INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL CAPACITY: 500 LTR

EQUIPMENT ID. No.	
LOCATION	**MANUFACTURING ROOM**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

PROTOCOL CONTENTS

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

1.0 PROTOCOL PRE- APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

2.0 OBJECTIVE:

- To prepare the installation Qualification on basis of User Requirement 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 Design Qualification for SS jacketed MFG tank (500 ltr.) procured

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- 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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review and Approval of the Protocol cum Report. • Protocol Training. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Post Approval of Qualification Protocol after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Post Approval of Qualification Protocol after Execution.

Engineering	• Review of the Protocol cum Report.
	• Assist in the Preparation of the Protocol cum Report.
	• To co-ordinate and support the Activity.
	• To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e.
	  ◦ GA Drawing
	  ◦ Specification of the sub-components / bought out items, their Make, Model, Quantity and Backup Records / Brochures.
	  ◦ Details of Utilities
	  ◦ Identification of components for Calibration
	  ◦ Material of Construction of all components
	  ◦ Brief Equipment Description
	  ◦ Safety Features and Alarms

	• Post Approval of Qualification Protocol after Execution

5.0 EQUIPMENT DETAILS:

Equipment Name	Manufacturing vessel
Equipment	
Manufacturer's Name	Bright Pharma Engineering Pvt. Ltd
Model	GMP Model
Supplier's Name	Bright Pharma Engineering Pvt. Ltd
Location of Installation	Manufacturing room

6.0 SYSTEM DESCRIPTION:

SS jacketed Mfg. tank and its components are designed to process pharmaceutical products in accordance with cGMP principles. Manufacturing Vessel is used for mixing of Pharmaceuticals product with bottom entry magnetic stirrer.

- Shell
- Jacket
- Spiral stiffner
- Insulation &cladding
- Stirrer
- SS panel
- Legs
- Rotating spray ball
- Compound gauge
- Sterile safety valve
- 0.2 micron plain vent filter
- Manual operated diapharagm valve

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

- Rupture disc
- Halogen lamp
- Temperature sensor with transmitter
- Manual operated flush bottom diaphragm valve with sampling valve arrangement.
- Safety valve for jacket.
- PG For Jacket
- Auto Ball Valve
- Manual ball valve
- Auto steam trap unit
- Variable frequency drive
- Load cell
- Flexible hose for utility
- SS skid with castor wheel
- SS304 PLC panel

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document
- Instrumentation diagram
- Technical specification of equipment
- Calibration certificate of components
- Certificate of material of construction of components.

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.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
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: ……

8.2 Utility Verification:

Installation Checks	Acceptance Criteria		Observation	Observed By (Engineering) Sign/Date
Equipment	Manufacturing vessel 500L			
Model	cGMP Model			
ELECTRICAL INSTALLATION:				
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			
All terminals are tightened	Should be tightened			
Earthing connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.			
UTILITY INSTALLATION FOR MANUFACTURING VESSEL				
Chilled Water	@ 2 bar (g) & 35° C Max.			
WFI connections have been provided	Should be provided@ 1.5 to 2.5 Bar(g) Pressure			
Filtered Compressed air connections have been provided	Should be provided (@ 1.5 -2 bar pressure			
Pure Steam connections have been provided	Dry and saturated at defined pressure. @@ 2 bar (g) &122 ° C			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

SIP Media	@ 2 Bar(g)		
CIP Media	@ 2 Bar(g)		
Cooling Water	@ 2 bar (g) & 35° C Max		
N2/Air	3 Bar(g)		

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 S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

8.3 Installation Checks:

S.No.	Specification	Observation	Observed By (Engineering) Sign/Date
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 of		
4.	Check the parts are working properly.		
5.	Check the equipment is free from any defects		
6.	Check the finishing of product contact parts		
7.	Check that all parts are getting lubricated		
8.	Verify that major components are securely anchored and protected from shock		
9.	Verify that all parts and materials used for the equipment are as per GMP requirements. Surfaces are easy to clean and non-particle shedding		
10.	Verify that there is no observable physical damage		
11.	Verify that "Room layout" drawing is OK and sufficient space for servicing is provided		

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12.	All bought out components (motors, pneumatics, starters, relays, timers, switches, circuit breakers etc.) adhere to the specifications/ brands mentioned in the equipment manual		

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 S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

