



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED  
MANUFACTURING VESSEL (4000 LITER)**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
SS JACKETED MANUFACTURING  
VESSEL**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Manufacturing Area</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



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**1.0 PROTOCOL PRE- APPROVAL:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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**2.0 OBJECTIVE:**

- To prepare the installation Qualification on the basis of Design Specification, Purchase Order and information given by Supplier.
- To ensure that all Critical Aspects of Equipment / Product Requirement, cGMP and Safety have been considered in designing the Equipment and is properly documented.
- To specify the performance basis for acceptance of equipment.

**3.0 SCOPE:**

- The Scope of this Qualification Document is limited to the Installation Qualification for SS jacketed Mfg tank. (**Make: Pharmatech Process Equipment.4000 ltr.**) to be installed in Manufacturing Area.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of jacketed manufacturing vessel.



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**4.0 RESPONSIBILITY:**

The Validation Group, comprising of a representative from each of the following Departments, shall be responsible for the overall compliance of this Protocol cum Report:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Authorization and Compilation of Installation Qualification Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.</li><li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li><li>• Monitoring of Design Qualification activity.</li><li>• Post Approval of Installation Qualification Protocol cum Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Approval of Installation Qualification Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.</li><li>• Post Approval of Installation Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Installation Qualification Protocol cum Report.</li><li>• To co-ordinate and support the Activity.</li><li>• To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e.<ul style="list-style-type: none"><li>• Specification of the sub-components / bought out items, their Make, Model, Quantity and Backup Records / Brochures.</li><li>• Details of Utilities</li><li>• Material of Construction of all components</li><li>• Brief Equipment Description</li><li>• Safety Features and Alarms</li></ul></li><li>• Post Approval of Installation Qualification Protocol cum Report after Execution.</li></ul>



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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	SS Jacketed Manufacturing vessel
<b>ID.Number</b>	
<b>Capacity</b>	4000 Ltr.
<b>Gross Capacity</b>	4805 Ltr.
<b>Manufacturer's Name</b>	Pharmatech Process Equipment
<b>Sr.No</b>	
<b>Model</b>	cGMP Model.
<b>Supplier's Name</b>	Pharmatech Process Equipment
<b>Location of Installation</b>	Manufacturing Area

**6.0 SYSTEM DESCRIPTION:**

**Application:** Jacketed (Limpeted) Manufacturing Vessel is used for Manufacturing of Pharmaceuticals product (LVP).

System Components

Jacketed (Limpeted) Manufacturing Vessel comprises of following parts.

• Shell

SS 316 L, Cylindrical, Vertical Shell, Top 10% Torispherical dish end & Bottom

10% Torispherical dish end welded to shell

Inside Surface Finish: Ra H 0.5 µm. Electro polish

• Limpet

SS 304, 4" NB x 3 mm Thick (Partial Limpet) @ 150 pitch Limpet coil.

• Insulation

38 mm Thick Armaflex insulation with 2 mm cladding on shell & 3 mm cladding on bottom cone. External surface finish: Ra H 0.9 µm. Mechanical polish

• Stirrer

Kweng make bottom entry magnetic stirrer

• Supports

3 Nos. of SS-304 Leg Support on load cell



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• Facility Devices

For vessel top

Spray ball

Sterile Safety valve

Compound gauge

Rupture disc

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for vent filter

Plain vent filter

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for vent filter condensate

Temperature sensor with transmitter

Sterile steam trap

Piping & fittings

Halogen lamp

N<sub>2</sub> Sparger tube

Manual operated Diaphragm (PTFE with EPDM back up) valve for sparger

Manual operated Diaphragm (PTFE with EPDM back up) valve for CA/N<sub>2</sub> transfer

Manual operated Diaphragm (PTFE with EPDM back up) valve for WFI inlet

Manual operated Diaphragm (PTFE with EPDM back up) valve for CIP inlet at spray ball

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for SIP at spray ball

Pressure sensor with transmitter

Dip Stick

For vessel bottom

Manual operated flush bottom Diaphragm (PTFE) valve with manual operated sampling valve

For shell side



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Resterilizable Diaphragm (Platinum cured silicon) Sample valve

