	10 L Manufacturing Vessel	50 L Manufacturing Vessel
GENERAL				
Capacity	Working Volume	L	10	50
	Gross Volume	L	12	60
	Min. Stirring Volume, Liters	L	DDE	DDE
Quantity		No	1 (Fixed)	1 (Fixed)
Type of vessel		-	Cylindrical, Vertical	Cylindrical, Vertical
Hazards Area Classification		-	Non-Flameproof	Non-Flameproof
DESIGN CONDITION				
Design Code			cGMP / ASME Guidelines	
Working Pressure	SHELL	bar(g)	(-) 1 to 2	
	JACKET	bar(g)	0 to 3	
Design Pressure	SHELL	bar(g)	-1 to 3	
	JACKET	bar(g)	4 Bar	
Working Temperature	SHELL	°C	0 to 130	
	JACKET	°C	0 to 150	
Design Temperature	SHELL	°C	0 to 150	
	JACKET	°C	0 to 180	
Hydrotest Pressure	SHELL	bar(g)	3.9	
	JACKET	bar(g)	5.2	
Material of Construction	Contact Parts		SS 316L	
	Non-Contact Parts		SS 304	
	Gasket		Food Grade Silicone	
Surface Finish	Internal surface finish	µm	Ra ≤ 0.4, Electro Polish	
	External surface finish	µm.	Ra ≤ 0.8, Matt finish	
Vessel Type			Jacketed & Insulated on Shell & Bottom Dish	
DIMENSIONAL DATA				
Head	Top Dish	mm	10 % Std. Torispherical	
	Bottom dish	mm	10 % Std. Torispherical	
Insulation	Type	-	Rock wool Insulation with SS welded cladding on shell only	
Support	Type	-	Leg Supported	

MIXER			
Model	-	BAGI 20	BAGI 50
Type	-	Magnetic mixer	Magnetic mixer
Mounting	-	Bottom	Bottom
Make of Stirrer	-	KWENG	KWENG
Impeller Type	-	Open	Open
RPM	RPM	50-400	50-400
Rating	Kw	0.13 Kw	0.25 Kw

1.2 10 L & 50 L Liters Holding Vessel

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PARAMETERS		UNIT	10 L Holding Vessel	50 L Holding Vessel
GENERAL				
Capacity	Working Volume	L	10	50
	Gross Volume	L	12	60
	Min. Stirring Volume, Liters	L	DDE	DDE
Quantity		No	1 (Movable)	1 (Movable)
Type of vessel		-	Cylindrical, Vertical	Cylindrical, Vertical
Hazards Area Classification		-	Non-Flameproof	Non-Flameproof
DESIGN CONDITION				
Design Code			cGMP / ASME Guidelines	
Working Pressure	SHELL	bar(g)	(-) 1 to 2	
	JACKET	bar(g)	NA	
Design Pressure	SHELL	bar(g)	3	
	JACKET	bar(g)	NA	
Working Temperature	SHELL	°C	0 to 130	
	JACKET	°C	NA	
Design Temperature	SHELL	°C	0 to 150	
	JACKET	°C	NA	
Hydrotest Pressure	SHELL	bar(g)	3.9	
	JACKET	bar(g)	NA	
Material of Construction	Contact Parts		SS 316L	
	Non-Contact Parts		SS 304	
	Gasket		Food Grade Silicone	
Surface Finish	Internal surface finish	µm	Ra ≤ 0.4, Electro Polish	
	External surface finish	µm.	Ra ≤ 0.8, Matt finish	

Vessel Type			Jacketed & Insulated on Shell & Bottom Dish
DIMENSIONAL DATA			
Head	Top Dish	mm	10 % Std. Torispherical
	Bottom dish	mm	10 % Std. Torispherical
Insulation	Type	-	Rock wool Insulation with SS welded cladding on shell only
Support	Type	-	Leg Supported

Functional Specifications

	10 L Manufacturing	10 L Holding Vessel	50 L Manufacturing	50 L Holding Vessel
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	Vessel		Vessel	
Bottom Mounted Magnetic Mixer-Gentle Mixer	Y	N	Y	N
Automatic Flush Bottom Valve without steam port	Y	Y	Y	Y
Manual Sampling Valve with inbuilt SIP port and valve	Y	Y	Y	Y
Pressure Transmitter on Vessel	Y	Y	Y	Y
PH Sensor on vessel for Monitoring	Y	Y	Y	Y
Sanitary Safety valve	Y	Y	Y	Y
Air Inlet / Vent Filter with Cartridge	Y	Y	Y	Y
Level Measurement- Load Cells	Y	Y	Y	Y
Spray Ball	Y	Y	Y	Y
Light Glass/Sight Glass	Y	Y	Y	Y