8.4 EQUIPMENT VERIFICATION:

MANUFACTURING VESSEL:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
The system comprises of following components.			
Shell	Cylindrical, Vertical Shell having contact parts in AISI 316 L, top and bottom welded Dish End, having Man hole on top, vessel Inside surface finish Ra < 0.5 µm Electro polish.		
Jacket	AISI SS 304 Jacket on Shell only.		
Spiral Stiffener	AISI SS 304, 40 mm (W) x 6 mm Thickness @ 150 mm Pitch on Shell		
Insulation	Outside surface finish Ra ≤ 0.9 µm Matt Finish.		
PANEL			
OPERATING PANEL			
Make	Pharamatech		
MOC	SS 304skid mounted operating panel		
Printer	Dot matrix online printer		
MOC Of Body :			
Contact part	AISI SS 316 L		
Non contact	AISI SS 304		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Silicon	Food grade silicon		
Capacity :			
Working Capacity	500 L		
Gross Capacity	600 L		
Max. Stirring Volume	500 L.		
Mini. Stirring Volume	50 L.		
Chamber Design Data :			
Working pressure	1 to 3.0 Kg/cm²		
Design Pressure	-1 to 3.5 Kg/cm²		
Hydro-Test Pressure	-1 to 5.0 Kg/cm²		
Working Temperature	0° to 135°C		
Design Temperature	0° to 150°C		
Jacket Design Data :			
Working pressure	1 to 3.0 Kg/cm²		
Design Pressure	-1 to 3.5 Kg/cm²		
Hydro-Test Pressure	-1 to 5.0 Kg/cm²		
Working Temperature	0° to 180°C		
Design Temperature	0° to 150°C		
Tank Working Cap.	500 L.		
Tank Gross Capacity	600 L.		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Chamber Size	Ø850 ID x 900 Ht. mm Excluding both Dish Ends		
Vessel Shell :			
Type	Cylindrical welded with body flange		
Thickness	6mm		
MOC	SS 316L		
Vessel Top :			
Type	Torrispherical dished end welded with body flange		
Make	Bright Pharma		
Thickness	6mm		
MOC	SS 316L		
Vessel Bottom :			
Type	Torrispherical dished end welded with vessel shell		
Make	Bright Pharma		
Thickness	6mm		
MOC	SS 316L		
Bottom Clearance	500mm from ground.		
Body Flanges :			
Body Flanges	Welded with Shell & Top Dish with gasket		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Size	18m thick…..2 Nos.		
MOC	SS 316L		
Make	Bright Pharma		
Size of Flange Bolts	M12 Bolts & Dom nuts		
MOC	SS 304		
No. of Flange Bolts	18 Nos.		
Body Flange Gasket :			
Type	"D" type		
Size	860 ID X 876 OD X 8mm		
Make	PDE		
Jacket	Silicon		
Jacket Shell :			
Type	Cylindrical with Spiral stiffeners, welded with bottom		
Make	Bright Pharma		
Thickness	5mm		
MOC	SS 304		
Jacket Bottom :			
Type	Torrispherical dished end with spiral stiffeners, welded shell		
Make	Bright Pharma		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Thickness	5mm		
MOC	SS 304		
Spiral Stiffeners :			
Type	Welded on main chamber shell		
Make	Bright Pharma		
Size	35 x 5mm thick		
MOC	SS 304		
Insulation :			
Type	bounded on external surface of jacket shell and bottom		
Make	Armaflex		
Thickness	40mm thick		
Cladding :			
Cladding Size	Ø1050mm OD		
Cladding Shell	Cylindrical welded on shell insulation		
Make	Bright Pharma		
Thickness	2mm		
MOC	SS 304		
Cladding Bottom			
Type	Torrispherical dished end welded over bottom insulation		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Thickness	2mm		
MOC	SS 304		
Legs :			
Make	Bright Pharma		
Type	Made of SS pipes with Base plate suitable for SBH Load cell		
MOC	SS 304		
No. of Legs	3 Nos.		
Load Cell :			
Make	Mettler		
Type	SBH-1000		
Qty.	3 Nos.		
Capacity	1000 Kg of each load cell		
Least Count	300 grams		
Accuracy	0.05% on Total Weight		
Top Dish Nozzle Specification :			
Hand Hole			
Type	Hinge type with Lid & O rings		
Make	Bright Pharma		
Size	Ø 250mm		
MOC	SS 316L		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Light / Sight glass :			
Size	Ø100mm Din combined with vessel lamp		
Make	Bright Pharma		
MOC	SS 316L		
Gasket	Suitable for Ø100mm Din		
Gasket Make	PDE		
MOC	Food grade silicon		
Lamp	Combined Sight & Light Port		
MOC	SS 304		
Type	Lumistar ME100		
Electrical Wattage	50 W		
Electrical supply	230 V		
Product Inlet :			
Size	1.5” SF with valve		
Make	Bright Pharma		
MOC	SS 316L		
Product Inlet Valve	Manual Operated Diaphragm Valve		
Size	25mm		
Diaphragm	PTFE backed by EPDM		