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for  
SIP of sample valve

Manual operated Diaphragm (PTFE with EPDM back up) valve for sampling

Temperature sensor with transmitter

Sterile steam trap

Piping & fittings

Temperature sensor with transmitter for vessel

For vessel limpet side

Pneumatic operated (on/off) Ball valve for steam inlet

Pneumatic operated (on/off) Ball valve for cooling water supply and return

Pneumatic operated (on/off) Ball valve for compressed air inlet

Safety valve for limpet

Pressure gauge for limpet

Pneumatic operated (on/off) Ball valve for limpet air vent

Auto steam trap unit

SS Braided hose pipe for utility

Other accessories

Load cell with IND 570 weight indicator

Variable Frequency drive

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for  
SIP at drain

Manual operated diaphragm (PTFE with EPDM back up) valve for CIP drain

Temperature sensor with transmitter

Sterile steam trap

Piping & fittings

Conductivity Sensor with Analyzer

Flexible hose for common drain header

Flexible hose, 1000 mm long (loose supply)

SS 304 fixed skid





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**7.0 PRE – QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

- Executed and approved design qualification document
- Verification of Certificate of material of construction of components.
- Verification of Calibration Certificate of test Instrument.

**7.1.1 Procedure:**

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

**7.1.2 Acceptance Criteria:**

All the documents should be available, complete and approved by respective authorities.



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**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 General Checks and Location Suitability:**

Installation Checks	Acceptance Criteria	Observation (Complies/Not Complies)	Observed By (Engineering) Sign/Date
Physical Damage	Should be no Damage to the jacketed mfg tank with stirrer		
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Manufacturing Room		
Room Condition	General working condition		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

**Checked By  
(Production)**  
Sign/Date: .....

**Verified By  
(Quality Assurance)**  
Sign/Date: .....

**Inference:**

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**Reviewed By  
(Manager QA)**  
Sign/Date: .....



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**8.2 Utility Verification:**

<b>Installation Checks</b>	<b>Acceptance Criteria</b>		<b>Observation (Complies / Not Complies)</b>	<b>Observed By (Engineering) Sign/Date</b>
Electricity	Voltage	415±10% V		
	Phases	3 Phase		
	Frequency	50 Hz		
Electrical connections have been provided and secured.	Should be provided & secured			
All components in the panel are properly secured	Should be properly secured			
Earthing connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.			

**Checked By  
(Production)**  
Sign/Date: .....

**Verified By  
(Quality Assurance)**  
Sign/Date: .....

**Inference:**

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**Reviewed By  
(Manager QA)**  
Sign/Date: .....



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**8.3 Installation Checks:**

<b>S.No.</b>	<b>SPECIFICATION</b>	<b>OBSERVATION (Complies/Not Complies)</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
1.	Verify that the "As built" drawings are complete and represent the design concept		
2.	Check the proper mechanical installation		
3.	Check the proper electrical installation		
4.	Check the equipment is free from any defects		
5.	Check the finishing of product contact parts		
6.	Verify that major components are securely anchored and protected from shock		
7.	Verify that there is no observable physical damage		
8.	Verify that "Room layout" drawing is OK and sufficient space for servicing is provided		

**Checked By  
(Production)**

**Sign/Date:** .....

**Verified By**

**(Quality Assurance)**

**Sign/Date:** .....

**Inference:**

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**Reviewed By**

**(Manager QA)**

**Sign/Date:** .....



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**8.4 Verification of Technical Specifications:**

**8.4.1 Technical Specifications for Jacketed Manufacturing Vessel.**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Equipment</b>	4000 Ltr. Jacketed Manufacturing			
<b>Sr. Number</b>	16- 17/ SJ/000564			
<b>Application</b>	Manufacturing of pharmaceuticals			
<b>Hazard area</b>	Non – Flameproof			
<b>Design Code</b>	cGMP / ASME Guidelines			
<b>Density</b>	1000 Kg/M <sup>3</sup>			
<b>Viscosity</b>	200 cPs Max.			
<b>Volume</b>	Working Gross	4000 Ur. 4805 Ur.		
<b>Working condition</b>	Shell Jacket	-0.9 to 3 Bar(g) @ 5 to 135°		
<b>Design Condition</b>	Shell Jacket	-1 to 4 Bar(g) @ 0 to 150°		
<b>MOC</b>	Contact Non Contact Gasket	AISI S 316 L AISI SS 304 Food Grade Silicon		
<b>Surface Finish</b>	Internal External	Ra ≤ 0.5 µm Electro Polish		
<b>Radiography</b>	Rectangle Shell Heads	Nil 100%		
<b>Shell</b>	Shell Heads	Ø 1750 X 1500 X 6 mm thick Top 10 % Torispherical, 10 mm thick (Nom.) Bottom 10 %		
<b>Limpet</b>	Shell  Pitch	4" NB x 3 mm Thick (Partial Limpet) 150mm		
<b>Insulation</b>	Type Thickness SS cladding	Armaflex 38 mm 2 mm thick SS cladding on shell & 3		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
Support	Type	3 Nos. SS 304 Legs support on load cell		
Support	Type	3 Nos. SS 304 Legs support on load cell		
Overall Size of vessel	Diameter Height	~ 1920 mm (ID) ~ 3320 mm (up to top of vent filter)		
Weight	Empty Full of Water	~1815 Kgs. ~6620 Kgs.		