MAJOR ACCESSORIES FOR ABOVE VESSEL:

10 Ltrs Manufacturing Vessel:

- Agitator Make : Kweng
- Agitator Model : BAGI 20
- Agitator Mounting : Bottom
- Agitator Motor : 0.13 Kw
- Agitator VFD : To vary the RPM up to 400 RPM.
- 1" Pneumatic Actuated Flush Bottom Zero dead leg Diaphragm valve
- 1/2 manual sampling valve Diaphragm

- 05" long Hydrophobic Vent filter (Sartorius/Parker Make) 0.2 micron with SS316L with actuated Valves, Steam trap & Temp. Transmitter.
- Sanitary Safety Relief Valve on Vessel Top
- (-1) to 4Kg/Cm² Compounding gauge diaphragm type
- Combined light glass/sight glass assembly
- (-1) to 4Kg/Cm² Pressure Transmitter
- Spray ball 360°rotating type with Detachable arrangement 01 nos.
- Temperature Sensor TC end 0 to 200-degree temp. Range with class 'A' accuracy Transmitter (Radix Make)
- Jacket Safety valve & Pressure gauge
- Pneumatic Actuated Angle Valves valve for cooling water, Compress air & Plant Steam Line.
- Pneumatic Actuated Angle Valves valve for Vessel Drain & Vessel Condensate Drain Line
- Load cell 3 Nos. for Vessel with junction box & digital weights indicator (Precia Molen make)
- Actuated Diaphragm Valves as per Vessel Requirement.

50 Ltrs Manufacturing Vessel:

- Agitator Make : Kweng
- Agitator Model : BAGI 50
- Agitator Mounting : Bottom
- Agitator Motor : 0.25 Kw
- Agitator VFD : To vary the RPM up to 400 RPM.
- 1" Pneumatic Actuated Flush Bottom Zero dead leg Diaphragm valve
- 1/2 manual sampling valve Diaphragm

- 05" long Hydrophobic Vent filter (Sartorius/Parker Make) 0.2 micron with SS316L with actuated Valves, Steam trap & Temp. Transmitter.
- Sanitary Safety Relief Valve on Vessel Top
- (-1) to 4Kg/Cm² Compounding gauge diaphragm type
- Combined light glass/sight glass assembly
- (-1) to 4Kg/Cm² Pressure Transmitter
- Spray ball 360°rotating type with Detachable arrangement 01 nos.
- Temperature Sensor TC end 0 to 200-degree temp. Range with class 'A' accuracy Transmitter (Radix Make)
- Jacket Safety valve & Pressure gauge
- Pneumatic Actuated Angle Valves valve for cooling water, Compress air & Plant Steam Line.
- Pneumatic Actuated Angle Valves valve for Vessel Drain & Vessel Condensate Drain Line
- Load cell 3 Nos. for Vessel with junction box & digital weights indicator (Precia Molen make)
- Actuated Diaphragm Valves as per Vessel Requirement.

10 Ltrs Holding Vessel:

- 1" Pneumatic Actuated Flush Bottom Zero dead leg Diaphragm valve
- 1/2" manual sampling valve Diaphragm
- 5" long Hydrophobic Vent filter (Sartorius/Parker Make) 0.2 micron with SS316L with actuated Valves, Steam trap & Temp. Transmitter.
- Sanitary Safety Relief Valve on Vessel Top
- (-1) to 4Kg/Cm² Compounding gauge diaphragm type
- Combined light glass/sight glass assembly
- (-1) to 4Kg/Cm² Pressure Transmitter

- Spray ball 360°rotating type with Detachable arrangement x 1 no.
- Temperature Sensor TC end 0 to 200-degree temp. Range with class 'A' accuracy Transmitter (Radix Make)
- Load cell 3 Nos. for Vessel with junction box & digital weights indicator (Precia Molen make)
- Pneumatic Actuated Angle Valves valve for Vessel Drain & Vessel Condensate Drain Line
- Actuated Diaphragm Valves as per Vessel Requirement.