Process Connection	1” TC		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
N2 Gas Blanketing :			
N2 Gas Blanketing	1" SF with ½" TC		
MOC	SS 316L		
Air vent :			
Air vent	1.5"SF with Vent filter, valves, PT100		
MOC	SS 316L		
Make	Bright Pharma		
Air Vent Housing :			
Type	Suitable for 5" Ht. Cartridge Filter		
Make	Pall/Millipore		
MOC	SS 316L		
Inlet Port	1.5" TC		
Pt 100 Port	1" TC		
Venting Port	½" TC		
Drain Port	½" TC		
Cartridge Filter :			
Type	Hydrophobic filter, 0.2 micron		
Make	Pall/Millipore		
MOC	Pleated PTFE		
Size	5" Long		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Temperature Sensor :			
Type	Pt-100 type with head mounted transmitter		
MOC	SS 316L		
Range	-25 to 200 ºC		
Probe Diameter	Ø6mm		
Probe Length	50mm below Triclover end		
Power Supply	24 V DC, 2 wires		
Process Connection	¾” SF		
Accuracy	Class A		
Output	4 to 20 Ma		
Chamber Vent Valve :			
Type	Manually operated Diaphragm Valve		
Size	25mm		
Make	Gemu		
Diaphragm	PTFE backed by EPDM		
Process Connection	1” TC		
Vent Filter Exhaust Valve :			
Type	Type		
Make	Gemu		
Size	15mm		
Diaphragm	PTFE backed by EPDM		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Process Connection	½ ” TC		
Flexible Hoses :			
Type	CIP/SIP able connect Vent housing Drain		
Size	15mm		
Make	Ven Air		
End Connection	25mm OD TC		
Compound gauge Conn :			
Type	1.5” SF with gauge		
MOC	SS 316L		
Make	Baumer		
Compound Gauge	Diaphragm Type Glycerin filled Bourdon gauge		
Dial Size	Ø100 mm		
MOC	SS 316L		
Range	1 to 4 kg/cm²		
Process Connection	1 ½ ” TC		
Sterile Safety Valve :			
Safety Valve Conn.	1”SF with sterile safety valve		
Make	Bright Pharma		
MOC	SS 316L		
Sterile Safety Valve	Sanitary Spring Loaded Type Make –Bright Pharma		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
- MOC	SS 316L		
Set Pressure	2.5 bar		
Process Connection	1"TC		
Conn. For Pressure Transmitter :			
Type of connection	1.5" SF		
- MOC	SS 316L		
CIP/SIP Connection :			
Type	1.5" SF with Detachable arrangement of spray ball and valves & T Connection for online SIP of Sampling valve		
Spray Ball	Removable Type		
Make	Lechler		
Model	Minispinner		
Size	3/4"		
MOC	SS 316L		
Flow rate	69 LPM @ 2 bar		
Process connection	3/4" BSP (F)		
CIP Inlet Valve :			
Type	Manual Operated Diaphragm Valve		
Size	25mm		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Diaphragm	PTFE backed by EPDM		
Process Connection	1" TC		
Rupture Disk Conn :			
Type	1.5" SF with rupture disc		
Make	Fike		
Model	AXIUS SC		
Size	1.5"		
MOC	SS 316L		
Gasket	PTFE		
Desired Bursting Pressure	3 Kg/Cm²		
Process Connection	1.5" TC		
Extra Connection :			
Type	1" SF with blind	Design Requirement	
Qty.	1 No.	Design Requirement	
Make	Bright Pharma		
MOC	SS 316L		
Bottom Dish Nozzle Specification :			
Outlet			
Type	Manually operated zero dead leg flush bottom diaphragm valve with sampling valve		
Make	Gemu		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
- Size	1 ½”		
Diaphragm	PTFE backed by EPDM		
Outlet End	1 ½” TC		
Sampling valve :			
Type	Manually Operated Diaphragm Valve		
Size	15mm		
Make	Gemu		
Diaphragm	PTFE backed by EPDM		
Process Connection	25mm OD TC		
Flexible Hoses for CIP/SIP :			
Type	CIP/SIP able		
Size	25mm		
End Connection	50.4mm OD TC		
Stirrer :			
Type	Bottom Entry Magnetic Stirrer		
Make	Kweng		
Model	BAGI 1K		
Drive	0.55 Kw		
Max. RPM	400		
Min. RPM	20		
Temperature Sensor :			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Type	Pt-100 type with head mounted transmitter		
MOC	SS 316L		
Range	-25 to 200 ºC		
Probe Diameter	Ø6mm		
Probe Length	50mm below TC		
Power Supply	24 V DC, 2 wires		
Process Connection	1" TC		
Accuracy	Class A		
Output	4 to 20 mA		
Jacket Shell Nozzle Specification :			
PG & SV Conn.	1" TC with pressure gauge & safety valve		
Make	Bright Pharma		
MOC	SS 304		
Pressure Gauge	Bourdon type		
- Dial Size	Ø63 mm		
Range	0 to 7 bar		
Process Connection	¼" BSP (M)		
Safety Valve	Spring Loaded Type		
MOC	SS 304		
- Set Pressure	3.5 Kg/cm²		
Process Connection	3/8" BSP (M)		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Jacket Steam Inlet Conn :			