**Checked By**  
**(Production)**  
**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** .....

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



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**8.1.1 Bottom Entry Magnetic Stirrer:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
Magnetic stirrer	Type Mounting Rating RPM Sweep Diameter Model no. Make Quantity	Magnetic Stirrer Bottom (off Centre) 2.2 KW 50-350 220 mm BAGI 10K Kweng 1 No.		
Drive Unit	Motor Type Power Speed Mounting Power supply Make Quantity	Geared motor Non Flameproof Motor 2.2 KW 2880 RPM Flange 415 V AC, 50 Hz, 3 phase Bonfiglioli 1 No.1 No.2880 RPM Flange 415 V AC, 50 Hz, 3 phase Bonfiglioli 1 No.		
	Gear box Type Ratio Mounting Make Quantity	Worm type 7 : 1 Ratio Flange mounting Bonfiglioli 1 No.		

**Checked By**  
**(Production)**  
**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** .....

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



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**8.1.2 Technical Specifications of Accessories & Bought-out Components:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Spray ball.</b>	Type MOC Size Mounting Water Flow	Self rotating, 360° rotating, detachable SS 316 L Ø 61 On top 73 LPM @ 2 Bar(g) 3/4" BSP FEMALE 569-139-1Y-AL SB Qty : 1 Nos Make : Lecher		
<b>Sterile Safety valve</b>	Type MOC Size Mounting Capacity Set Press. Tag no. Make Qty.	Sterile Diaphragm Contact SS 316 L Diaphragm Silicon Non contact SS 304 Ø 9.3 x 12.5 mm (Inlet/Outlet) Ø 25 T/C 100 M3/Hr of Steam @ 2.5Barg and 60 M3/Hr of air 3.24 Bar(g) SSV Pharmatech 1 Nos		





