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

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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

PROTOCOL CONTENTS

DESIGN 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)			

DESIGN 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.) module procured from ……. at the site.
- The Equipment shall operate under the Controlled Environmental Conditions as per the cGMP requirements.
- The drawings and P & ID’s provided by Vendor shall be verified during Design Qualification.

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

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5.0 PROJECT REQUIREMENTS:

To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no Unauthorized and / or Unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.

The Compounding Vessel, its associated components and stirrer are designed to process pharmaceutical products in accordance with cGMP principles.

6.0 BRIEF EQUIPMENT 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
- Sparger tube
- Rupture disc

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- 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 EQUIPMENT SPECIFICATION :

Equipment Specification is a document provided by ……. to manufacturer for Engineering Equipment as per the specifications mentioned in User Requirement Specification.

Equipment Name	Manufacturing vessel
Capacity	500 L
Equipment	…….
Manufacturer's Name	Bright Pharma Engineering Pvt. Ltd
Model	cGMP Model
Supplier's Name	Bright Pharma Engineering Pvt. Ltd
Location of Installation	Manufacturing

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS / PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: The purpose of manufacturing vessel is mixing of pharmaceutical product with magnetic stirrer.	Manufacturing vessel shall be • Able to dissolve the Solid content in the Solvent Media to provide solution • Leak free • Jacketed to control the temperature of the solution	Process Requirement
Working	Should work smoothly and should run without producing any unwanted sound.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

8.2 UTILITIY REQUIREMENTS / LOCATION SUITABILITY :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	415 ±10% Volts AC , 50 Hz & 3 phase	Design Requirement
Room Condition	Should be able to meet the requirement of Clean Environment.	cGMP Requirement
Compressed Air Supply	@ 1.5 -2 bar pressure	As per requirement
SIP Media	@ 2 Bar(g)	As per requirement
CIP Media	@ 2 Bar(g)	As per requirement
Cooling Water	@ 2 bar (g) & 35° C Max	As per requirement
Chilled Water	@ 2 bar (g) & 35° C Max.	As per requirement

8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES

MANUFACTURING VESSEL:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
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.	Design Requirement
Jacket	AISI SS 304 Jacket on Shell only.	Design Requirement
Spiral Stiffner	AISI SS 304, 40 mm (W) x 6 mm Thickness @ 150 mm Pitch on Shell	Design Requirement
Insulation & Cladding	38 mm Thick Armaflex Insulation with 2 mm thick SS 304 welded cladding on Shell &3 mm thick on Bottom Dish. Outside surface finish Ra ≤ 0.9 µm Matt Finish.	Design Requirement
PANEL		
Operating panel		
Make	Pharamatech	Design Requirement
MOC	SS 304skid mounted operating panel	Design Requirement
	• ML 1400 with Input/output module	Design Requirement
	• 5.7 color touch screen	Design Requirement

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
	• Phase indication lamps, On off switch ,Out put relays ,transformers , SMPS , panel lights, emergency button, hooter, air pressure switch, FRL, MCB, contractors and other electrical and pneumatic accessories.	Design Requirement
	• Dot matrix online printer	Design Requirement
	• 5 mtrs route length cables from each instruments and motors to control panel and 5 mtrs route length pneumatic tubing from each valves to control panel	Design Requirement
MOC Of Body :		
Contact part	AISI SS 316 L	Design Requirement
Non contact	AISI SS 304	Design Requirement
Silicon	Food grade silicon	Design Requirement
Capacity :		
Working Capacity	500 L	Design Requirement
Gross Capacity	600 L	Design Requirement
Max. Stirring Volume	500 L.	Design Requirement
Mini. Stirring Volume	50 L.	Design Requirement
Chamber Design Data :		
Working pressure	1 to 3.0 Kg/cm²	Design Requirement
Design Pressure	-1 to 3.5 Kg/cm²	Design Requirement
Hydro-Test Pressure	-1 to 5.0 Kg/cm²	Design Requirement
Working Temperature	0° to 135°C	Design Requirement
Design Temperature	0° to 150°C	Design Requirement
Jacket Design Data :		
Working pressure	1 to 3.0 Kg/cm²	Design Requirement
Design Pressure	-1 to 3.5 Kg/cm²	Design Requirement
Hydro-Test Pressure	-1 to 5.0 Kg/cm²	Design Requirement