50 Ltrs Holding Vessel:

- 1" Pneumatic Actuated Flush Bottom Zero dead leg Diaphragm valve
- 1/2" manual sampling valve Diaphragm
- 5" long Hydrophobic Vent filter (Sartorius/Parker Make) 0.2 micron with SS316L with actuated Valves, Steam trap & Temp. Transmitter.
- Sanitary Safety Relief Valve on Vessel Top
- (-1) to 4Kg/Cm² Compounding gauge diaphragm type
- Combined light glass/sight glass assembly
- (-1) to 4Kg/Cm² Pressure Transmitter
- Spray ball 360°rotating type with Detachable arrangement x 1 no.
- Temperature Sensor TC end 0 to 200-degree temp. Range with class 'A' accuracy Transmitter (Radix Make)
- Load cell 3 Nos. for Vessel with junction box & digital weights indicator (Precia Molen make)
- Pneumatic Actuated Angle Valves valve for Vessel Drain & Vessel Condensate Drain Line
- Actuated Diaphragm Valves as per Vessel Requirement.

DESIGN DESCRIPTION

Manufacturing vessels (10 L & 50 L):

The process vessels are designed to manufacture, hold and transfer product in automatic mode. The manufacturing vessels are fixed vessel with jacketed / insulated & cylindrical vessel with top and bottom 10% tori spherical dish placed under Isolator. The Manufacturing vessel will first undergo Cleaning in place followed by sterilization in place before receiving WFI for batch preparation. The CIP and SIP of the vessel is done to reduce the microbial load inside the tank. The Hot WFI is charged in the Manufacturing vessel as per the set point automatically and then cooled by applying the chilled water in the vessel jacket. The mixer will start automatically once the minimum water is charged inside the tank. All respective ingredients, Raw Materials will be added in the vessel through Hand hole provided on the top dish under Isolator. Bottom driven Magnetic mixer low shear (50 -400 rpm), is provided in the vessel for mixing of the product. Presently we have considered the viscosity of the product is 1 cps for 10 L vessel and 50 L Vessel. The speed can be increased / reduced until 400 RPM with the help of variable frequency drive (VFD). The product in Manufacturing Vessel is further diluted by adding makeup WFI in the vessel and the intake of the WFI will be controlled by load cell and actuated valves located on the inlet. The jacket will simultaneously start cooling the Product. Once the desired temperature is achieved, the jacket cooling will be stopped and the mixing will continue. Vessels are provided with in-situ aseptic sampling provision for lab testing. A pH Sensor and transmitter is provided on the vessel shell for online monitoring of the pH of the Product inside the vessel.

To Monitor and control the pressure automatically inside the vessel, pressure transmitter and compound pressure gauge is provided on the top dish of the compounding vessel. Sanitary Safety valve is provided on the vessel shell to release the excess pressure beyond design pressure. Jacket Safety relief valve is also provided on vessel jacket to release excess pressure beyond design pressure inside jacket. Combined light and sight glass assembly is provided along view inside the vessel.

To transfer the product prepared inside the Manufacturing vessel, Nitrogen / Compressed air blanketing facility is provided on the vessel shell by taking the pressure inside the vessel through filtered nitrogen / Compressed air.

Resterilizable filter cartridges along with filter housing is provided for air/ N2 inlet and exhaust of the vessel.

The temperature of vessel is controlled automatically through jacket valves. To measure and control the volume/ level inside the vessel, load cells are provided on the vessel. To calibrate the load cell a plate is provided on the three legs of the vessel. The vessels are provided with spray ball for cleaning of the inside of the vessel. The vessel is provided with actuated flush bottom valve without SIP port for product

transfer. A flushed sampling valve with steam port is provided to do the sampling of the product from inside of the vessel.

A fixed rigid process piping will be used for all process transfers by pressurized Nitrogen transfer through a series of filters 0.45 Micron and followed by 0.22 micron filter to 10 L or 50 L holding vessel. A common PLC + 7" HMI is provided for vessel operations.