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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Compound gauge</b>	Type MOC  Size Mounting Range Accuracy Tag no. Make Qty	Sterile Diaphragm Gauge Contact SS 316 L Non-Contact SS 304 4" Dial Ø 38 mm T/C end -760 mm Hg to 6 Bar(g) ± 1.6% FSD CG  Baumer 1 Nos		
<b>Ruptured Disc</b>	MOC  Size End connection Burst pressure Tag no. Make Qty	Contact parts : SS 316L Gasket : PTFE 1.5" T/C Suitable for 50.5 mm OD T/C 3.5 kg/cm <sup>2</sup> @ 180 °C  RD Fike 1Nos		
<b>Diaphragm valve for vent filter</b>	Type  Size MOC  End connection Make Qty.	Pneumatic operated (on/off) Diaphragm valve Dia. 38 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended CV1, CV2 Gamu 1 Nos		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Plain Vent Filter</b>	Type Rating Size Filter Area MOC  Mounting Model  Make. Qty.	Emflon, code7, Hydrophobic 0.2 micron 10" Long ~0.29 M2 Housing SS 316L Cartridge Double Layer PTFE Gasket Silicon 25 mm T/C Cartridge: CTGR71TP1 Housing : Millipore 1 Nos		
<b>Diaphragm valve for vent filter condensate</b>	Type  Size MOC  Make Qty.	Pneumatic operated (on/off) Diaphragm valve Dia. 12 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up Gamu 1 Nos		
<b>Temperature sensor with transmitter for vent filter SIP line</b>	Type MOC Mounting Range Accuracy Sheath Diameter Length Output .Make Qty.	PT 100, RTD, 3 Wire Sensor SS316L Thermowell SS316L Mini T/C 0° to 200°C Class 'A' 8 mm Ø 65 Long 4-20 mA TS2  Radix 1 Nos		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Sterile steam trap</b>	Type	Bellows type thermostatic steam trap		
	MOC	Body – SS 316L Thermal element – SS 316L 'O' ring – Teflon encapsulated Viton		
	Size	Ø 12 mm		
	Steam trap Model	Sterile flow – MK 93		
	Capacity	249 LPH @ 2 Bar(g)		
	Surface finish	Internally 0.5 Ra mech. Polish		
	Sub cooling	Approx. 5 °F		
	Max. Allow. Pressure	145 psig		
	Max. Allow. Temperature	350 °F Mini T/C ST1		
	End Conn.	Jorden		
	Make	1 Nos		
	Qty.			
<b>Halogen lamp</b>	Type	Halogen lamp with bracket		
	Power supply	230V AC		
	Consumption	50W halogen On light glass		
	Mounting	Stainless steel		
	MOC			
	Make.	Papenmeire		
	Qty.	1 Nos		
<b>N2 Sparger tube</b>	MOC	SS 316 L Sparger tube		
	Size	Dia. 12 mm		
	End Connection	T/C ended		
	Make.	Pharmatech		
	Qty.	1 Nos		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Diaphragm valve for sparger tube</b>	Type Size MOC End connection Make Qty.	Manual operated Diaphragm valve Dia. 12 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended MV4 Gamu 1 Nos		
<b>Diaphragm valve for CA/N<sub>2</sub></b>	Type Size MOC End connection Tag no. Make Qty.	Manual operated Diaphragm valve Dia. 25 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended MV3 Gamu 1 Nos		
<b>Diaphragm valve for WFI inlet</b>	Type Size MOC End connection Tag no Make Qty.	Manual operated Diaphragm valve Dia. 38 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended MV1 Gamu 1 Nos		



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<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>		<b>OBSERVATION (Complies/Not Complies)</b>	<b>Observed by (Engineering) Sign/Date</b>
<b>Diaphragm valve for CIP inlet at Spray Ball</b>	Type Size MOC  End connection Tag no  Make Qty.	Manual operated Diaphragm valve Dia. 50 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended MV2 Gamu 1 Nos		
<b>Diaphragm valve for SIP at Inlet at Spray Ball</b>	Type Size MOC  End connection Tag no  Make Qty.	Peumatic operated Diaphragm valve Dia. 38 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended CV4 Gamu 1 Nos		



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<b>Pressure Sensor with Transmitter</b>	Type	D TRANS p31, 402050 Stainless Steel, Mat Ref. 1. 43301		
	Housing	Polycarbonate GF		
	Output			
	Pressure Range	4-20 ma, 2 Wire		
	Process	-1 to 5 Barg		
	Connection	T/C Clamp		
	Response Time	3msec Max		
	Protection	IP65 to EN 60 529		
	Model No.	43010260		
	Tag No.	PS- PT		
	Make	Jumo		
<b>Diaphragm valve for CIP drain</b>	Type	Manual operated Diaphragm valve		
	Size	Dia. 50 mm		
	MOC	Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM		
	End connection	back up T/C ended		
	Tag no.	MV8		
	Make	Gamu		
	Qty.	1 Nos		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Temperature Sensor with transmitter for vessel</b>	Type MOC  Mounting Range Accuracy Sheath Diameter Length Connection Output Tag no. Make Qty.	PT 100 RTD, 3 wire Thermo well SS 316L Sensor SS 316L  1 1/4" BSP 0° to 200°C Class 'A' 8 mm Ø 65 Long 3 Wire 4-20mA, 2 wire TS3 Radix 1 Nos		
<b>Sterile steam trap</b>	Type MOC  Size Steam trap Model Capacity Surface finish Sub cooling Max. Allow. Pressure Max. Allow. Temperature End Conn. Tag no Make Qty..	Bellows type thermostatic steam trap Body – SS 316L Thermal element – SS 316L 'O' ring – Teflon encapsulated Viton Ø 25 mm  Sterile flow – MK 93 249 LPH @ 2 Bar(g) Internally 0.5 Ra mech. Polish Approx. 5 °F 145 psig 350 °F Mini T/C ST2 Jordan 1 Nos		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Restrillizable Sample Valve</b>	Type Size MOC End connection Make	Resterizable Sample Valve Dia. 12 mm  Contact Parts : SS 316 L Non Contact Parts : SS 304 Diaphragm : Platinum Curved Silicon  T/C ended Novaseptic		
<b>Diaphragm valve for SIP of Sampling Valve</b>	Type Size MOC End connection Tag no Make Qty.	Peumatic operated Diaphragm valve Dia. 12 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended CV14 , CV13 Gamu 1 Nos		
<b>Diaphragm Valve for sampling</b>	Type Size MOC End Connection Tag No. Make	Manual Operated Diaphragm Valve  Dia. 12 mm  Contact Parts : SS316L Non Contact Parts : SS304 Diaphragm PTFE with EPDM back up  T/C/ end MV8 Gemu		