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Working Temperature	0° to 180°C	Design Requirement
Design Temperature	0° to 150°C	Design Requirement
Tank Working Cap.	500 Ltrs.	Design Requirement
Tank Gross Capacity	600 Ltrs.	Design Requirement
Chamber Size	Ø850 ID x 900 Ht. mm Excluding both Dish Ends	Design Requirement
Vessel Shell :		
Type	Cylindrical welded with body flange	Design Requirement
Thickness	6mm	Design Requirement
MOC	SS 316L	Design Requirement
Vessel Top :		
Type	Torrispherical dished end welded with body flange	Design Requirement
Make	Bright Pharma	Design Requirement
Thickness	6mm	Design Requirement
MOC	SS 316L	Design Requirement
Vessel Bottom :		
Type	Torrispherical dished end welded with vessel shell	Design Requirement
Make	Bright Pharma	Design Requirement
Thickness	6mm	Design Requirement
MOC	SS 316L	Design Requirement
Bottom Clearance	500mm from ground.	Design Requirement
Body Flanges :		
Body Flanges	Welded with Shell & Top Dish with gasket	Design Requirement
Size	18m thick…..2 Nos.	Design Requirement
MOC	SS 316L	Design Requirement
Make	Bright Pharma	Design Requirement
Size of Flange Bolts	M12 Bolts & Dom nuts	Design Requirement
MOC	SS 304	Design Requirement

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
No. of Flange Bolts	18 Nos.	Design Requirement
Body Flange Gasket :		
Type	"D" type	Design Requirement
Size	860 ID X 876 OD X 8mm	Design Requirement
Make	PDE	Design Requirement
Jacket	Silicon	Design Requirement
Jacket Shell :		
Type	Cylindrical with Spiral stiffeners, welded with bottom	Design Requirement
Make	Bright Pharma	Design Requirement
Thickness	5mm	Design Requirement
MOC	SS 304	Design Requirement
Jacket Bottom :		
Type	Torrispherical dished end with spiral stiffeners, welded shell	Design Requirement
Make	Bright Pharma	Design Requirement
Thickness	5mm	Design Requirement
MOC	SS 304	Design Requirement
Spiral Stiffeners :		
Type	Welded on main chamber shell	Design Requirement
Make	Bright Pharma	Design Requirement
Size	35 x 5mm thick	Design Requirement
MOC	SS 304	Design Requirement
Insulation :		
Type	bounded on external surface of jacket shell and bottom	Design Requirement
Make	Armaflex	Design Requirement
Thickness	40mm thick	Design Requirement
Cladding :		
Claddi ng Size	Ø1050mm OD	Design Requirement

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Cladding Shell	Cylindrical welded on shell insulation	Design Requirement
Make	Bright Pharma	Design Requirement
Thickness	2mm	Design Requirement
MOC	SS 304	Design Requirement
Cladding Bottom		
Type	Torrispherical dished end welded over bottom insulation	Design Requirement
Thickness	2mm	Design Requirement
MOC	SS 304	Design Requirement
Legs :		
Make	Bright Pharma	Design Requirement
Type	Made of SS pipes with Base plate suitable for SBH Loadcell	Design Requirement
MOC	SS 304	Design Requirement
No. of Legs	3 Nos.	Design Requirement
Load Cell :		
Make	Mettler	Design Requirement
Type	SBH-1000	Design Requirement
Qty.	3 Nos.	Design Requirement
Capacity	1000 Kg of each load cell	Design Requirement
Least Count	300 grams	Design Requirement
Accuracy	0.05% on Total Weight	Design Requirement

Top Dish Nozzle Specification :		
Hand Hole		
Type	Hinge type with Lid & O rings	Design Requirement
Make	Bright Pharma	Design Requirement
Size	Ø 250mm	Design Requirement
MOC	SS 316L	Design Requirement
Light / Sight glass :		