Holding vessel 10 L & 50 L:

The Holding vessels are designed plane insulated mobile vessels with tori spherical top and bottom dish placed under isolator. The vessel designed CIP able and SIP able. J tube with four way valve assembly is provided to receive the filtered product from manufacturing vessels. Automatic flush bottom valve without steam port is provided at the bottom of the vessel. To do the aseptic sampling, flushed manual sampling valve with steam port and valve is provided on the vessel shell. To monitor and control the level of the product a load cell is provided. To do the CIP of the vessel, Dynamic type spray ball is provided on vessel top dish. Before receiving the filtered material from manufacturing area, the material will be filtered through a series of filters of 0.45 micron and 0.22 μ filter. The received final bulk in the holding vessel is stored under nitrogen blanketing and is transferred to filling line by Nitrogen transfer through a 0.22 micron Filter. A common PLC + 7" HMI is provided for vessel operations. Each vessel is also provided with individual RIO Panel

Manufacturing vessel product will be manufactured in 10 L or 50 L vessel depending on the batch to be manufactured. The Holding vessel of 10 L vessel & 50 L will be connected at the end of the transfer line and kept ready for transfer post completion of the manufacturing of batch of 10 L. Or 50 L vessel will be directly transferred to the filling machine.

Once the product is ready for transfer to storage vessel, product will be transferred with the help of N₂ pressure applied in the 10 or 50 L vessel. The filtration skid 5" x1R (02 nos.) will be placed on the downstream of the manufacturing vessels through which the product will be transferred for next stage.

The product transferred to the 10 / 50 L holding vessel in which the product was transferred from 10 / 50 L manufacturing vessel, will start transferring the batch with the help of N₂ Purging (Pressure Transfer) through 5"x 1R filter skid to the filling machine.

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Cleaning in Place (CIP):

Fully Automatic tankless CIP trolley is provided each in compounding area and holding area to clean and assure the cleaning of all vessels, filtration skids and transfer lines inside the manufacturing area and holding area. The vessels CIP is recirculation based whereas filtration skid & transfer lines will be cleaned by once through CIP concept. Conductivity sensors are provided on drain line of holding vessel product inlet line for CIP completion. The CIP system is provided with flow switch with recirculation pump and inlet out let valves along with flexible hose to connect the vessel with transfer pumps. The CIP skid designed tank less to supply/recirculation of CIP fluid. The fluid will be recirculated to for pre-validated time. After set concentration is achieved; recirculation will stop and the CIP fluid will be heated to set point provided. During the final rinse, WFI supplied to the vessel under cleaning and will be recirculated until final rinse conductivity sensor achieves the set parameters (0-20 µS/cm). The skid is mounted with conductivity sensor with transmitter and controlling/ reporting will be done through PLC based control system.

Sterilization in place:

The empty vessel sterilization of vessel (ESIP) of the vessels will be carried by introducing the clean steam through spray ball inside the subjected vessel. Lowest point drain point temperature sensor will control the temperature by controlling an auto valve on spray ball. The temperature sensors located on the vessel and transfer line piping will provide the confirmation if the temperature has achieved 121 Deg C. The temperature at the farthest most point of the transfer line will validate the effective sterilization of the system. Once the sterilization cycle is complete, the vessels and associated pipings will be cooled down with the help of filtered compressed air before beginning of the manufacturing of the next batch

1.3 Filtration Skid between 10 L / 50 L Manufacturing & 10 L / 50 L Holding Vessel

Description	Capacity	Quantity
Liquid Filter Housing	1R x 5"	2 Nos.
Housing Contact Parts MOC	SS316L	
Housing Non-Contact Parts MOC	SS304	
Configuration	Code 7	
End Connection	TC end	
Liquid filter MOC	PP	

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Filtration Rating	0.45 & 0.22 micron	
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1.4 Filtration Skid between 10 L / 50 L Holding Vessel & Filling Machine

1.5

Description	Capacity	Quantity
Liquid Filter Housing	1R x 5"	1 No.
Housing Contact Parts MOC	SS316L	
Housing Non-Contact Parts MOC	SS304	
Configuration	Code 7	
End Connection	TC end	
Liquid filter MOC	PTFE / PVDF	
Filtration Rating	0.22 micron	

Imp Note for Product filter element :- Product filter elements are included in scope, but product chemical configuration is not given, if there is any blockage or batch failure due to Product filter (element) FABTECH will not be responsible for the same.