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QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED  
MANUFACTURING VESSEL (4000 LITER)**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>		<b>OBSERVATION (Complies/Not Complies)</b>	<b>Observed by (Engineering) Sign/Date</b>
<b>Temperature sensor with transmitter for sampling Valve SIP line</b>	Type MOC Mounting Make Qty  Range Accuracy Sheath Diameter Length Output  Tag no.  Make	PT 100, RTD, 3 Wire Sensor SS316L Thermowell SS316L Mini T/C  Radix  1 Nos 0° to 200°C Class 'A' 8 mm Ø 65 Long 4-20 mA  TS4  Radix		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Sterile steam trap</b>	Type	Bellows type thermostatic steam trap		
	MOC	Body – SS 316L Thermal element – SS 316L 'O' ring – Teflon encapsulated Viton		
	Size	Ø 12 mm		
	Steam trap Model	Sterile flow – MK 93		
	Capacity	249 LPH @ 2 Bar(g)		
	Surface finish	Internally 0.5 Ra mech. Polish		
	Sub cooling	Approx. 5 °F		
	Max. Allow. Pressure	145 psig		
	Max. Allow. Temperature	ST 3 350 °F Mini T/C		
	End Conn.	ST2		
	Tag no			
	Make	Jorden		
	Qty..	1 Nos		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Conductivity Sensor with Analyzer</b>	Series	<b><u>Conductivity Sensor</u></b>		
	Cell Constant	Thortan		
	Measurement	0.1 /cm		
	principal	2- Electrode Sensor		
	Body			
	Temperature	SS 316 L		
	Device	Pt 1000 IEC Class A		
	Accuracy of			
	Cell	± 1%		
	Measuring	0.02 to 3000 µS/Cm		
	Range			
		85 mm		
	Insertion length			
		1.5 “ T/C Clamp		
	Connection	58031414		
	Part. No.	<b><u>Transmitter</u></b>		
	Model	M200		
	Type	Single Chanel analyzer		
	Power Supply	110 to 240 V AC		
	Current Output	4- 20 mA		
	Display	Backlit LCD, 4 Lines		
	Mounted	Panel Mounted		
	Part No.	52121554		
	Tag No.	CS-CT		
	Make	Mettler Toledo		
<b>Dip Stick</b>	Type	Dip Stick with Marking		
	MOC	Contact Part – SS 316 L		
	Size	Non Contact SS304		
	End Connection	25 W x 6 thk. Ø 38 mm TC end		
	Make	Pharmatech		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Safety Valve for Jacket</b>	Type	Conventional FLS-549		
	Model	06/CS44 SS2		
	MOC			
	Inlet Body			
	Outlet Chamber	AISI316 L		
	Bonnet	ASTM A 351 CF 8		
	Trim	ASTM A 351 CF 8		
	Disc Spring	AISI 316 L		
	Gasket	AISI 316 L Stainless Steel		
	Inter Con.			
	Rating	PTFE		
	Outlet			
	Connection	1'' BSP ( F)		
	Rating	10 %		
	Over Pressure			
	Set Pressure	3.24		
	Service	Steam		
	Temperature	150 ° C		
	Cap Type	Closed, H2		
	Make	Fainger Leser		
<b>Pressure Gauge for Jacket</b>	Type MOC	Bourden		
	Size Range	SS 304		
	Accuracy	Ø 2.5'' Dial		
	End connection	0 to 7 Bar(g) ± 1% FSD 1/4'' BSP Threaded		
	Make	Baumer		
	Qty.	1 Nos		