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Size	Ø100mm Din combined with vessel lamp	Design Requirement
Make	Bright Pharma	Design Requirement
MOC	SS 316L	Design Requirement
Gasket	Suitable for Ø100mm Din	Design Requirement
Gasket Make	PDE	Design Requirement
- MOC	Food grade silicon	Design Requirement
Lamp	Combined Sight & Light Port	Design Requirement
MOC	SS 304	Design Requirement
Type	Lumistar ME100	Design Requirement
Electrical Wattage	50 W	Design Requirement
Electrical supply	230 V	Design Requirement
Product Inlet :		
Size	1.5” SF with valve	Design Requirement
Make	Bright Pharma	Design Requirement
MOC	SS 316L	Design Requirement
Product Inlet Valve	Manual Operated Diaphragm Valve	Design Requirement
Size	25mm	Design Requirement
Diaphragm	PTFE backed by EPDM	Design Requirement
Process Connection	1” TC	Design Requirement
N2 Gas Blanketing :		
N2 Gas Blanketing	1” SF with ½” TC	Design Requirement
MOC	SS 316L	Design Requirement
Air vent :		
Air vent	1.5”SF with Vent filter, valves, PT100	Design Requirement
MOC	SS 316L	Design Requirement
Make	Bright Pharma	Design Requirement
Air Vent Housing :		
Type	Suitable for 5” Ht. Cartridge Filter	Design Requirement
Make	Pall/Millipore	Design Requirement
MOC	SS 316L	Design Requirement

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Inlet Port	1.5" TC	Design Requirement
Pt 100 Port	1" TC	Design Requirement
Venting Port	½" TC	Design Requirement
Drain Port	½" TC	Design Requirement
Cartridge Filter :		
Type	Hydrophobic filter, 0.2 micron	Design Requirement
Make	Pall/Millipore	Design Requirement
MOC	Pleated PTFE	Design Requirement
Size	5" Long	Design Requirement
Temperature Sensor :		
Type	Pt-100 type with head mounted transmitter	Design Requirement
MOC	SS 316L	Design Requirement
Range	-25 to 200 ºC	Design Requirement
Probe Diameter	Ø6mm	Design Requirement
Probe Length	50mm below Triclover end	Design Requirement
Power Supply	24 V DC, 2 wires	Design Requirement
Process Connection	¾" SF	Design Requirement
Accuracy	Class A	Design Requirement
Output	4 to 20 Ma	Design Requirement
Chamber Vent Valve :		
Type	Manually operated Diaphragm Valve	Design Requirement
Size	25mm	Design Requirement
Make	Gemu	Design Requirement
Diaphragm	PTFE backed by EPDM	Design Requirement
Process Connection	1" TC	Design Requirement
Vent Filter Exhaust Valve :		
Type	Type	Design Requirement
Make	Gemu	Design Requirement
Size	15mm	Design Requirement
Diaphragm	PTFE backed by EPDM	Design Requirement

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Process Connection	½ ” TC	Design Requirement
Flexible Hoses :		
Type	CIP/SIP able connect Vent housing Drain	Design Requirement
Size	15mm	Design Requirement
Make	Ven Air	Design Requirement
End Connection	25mm OD TC	Design Requirement
Compound gauge Conn :		
Type	1.5” SF with gauge	Design Requirement
MOC	SS 316L	Design Requirement
Make	Baumer	Design Requirement
Compound Gauge	Diaphragm Type Glycerin filled Bourdon gauge	Design Requirement
Dial Size	Ø100 mm	Design Requirement
MOC	SS 316L	Design Requirement
Range	1 to 4 kg/cm²	Design Requirement
Process Connection	1 ½ ” TC	Design Requirement
Sterile Safety Valve :		
Safety Valve Conn.	1”SF with sterile safety valve	Design Requirement
Make	Bright Pharma	Design Requirement
MOC	SS 316L	Design Requirement
Sterile Safety Valve	Sanitary Spring Loaded Type Make –Bright Pharma	Design Requirement
- MOC	SS 316L	Design Requirement
Set Pressure	2.5 bar	Design Requirement
Process Connection	1”TC	Design Requirement
Conn. For Pressure Transmitter :		
Type of connection	1.5” SF	Design Requirement
- MOC	SS 316L	Design Requirement
CIP/SIP Connection :		
Type	1.5” SF with Detachable arrangement of spray ball and valves & T Connection for online SIP of Sampling valve	Design Requirement
Spray Ball	Removable Type	Design Requirement