1.6 Interconnecting Piping


Transfer piping between vessels shall be with contact parts SS316L ASME BPE and non-contact parts SS304 with internal finish <0.4 Ra EP for SS316L. Flexible hoses for load cell isolation shall be platinum cured silicon for process lines and corrugated PTFE for non-product contact lines (vessel jacket)

Pipe in pipe insulation Considered for Transfer piping, (Zotefom Insulation not considered)

1.7 Tank Less Mobile CIP Skid

CIP System is provided with tank less mobile CIP skid (02 no.) Each one in Manufacturing area and holding area which will enable the clean in place (CIP) of the vessels and associated piping with valves. The mobile skid is provided with single stage centrifugal pump to provide efficient cleaning through spray ball. The skid is provided with Junction box which will be connected with the PLC of the respective vessel under cleaning. The control panel will communicate with areas control panel for report generation.

Description	Capacity	Quantity
Type of Pump	Single stage centrifugal pump	1 No.
Capacity	3.0 m3/hr @ 3.0 Bar(g)	
Mechanical Seal	Single SiC/C	
Contact Parts MOC	SS316L	
Non Contact Parts MOC	SS304	

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End Connection	TC end	
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PROCESS FLOW DESCRIPTION

The CIP system is consisting of skid as per Process equipment's requirement. Necessary piping, fitting, valves, field instruments & other Components are included. The unit is skid mounted type having its junction box on the skid. The system has provision for additio CIP Solution transferred to the vessel to be cleaned with help of centrifugal pump. Recirculation of CIP solution shall be achieved with help of same pump.

CENTRIFUGAL PUMP

1 no. of sanitary type centrifugal pump is provided in the system. The pump shall be used for:

(a) for generating CIP solution by diluting concentrated alkali with help of recirculation in process vessel. (b) recirculation of CIP solution in the process vessel. Recirculation shall be for pre validated time. This time is settable and can be changed (increased or decreased) as per process requirement. Necessary valves & controls shall be provided as shown in P&I diagram for trouble free operation of pump.

MEASUREMENT & CONTROL

The CIP-SIP system is provided with recording facility for Temperature.

TEMPERATURE

Temperature is measured in condensate line of vessel. It shall be controlled with help of pneumatically operated valves.

CONDUCTIVITY

Conductivity Sensor is provided at discharge line of filtration skid for final validation of the CIP cycle. It shall be used for checking CIP solution conductivity during its conductivity of WFI / PW during final flushing cycle.

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2. Automation Architecture

SVP line is provided with one number of common PLC based control panels 7" HMI for Manufacturing area and one number of PLC + 7" HMI for holding area. Each vessel in holding area will be provided with dedicated RIO panel to carry out the necessary operations of the vessels and valves on the allied piping. All the electrical including transmitters, VFDS will be enclosed in SS304 control panel. All the control recipes along with different levels of authorization matrix will be programmed in this panel. Feedback from all the components shall be visible here.

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3. Make List

Component	Make
Vessels	FABTECH
Diaphragm Valves	Crane
Flush Bottom Valves	Crane/Cippriani Harrison
Sampling Valves	Crane/ Cipriani Harrison
Sanitary Safety Valve	Cipriani Harrison
Non Sanitary Safety Valve	Forbes Marshall/Equivalent
Sanitary Steam Trap	Steriflow
Auto Ball Valves	Cippriani
Bottom Mounted Agitators	Kweng
PLC	Siemens
Vent Filter Housing	FABTECH
Vent Filter Cartridge	Parker/Equivalent
Liquid Filter Housing	FABTECH
Temperature Sensor	Radix
Load Cells	Precia Molen
Pressure Gauge	Baumer/Equivalent
Centrifugal Pump	Fristam/Inoxpa

4. Design Assumptions

- The viscosity for vessels are considered to not to exceed 1 cps. Change in viscosity will require redesign of the agitators.
- CIP/SIP of filling machine is subject to the provision available on the filling machine. The same has to be confirmed with details from filling machine supplier.
- All the systems are designed to operate in non-hazardous area.
- Load cell accuracy shall be confirmed during detailed engineering stage as it mainly depends on the vessel weights.
- Operations in Manufacturing & Holding areas considered to be performed under Isolator (not considered in scope) to ensure the safety and sterility of the transfer piping.
- Client to ensure that enough space, door width & height is available for vessel movement
- All agitators are provided with VFD for speed control.