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MANUFACTURING VESSEL (4000 LITER)**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>		<b>OBSERVATION (Complies/Not Complies)</b>	<b>Observed by (Engineering) Sign/Date</b>
<b>Ball valve for Air vent</b>	Type  Size MOC End Connection Tag no. Make Qty	Pneumatic operated (on/off) Ball valve  Dia. 12 mm SS 304 T/C ended  CV5 Micro 1 Nos		
<b>Ball valve for Compressed air inlet</b>	Type  Size MOC End Connection Tag no. Make Qty.	Pneumatic operated (on/off) Ball valve Dia. 12 mm SS 304 T/C ended  CV8 Micro 1 Nos		
<b>Ball valve for Steam inlet</b>	Type  Size MOC End Connection Tag no. Make Qty.	Pneumatic operated (on/off) Ball valve 40 NB SS 304 T/C end  CV6 Micro 1 Nos		



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MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Ball valve for cooling water supply and return</b>	Type Size MOC End Connection Tag no. Make Qty.	Pneumatic operated (on/off) Ball valve Dia. 25 mm SS 304 T/C End CV7, CV9  Micro 1 Nos		
<b>Steam Trap Unit</b>	Type MOC Size End connection  Make	<b>Steam Trap</b> Thermodynamic Body – SS 316 Strainer – SS 304 20 NB 3/4” BSP Threaded Rex 1nos		
	Type Size MOC End connection  Tag no. Make Qty.	Valve Pneumatic Operated Ball Valve 25 NB SS 304 T/C end CV10, CV11 Micro 2 nos		



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MANUFACTURING VESSEL (4000 LITER)**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>		<b>OBSERVATION (Complies/Not Complies)</b>	<b>Observed by (Engineering) Sign/Date</b>
	Type Size MOC End connection Tag no <b>Make</b> <b>Qty.</b>	<b>Piping</b> Dia. 38 mm ERW SS 304 T/C End  Pharmatech 1 Nos		
<b>Flexible hose for utility</b>	Type Size MOC End connection  <b>Make</b> <b>Qty.</b>	SS Braided hose pipe, Dia. 25 mm, 500 mm long SS Braided T/C ended  Shanti 2 Nos		
<b>Load Cell</b>	Model Max. Capacity of single load cell Readability System Accuracy MOC Indicator  <b>Make</b> <b>Qty.</b>	0745A -550 Kg load cell  2200 Kg 100 gm $\pm 0.05\%$ of FSD SS 304 IND 570  Mettler Toledo 3 Nos		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Variable Frequency Drive</b>	Series	ACS550		
	Rating	3 HP		
	Power supply	380-500 V AC +10%/-15%,3 ph		
	Output	50 ... 60 Hz		
	Frequency	±5% IP20		
	Protection	-10 to 55° C		
	Ambient temp.			
	Ambient humidity	max 95% non-condensing		
	EMC Filter	Inbuilt		
	Make	ABB		
	Qty.	1 Nos		
<b>Flexible hose for common drain header</b>	Type	Platinum Cured SS Wire Silicon Braided Hose		
	Size	Dia. 63.5 mm, 1000 mm long		
	MOC	Platinum cured silicon		
	End connection	T/C ended		
	Make	Amipolymer		
	Qty.	1 Nos		
<b>Flexible hose (loose supply)</b>	Type	Platinum Cured SS Wire Silicon Braided Hose		
	Size	Dia. 25 mm, 1000 mm long		
	MOC	Platinum cured silicon		
	End connection	T/C ended		
	Make	Amipolymer		
	Qty.	1 Nos		