Type	1.5” TC with Valve		
Make	Bright Pharma		
Size	25mm		
MOC	SS 304		
Seating	PTFE		
Process End	50.4mm		
Jacket Steam Inlet Valve	Pneumatically operated Modulating Ball valve Make - Avcon		
Process End	50.4mm		
Comp. Air Required	4.5 to 6 Kg / cm sq.		
Jacket Cooling Outlet Conn :			
Type	1.5” TC with Valve		
Make	Bright Pharma		
MOC	SS 304		
Jacket Cooling Outlet Valve	Pneumatically operated Ball valve		
Make	Avcon		
Size	25mm		
- MOC	SS 304		
- Seating	PTFE		
Process End	50.4mm		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Jacket Air vent Conn :			
Type	1.5"TC with Valve		
Make	Bright Pharma		
MOC	SS 304		
Jacket Air-vent Valve	Pneumatically operated Ball valve Make - Avcon		
Size	25mm		
MOC	SS 304		
Seating	PTFE		
Process End	50.4mm		
Comp. Air Required	4.5 to 6 Kg / cm sq.		
Jacket Bottom Dish Nozzle Specification :			
Condensate Out Connection			
Type	1.5" TC with Valve & steam trap		
Make	Bright Pharma		
MOC	SS 304		
Condensate Out Valve	Pneumatically operated Ball valve Make - Avcon		
Size	25mm		
MOC	SS 304		
Seating	PTFE		
Process End	50.4mm		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Comp. Air Required	4.5 to 6 Kg/cm² for actuation		
Steam trap	Thermodynamic type sterile steam trap Make - Steriflow		
Type	MK93		
MOC	SS 316L		
Seating	SS 316L		
Seal	Viton		
Process End	1 ” TC		
Jacket Cool Inlet Conn :			
Type	1.5” TC with Valve		
Make	Bright Pharma		
MOC	SS 304		
Jacket Cool Inlet Valve	Pneumatically operated Modulating Ball valve Make - Avcon		
Size	25mm		
MOC	SS 304		
Seating	PTFE		
Process End	50.4mm		
Comp. Air Required	4.5 to 6 Kg/cm² for actuation		
Jacket Drain Conn :			
Type	1.5” TC with Valve		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Make	Bright Pharma		
MOC	SS 304		
Jacket Drain Valve	Pneumatically operated Ball valve Make - Avcon		
Size	25mm		
MOC	SS 304		
Seating	PTFE		
Process End	50.4mm		
Comp. Air Required	4.5 to 6 Kg/cm² for actuation		
Skid :			
Size	1500 (L) x 1200 (W)		
Make	Bright Pharma		
Construction	Made of SS rectangular pipes		
- MOC	SS 304		
Control Panel :			
Size	250 (W) X 800 (D) X 1200 (H) Appx.		
Make	Bright Pharma		
MOC	SS 304		
3 Phase Indication	R Y B indication lamps Make - Teknic		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
HMI	5.7” Color touch screen Make - AB		
Electrical supply	24 V DC		
Hooter	24 V DC supply Make - Teknic		
Emergency button	Push button type Make - Salzer		
Main Switch	3 Pole, 16 A Make - Salzer		
Filter Pads	100 x 100mm with Exhaust Fan Make - Jainson		
Exhaust Fan	Ø4” Make - Rexnord		
Power Supply	230 V AC		
PLC	Micrologix 1400 Make - AB		
Electrical supply	24 V DC		
Control MCB	2 pole, 10A Make- Siemens		
VFD MCB for Low shear mixer	3 pole, 6A Make- Siemens		
VFD for GMP Low shear mixer	Panel Mounted AB		
HP Rating	0.75 HP		
Electrical supply	3 Phase to 3 Phase		
Vessel Lamp MCB	1 pole, 6A Make- Siemens		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Plug Point MCB	2 pole, 10A Make- Siemens		
Control	Start/Stop Contactor Make- Siemens		
Electrical supply	220 V AC		
Phase Preventer Relay	Panel Mounted Make - Salzer		
Electrical supply	220 V AC		
SMPS	Panel mounted		
Input	220 V AC Make - Omron		
Output	24 VDC		
SMPS output fuse	6 A		
Air Pressure Switch	Bellow Type Potential Free Make- Baumer		
Type	UT-10		
Range	0 to 10 bar		
Process Connection	¼” BSP (F)		
Electrical Supply	Universal 230 V AC / 24 V DC		
Pneumatic coils	2 way miniature coils Make - SPAC		
Model	TG23-06E		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Size	1/8”		
Electrical supply	230 V AC		
Load Cell Indicator	Panel Mounted		
Make	Mettler		
Model	IND 331		
Electrical supply	230 V AC		
Output	4 to 20 mA		
FINISHING :			
Vessel			
Internal Finishing	Ra ≤ 0.5 µm, Electro Polish		
External Finishing	Ra ≤ 0.8 µm, Matt Finish		
Make	Bright Pharma		
Control Panel			
External Finishing	Ra ≤ 0.8 µm, Matt Finish		
Make	Bright Pharma		
Skid			
External Finishing	Ra ≤ 0.8 µm, Matt Finish		
Make	Bright Pharma		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.5 MATERIAL OF CONSTRUCTION:

S.No.	Components	Acceptance Criteria	Observations	Observed By (Engineering) Sign/Date
1	Main chamber Shell	SS 316L		
2	Main chamber top & bottom	SS 316L		
3	Main chamber Shell	SS 316L		
4	Jacket shell	SS 304		
5	Jacket bottom dish end	SS 304		
6	N2 Gas Inlet Dip Tube	SS 316L		
7	Body Flange Gasket	Silicon		
8	Safety Valve	SS 316L		
9	Product Inlet Valve	SS 304		
10	N2 gas Inlet manual diaphragm valve	SS 316L		
11	Vent filter Isolation manual diaphragm valve	SS316 L		
12	Spray Balls	SS316 L		
13	CIP/SIP Inlet manual diaphragm valve	SS316 L		
14	Outlet Valve	SS316 L		
15	Rupture Disc	SS316 L		
16	Temperature Sensor	SS316 L		
17	Pressure gauge for jacket	SS304		
18	Manual Ball Valve	SS304		
19	Sampling Valve	SS316 L		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

S.No.	Components	Acceptance Criteria	Observations	Observed By (Engineering) Sign/Date
20	Rupture Disk	SS304		
22	Ball Valve (Contact part)	SS316 L		
23	Ball Valve (Non Contact part)	SS304		
24	Safety valve for jacket	AISI304		
25	Flush Bottom Diaphragm valve (Contact part)	SS316 L		
26	Flush Bottom Diaphragm valve (Non Contact part)	SS304		

Checked By
(Engineering)
Sign/Date:…….