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Make	Lechler	Design Requirement
Model	Minispinner	Design Requirement
Size	3/4”	Design Requirement
MOC	SS 316L	Design Requirement
Flow rate	69 LPM @ 2 bar	Design Requirement
Process connection	3/4” BSP (F)	Design Requirement
CIP Inlet Valve :		
Type	Manual Operated Diaphragm Valve	Design Requirement
Size	25mm	Design Requirement
Diaphragm	PTFE backed by EPDM	Design Requirement
Process Connection	1” TC	Design Requirement
Rupture Disk Conn :		
Type	1.5” SF with rupture disc	Design Requirement
Make	Fike	Design Requirement
Model	AXIUS SC	Design Requirement
Size	1.5”	Design Requirement
MOC	SS 316L	Design Requirement
Gasket	PTFE	Design Requirement
Desired Bursting Pressure	3 Kg/Cm²	Design Requirement
Process Connection	1.5” TC	Design Requirement
Extra Connection :		
Type	1” SF with blind	Design Requirement
Qty.	1 No.	Design Requirement
Make	Bright Pharma	Design Requirement
MOC	SS 316L	Design Requirement
Bottom Dish Nozzle Specification :		
Outlet		
Type	Manually operated zero dead leg flush bottom diaphragm valve with sampling valve	Design Requirement
Make	Gemu	Design Requirement
- Size	1 ½”	Design Requirement
Diaphragm	PTFE backed by EPDM	Design Requirement

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

Outlet End	1 ½" TC	Design Requirement
Sampling valve :		
Type	Manually Operated Diaphragm Valve	Design Requirement
Size	15mm	Design Requirement
Make	Gemu	Design Requirement
Diaphragm	PTFE backed by EPDM	Design Requirement
Process Connection	25mm OD TC	Design Requirement
Flexible Hoses for CIP/SIP :		
Type	CIP/SIP able	Design Requirement
Size	25mm	Design Requirement
End Connection	50.4mm OD TC	Design Requirement
Stirrer :		
Type	Bottom Entry Magnetic Stirrer	Design Requirement
Make	Kweng	Design Requirement
Model	BAGI 1K	Design Requirement
Drive	0.55 Kw	Design Requirement
Max. RPM	400	Design Requirement
Min. RPM	20	Design Requirement
Temperature Sensor :		
Type	Pt-100 type with head mounted transmitter	Design Requirement
MOC	SS 316L	Design Requirement
Range	-25 to 200 ºC	Design Requirement
Probe Diameter	Ø6mm	Design Requirement
Probe Length	50mm below TC	Design Requirement
Power Supply	24 V DC, 2 wires	Design Requirement
Process Connection	1" TC	Design Requirement
Accuracy	Class A	Design Requirement
Output	4 to 20 mA	Design Requirement
Jacket Shell Nozzle Specification :		
PG & SV Conn.	1" TC with pressure gauge & safety valve	Design Requirement
Make	Bright Pharma	Design Requirement
MOC	SS 304	Design Requirement

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Pressure Gauge	Bourdon type	Design Requirement
- Dial Size	Ø63 mm	Design Requirement
Range	0 to 7 bar	Design Requirement
Process Connection	¼" BSP (M)	Design Requirement
Safety Valve	Spring Loaded Type	Design Requirement
MOC	SS 304	Design Requirement
- Set Pressure	3.5 Kg/cm²	Design Requirement
Process Connection	3/8" BSP (M)	Design Requirement
Jacket Steam Inlet Conn :		
Type	1.5" TC with Valve	Design Requirement
Make	Bright Pharma	Design Requirement
Size	25mm	Design Requirement
MOC	SS 304	Design Requirement
Seating	PTFE	Design Requirement
Process End	50.4mm	Design Requirement
Jacket Steam Inlet Valve	Pneumatically operated Modulating Ball valve Make - Avcon	Design Requirement
Process End	50.4mm	Design Requirement
Comp. Air Required	4.5 to 6 Kg / cm sq.	Design Requirement
Jacket Cooling Outlet Conn :		
Type	1.5" TC with Valve	Design Requirement
Make	Bright Pharma	Design Requirement
MOC	SS 304	Design Requirement
Jacket Cooling Outlet Valve	Pneumatically operated Ball valve	Design Requirement
Make	Avcon	Design Requirement
Size	25mm	Design Requirement
- MOC	SS 304	Design Requirement
- Seating	PTFE	Design Requirement
Process End	50.4mm	Design Requirement
Jacket Air vent Conn :		
Type	1.5"TC with Valve	Design Requirement
Make	Bright Pharma	Design Requirement
MOC	SS 304	Design Requirement