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MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Control Panel</b>	Type MOC Mounting Gasket Size Finish Size	Dust Proof SS 304 Suitable Rubber 1000 x 800 x 300  Rittal 1 Nos		
<b>PLC</b>	Type Model No. Power Supply Make Qty Ports Software Oper. Temperature	Programmable Logic Controller ML-1400 24 VDC  Allen Bradley 1 Nos Serial and Ethernet RS Logix 500 -20°C to +65°C		
<b>HMI</b>	Type Model No. Power Supply Inch Resolution Backlight Comm. Port Software Oper. Temperature Relative Humidity Make qty	Color touch screen PVP-600 18-30VDC  5.7" 320X240, 18-bit color graphics CCFL, 50, 000H RS232, USB and Ethernet Port RS view Factory 0-55°C 5-95%  Allen Bradley 1 Nos		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		OBSERVATION (Complies/Not Complies)	Observed by (Engineering) Sign/Date
<b>Printer</b>	Type Model no Power supply Location Communication Port Make Qty	Dot matrix/Online printer LX-310 + II 230 VAC, Single phase On SS printer stand  25Pin – RS 232  Epson  1 Nos		
<b>FRL Unit</b>	Model Range Mounting location]  Make Qty	FRC 1/4-D-MINI 0 -16 Bar  Panel Mounted  Festo 1 Nos		
<b>Buzzer</b>	Type Supply Make Qty	Panel Mounted 220 V Ozzo 1 Nos		

**Checked By**  
(Production)  
**Sign/Date:** .....

**Verified By**  
(Quality Assurance)  
**Sign/Date:** .....

**Inference:**

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**Reviewed By**  
(Manager QA)  
**Sign/Date:** .....



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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED  
MANUFACTURING VESSEL (4000 LITER)**

**8.5 MATERIAL OF CONSTRUCTION:**

COMPONENTS	MOC	OBSERVATIONS
Vessel shell	SS316L	
Jacket shell	SS 304	
legs	SS 304	
Manhole gasket	Food Grade Silicon	
Insulation	SS 304	
Spray ball	SS 316L	
Rupture Disk	SS 316L	
Safety valve	SS 316L	
Compound Gauge	SS316 L	
Pressure gauge for jacket	SS316 L	
Manual Ball Valve	SS304	
Steam Trap unit	SS316 L	
SS Skid	SS304	
Control Panel	SS304	
Contact part	SS316 L	
Non Contact part	SS304	

**Checked By**  
**(Production)**  
**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** .....

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED  
MANUFACTURING VESSEL (4000 LITER)**

**8.6 Safety:**

<b>SAFETY DEVICE</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION (Complies/Not Complies)</b>	<b>OBSERVED BY ENGINEERING SIGN/DATE</b>
SS Cover on Drive unit	For operator safety		
Variable Frequency Drive	Motor safety from overload		
Safety valve	Safety against pressure		
Rupture Disc	Safety against Over pressure		
Earthing boss	Reducing risk from shock		
Insulation	For operator safety &		
Emergency Button	Protection against abnormal condition		
Instruments air pressure switch	Low air pressure protection		

**Checked By  
(Production)  
Sign/Date:.....**

**Verified By  
(Quality Assurance)  
Sign/Date: .....**

**Inference:**

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**Reviewed By  
(Manager QA)  
Sign/Date:.....**



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED  
MANUFACTURING VESSEL (4000 LITER)**

**9.0 REFERENCES:**

**The Principle Reference is the following:**

- Validation Master Plan
- Schedule-M – “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection

**10.0 DOCUMENTS TO BE ATTACHED:**

- Any other relevant Documents

**11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:**

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**12.0 CHANGE CONTROL, IF ANY:**

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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED  
MANUFACTURING VESSEL (4000 LITER)**

**13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):**

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**14.0 CONCLUSION:**

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**15.0 RECOMMENDATION:**

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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED  
MANUFACTURING VESSEL (4000 LITER)**

**16.0 ABBREVIATIONS:**

AC	:	Alternate current
BSP	:	British Standard Pipe
cGMP	:	Current Good Manufacturing Practices
CIP	:	Clean in Place
EPDM	:	Ethylene Propylene Dyne monomer
HMI	:	Human Machine Interface
HP	:	Horse Power
Hz	:	Hertz
IQ	:	Installation Qualification
Kg	:	Kilograms
KW	:	Kilo Watt
MFT	:	Manufacturing Tank
mm	:	Millimeter
MOC	:	Material of Construction
PLC	:	Programmable Logic Controller
PTFE	:	Poly tetra Fluoro Ethylene
RPM	:	Revolution Per Minute
SF	:	Steri Flange
SIP	:	Sterilization in Place
SMPS	:	Switch Mode power Supply
SS	:	Stainless Steel
TC	:	Triclover
VFD	:	Variable Frequency Drive
WFI	:	Water for injection



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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED  
MANUFACTURING VESSEL (4000 LITER)**

**17.0 PROTOCOL POST APPROVAL:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			