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

8.6 BOUGHT – OUT COMPONENTS CERTIFICATION & CALIBRATION VERIFICATION :

Component	MOC	Certificate No.	S.No.	Observation	Observed by (Engineering) Sign/Date
Main chamber Shell	SS 316L	-15090304			
Main chamber top & bottom dish	SS 316L	15090304			
Body Flange	SS 316L	51288			
Jacket shell	SS 304	15090305			
Jacket bottom dish end	SS 304	5090305			
Cladding shell	SS 304	15090305			
Cladding bottom dish end	SS 304	15090305			
N2 Gas Inlet Dip Tube	SS 316L	150702405			
Steri flange	SS 316L	1522617			
Body Flange Gasket	“Silicon	-458			
Safety valve	304	5090210			
	SS 304	15081821			
	SS 316L	15081822-A			
	SS 316L	15081822-A			
	SS 316L	15081822-B			
	SS 316L	15081822-B			
	SS 316L	No.:-15081822-B			
Product Inlet Valve	SS 316L	Check visually on name plate, body & refer certificate No:-021162			
N2 gas Inlet manual diaphragm valve	SS 316L EPDM	141118-01			
Vent filter Isolation manual diaphragm valve	SS 316L EPDM	014780			
Spray Balls	SS 316L	1994/15			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Component	MOC	Certificate No.	S.No.	Observation	Observed by (Engineering) Sign/Date
CIP/SIP Inlet manual diaphragm valve	SS 316L	141118-01			
Outlet Valve	SS 316L	018423			
Sampling Valve	SS 316L	021168			
Rupture Disk	SS 316L	030001418277			
Compound Gauge	SS 316L	3131210686-77405			
Jacket Pressure Gauge	SS 316L	3141210829-103578			
Switch	-	3141210829-103578			
Steam inlet valve	-	15/0001456			
Cooling water outlet valve	-	15/0001456			
Jacket air vent valve	-	15/0001456			
Steam condensate valve	-	15/0001456			
Cooling water inlet valve	-	15/0001456			
Jacket drain valve	-	15/0001456			
Sensors for air vent	-	15-1279002			
Product Temperature Sensors	-	15-1279002			
Magnetic low shear Mixer	-				
Jacket steam trap	SS 316L	4J855 & 97822			
Vent filter housing	MOC: SS 316L	visually on housing			
Jacket safety valve	MOC: SS 304 -	Refer certificate			
Load Cells	-	Check visually on each load cell & refer certificates			
Load cell Indicator	-	Check visually on load cell indicator &			

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

Component	MOC	Certificate No.	S.No.	Observation	Observed by (Engineering) Sign/Date
		refer certificate No:-20064103			
Flexible hose	food grade silicon	Check visually on hose & refer certificate No:-0084			
HMI	-	Check visually on name plate			
PLC	-	Check visually on name plate			
Triclover gaskets	-	Refer certificates No:-A149698			

Checked By
(Engineering)
Sign/Date:…….

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

Inference:

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

8.7 DRAWING VERIFICATION

REFERENCE ENGINEERING DRAWINGS	DRAWING NO.	AVAILABLE [Y/N]	OBSERVED BY (ENGINEERING) (SIGN/DATE)
General arrangement & detail diagram			
G.A Drawing of Control Panel			
Wiring Drawing of Control panel			

Checked By
(Engineering)
Sign/Date:…….

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

8.8 Safety:

Checks	Acceptance Criteria	Observation	Observed By Engineering Sign/Date
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine (Panel and Motors) and operator should be provided		
Guards	Guards for all Moving Parts		
Noise Level	Below 80 db		
Main Supply	Main power supply should be always switched off when not in use.		
Safety valve	Safety against over pressure		
SS cover on pump	For operator safety		
Emergency stop	Protection from abnormal condition		
Air pressure switch	Protection for low air pressure for pneumatic valves		

Checked By
(Engineering)
Sign/Date:……..

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

Inference:

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

9.0 REFERENCES:

The Principle Reference is the following:

- Master Validation 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:

- GA drawing
- Minutes of meeting held with the Supplier, if any.
- MOC certificate

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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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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16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
CQA	:	Corporate Quality Assurance
PO	:	Purchase Order
SS	:	Stainless Steel
MOC	:	Material of Construction
AISI	:	American Iron & Steel Institute
SS	:	Stainless Steel
T/C	:	Triclover
MOC	:	Material of Construction
KW	:	Kilo Watt
HP	:	Horse Power
DQ	:	Design Qualification
EPDM	:	Ethylene Propylene Diene Monomer
PTFE Poly	:	Tetra Flouro Ethylene.
BSP	:	British Standard Pipe
O.D.	:	Outside Diameter
Temp.	:	Temperature
mm	:	Millimeter
MFT	:	Manufacturing Vessel
GA	:	General Arrangement
NO	:	Number

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT S.S. JACKETED MANUFACTURING VESSEL (500 LITER)

PVT.	:	Private
Ltd.	:	limited
%	:	Percent
°C	:	Degree Centigrade
RPM	:	Revolution per Minute
Hz	:	Hertz
HP	:	Horse Power
PLC	:	Programmable Logic Controller
FSD	:	Full Scale Display
CIP/SIP	:	Cleaning in place/sterilization in place
AC	:	Alternate current
V	:	Volt

17.0 PROTOCOL POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			