Jacket Air-vent Valve	Pneumatically operated Ball valve Make - Avcon	Design Requirement
Size	25mm	Design Requirement
MOC	SS 304	Design Requirement
Seating	PTFE	Design Requirement
Process End	50.4mm	Design Requirement
Comp. Air Required	4.5 to 6 Kg / cm sq.	Design Requirement
Jacket Bottom Dish Nozzle Specification :		
Condensate Out Connection		
Type	1.5” TC with Valve & steam trap	Design Requirement
Make	Bright Pharma	Design Requirement
MOC	SS 304	Design Requirement
Condensate Out Valve	Pneumatically operated Ball valve Make - Avcon	Design Requirement
Size	25mm	Design Requirement
MOC	SS 304	Design Requirement
Seating	PTFE	Design Requirement
Process End	50.4mm	Design Requirement
Comp. Air Required	4.5 to 6 Kg/cm² for actuation	Design Requirement
Steam trap	Thermodynamic type sterile steam trap Make - Steriflow	Design Requirement
Type	MK93	Design Requirement
MOC	SS 316L	Design Requirement
Seating	SS 316L	Design Requirement
Seal	Viton	Design Requirement
Process End	1 ” TC	Design Requirement
Jacket Cool Inlet Conn :		
Type	1.5” TC with Valve	Design Requirement
Make	Bright Pharma	Design Requirement
MOC	SS 304	Design Requirement
Jacket Cool Inlet Valve	Pneumatically operated Modulating Ball valve Make - Avcon	Design Requirement
Size	25mm	Design Requirement
MOC	SS 304	Design Requirement

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Seating	PTFE	Design Requirement
Process End	50.4mm	Design Requirement
Comp. Air Required	4.5 to 6 Kg/cm² for actuation	Design Requirement
Jacket Drain Conn :		
Type	1.5” TC with Valve	Design Requirement
Make	Bright Pharma	Design Requirement
MOC	SS 304	Design Requirement
Jacket Drain Valve	Pneumatically operated Ball valve Make - Avcon	Design Requirement
Size	25mm	Design Requirement
MOC	SS 304	Design Requirement
Seating	PTFE	Design Requirement
Process End	50.4mm	Design Requirement
Comp. Air Required	4.5 to 6 Kg/cm² for actuation	Design Requirement
Skid :		
Size	1500 (L) x 1200 (W)	Design Requirement
Make	Bright Pharma	Design Requirement
Construction	Made of SS rectangular pipes	Design Requirement
- MOC	SS 304	Design Requirement
Control Panel :		
Size	250 (W) X 800 (D) X 1200 (H) Appx.	Design Requirement
Make	Bright Pharma	Design Requirement
MOC	SS 304	Design Requirement
3 Phase Indication	R Y B indication lamps Make - Teknic	Design Requirement
HMI	5.7” Color touch screen Make - AB	Design Requirement
Electrical supply	24 V DC	Design Requirement
Hooter	24 V DC supply Make - Teknic	Design Requirement
Emergency button	Push button type Make - Salzer	Design Requirement
Main Switch	3 Pole, 16 A Make - Salzer	Design Requirement
Filter Pads	100 x 100mm with Exhaust Fan Make - Jainson	Design Requirement

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Exhaust Fan	Ø4” Make - Rexnord	Design Requirement
Power Supply	230 V AC	Design Requirement
PLC	Micrologix 1400 Make - AB	Design Requirement
Electrical supply	24 V DC	Design Requirement
Control MCB	2 pole, 10A Make- Siemens	Design Requirement
VFD MCB for Low shear mixer	3 pole, 6A Make- Siemens	Design Requirement
VFD for GMP Low shear mixer	Panel Mounted AB	Design Requirement
HP Rating	0.75 HP	Design Requirement
Electrical supply	3 Phase to 3 Phase	Design Requirement
Vessel Lamp MCB	1 pole, 6A Make- Siemens	Design Requirement
Plug Point MCB	2 pole, 10A Make- Siemens	Design Requirement
Control	Start/Stop Contactor Make- Siemens	Design Requirement
Electrical supply	220 V AC	Design Requirement
Phase Preventer Relay	Panel Mounted Make - Salzer	Design Requirement
Electrical supply	220 V AC	Design Requirement
SMPS	Panel mounted	Design Requirement
Input	220 V AC Make - Omron	Design Requirement
Output	24 VDC	Design Requirement
SMPS output fuse	6 A	Design Requirement
Air Pressure Switch	Bellow Type Potential Free Make- Baumer	Design Requirement
Type	UT-10	Design Requirement
Range	0 to 10 bar	Design Requirement
Process Connection	¼” BSP (F)	Design Requirement
Electrical Supply	Universal 230 V AC / 24 V DC	Design Requirement
Pneumatic coils	2 way miniature coils Make - SPAC	Design Requirement
Model	TG23-06E	Design Requirement
Size	1/8”	Design Requirement
Electrical supply	230 V AC	Design Requirement

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Load Cell Indicator	Panel Mounted	Design Requirement
Make	Mettler	Design Requirement
Model	IND 331	Design Requirement
Electrical supply	230 V AC	Design Requirement
Output	4 to 20 mA	Design Requirement
FINISHING :		
Vessel		
Internal Finishing	Ra ≤ 0.5 µm, Electro Polish	Design Requirement
External Finishing	Ra ≤ 0.8 µm, Matt Finish	Design Requirement
Make	Bright Pharma	Design Requirement
Control Panel		
External Finishing	Ra ≤ 0.8 µm, Matt Finish	Design Requirement
Make	Bright Pharma	Design Requirement
Skid		
External Finishing	Ra ≤ 0.8 µm, Matt Finish	Design Requirement
Make	Bright Pharma	Design Requirement

Checked By
(Engineering)
Sign/Date: _____

Verified By
(Quality Assurance)
Sign/Date: _____

Inference: _____

_____

_____

_____

_____

_____

Reviewed By
(Manager QA)
Sign/Date: _____

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8.4 MATERIAL OF CONSTRUCTION

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Vessel shell	AISI 316L
2.	Jacket shell	SS 304
3.	Spiral Stiffner	AISI304
4.	Support	SS 304
5.	Impeller	AISI 316L
6.	Spray Ball	SS 316L
7.	Compounding gauge non contact part	SS 304
8.	Compounding gauge Contact part	SS 316L
9.	Sterile Safety Valve non contact part	SS 304
10.	Sterile Safety Valve Contact part	SS 316L
11.	Plain vent filter housing	SS316 L
12.	Manual Diaphragm valve (Contact Part)	SS316 L
13.	Manual Diaphragm valve (Non Contact Part)	AA304
14.	Sparger Tube	SS316 L
15.	Rupture Disc	SS316 L
16.	Temperature Sensor	SS316 L
17.	Pressure gauge for jacket	SS304
18.	Manual Ball Valve	SS304
20.	SS Skid	SS304
21.	Control Panel	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: _____

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

8.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
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	Safety Requirement
Guards	Guards for all Moving Parts	Safety Requirement
Noise Level	Below 80 db	Safety Requirement
Operation	Manufacturing vessel should be in working condition, and it should be repeated during shutting also.	Safety Requirement
Variable Frequency Drive	Motor safety from overload	Safety Requirement
Main Supply	Main power supply should be always switched off when not in use.	Safety Requirement
Safety valve	Safety against over pressure	Safety Requirement
SS cover on drive unit	For operator safety	Safety Requirement
Emergency stop	Protection from abnormal condition	Safety Requirement
Air pressure switch	Protection for low air pressure for pneumatic valves	Safety Requirement
Rupture Disc	Safety against Over pressure	Safety Requirement
Earthing boss	Reducing risk from shock	Safety Requirement
Insulation	For operator safety & Heat loss prevention	Safety Requirement
Emergency Button	Protection against abnormal condition	Safety Requirement
Instrument air pressure	Low air pressure protection	Safety Requirement

Checked By
(Engineering)
Sign/Date: _____

Verified By
(Quality Assurance)
Sign/Date: _____

Inference: _____

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Reviewed By
(Manager QA)
Sign/Date: _____

8.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for Manufacturing vessel.	Selection of Vendor is done on the basis of review of vendor. Criteria for review includes Vendor Background (General / Financial), Technical know -how, Quality Standards, Inspection of Site, Costing, feedback from Market .	cGMP Requirement

Reference: **(1)** The equipment shall confirm to the Specifications and Requirement as specified in URS.

(2) Operating and service manual for Manufacturing vessel.

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the Supplier, if any.
- Purchase Order Copy
- Any other relevant Documents

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

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

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11.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
PO	:	Purchase Order
SS	:	Stainless Steel
MOC	:	Material of Construction
ASME	:	American Society for Mechanical Engineers
cGMP	:	Current Good Manufacturing Practice
AISI	:	American Iron & Steel Institute
SS	:	Stainless Steel
T/C	:	Triclover
ASA	:	American Standard Association
PO	:	Purchase Order
MOC	:	Material of Construction
FAT	:	Factory Acceptance Test
EPDM	:	Ethylene Propylene Diene Monomer
PTFE Poly	:	Tetra Flouro Ethylene.
BSP	:	British Standard Pipe
O.D.	:	Outside Diameter
CG	:	Compound Gauge
SV	:	Safety Valve
MFT	:	Manufacturing Vessel

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

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			