



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

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

EQUIPMENT ID. No.	
LOCATION	MANUFACTURING AREA
DATE OF	
SUPERSEDE	NIL



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

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 verify that the equipment operates in accordance with the design and user requirements as defined by set acceptance criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of manufacturing vessel 4000 Liter and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Operational Qualification Protocol Cum Report is limited to qualification of Manufacturing Vessel (**Make:** Pharmatech Process Equipment) installed in the Manufacturing Area.
- This Protocol Cum Report will define the methods and documentation used to perform OQ activity of Manufacturing Vessel
- Successful completion of this Protocol Cum Report will verify that Manufacturing Vessel meet all acceptance criteria and ready for Performance Qualification.



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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	<ul style="list-style-type: none">• Preparation, Review, Approval and compilation of the operational Qualification Protocol Cum Report.• Co-ordination with Production and Engineering to carryout Operational Qualification.• Monitoring of Operation Process• Post Approval of Operational Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Operational Qualification Protocol cum Report.• To Co-ordinate and support for execution of Operational Qualification study as per Protocol Cum Report.• Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Operational Qualification Protocol cum Report.• To co-ordinate and support Operational Qualification Activity.• Calibration of Process Instruments.• Post Approval of Operational Qualification Protocol cum Report after Execution.



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5.0 EQUIPMENT DETAILS:

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

- Facility Devices



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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

N₂ Sparger tube

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

Manual operated Diaphragm (PTFE with EPDM back up) valve for CA/N₂ 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

Resterilizable Diaphragm (Platinum cured silicon) Sample valve

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



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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 Documents Verification:

S. NO	DOCUMENT NAME	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE
1.	Executed and approved Design Qualification cum report		
2.	Executed and approved Installation Qualification cum report		
3.	SOP for Operation & Cleaning of manufacturing vessel		
4.	SOP for Preventive Maintenance of manufacturing vessel		

**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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7.2 Measuring Instrument Calibration:

Verify that all critical instruments associated with the system will be in a calibrated state.

EQUIPMENT/ INSTRUMENTS NAME	EQUIPMENT/ INSTRUMENT ID	CALIBRATION ON	DUE ON

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 EQUIPMENT START-UP VERIFICATION:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION (Complies/Not Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Power Supply	415 ±10% Volts AC , 50 Hz & 3 phase		
Electrical Wiring and Earthing	Electrical Wiring should be as per Approved Drawings. Double External Earthing to Control Machine and Operator should be provided.		
Noise Level	Below 80 db.		
Switch ON the main incoming supply by main switch.	The light on the front panel should glow.		
Start Magnetic Stirrer through HMI	Magnetic Stirrer should start immediately.		
Turn ON the Vessel Lamp ON/OFF Turn toggle key	Vessel lamp should ON.		



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ITEM	ACCEPTANCE CRITERIA	OBSERVATION (Complies/Not Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Enter speed on HMI to vary the speed of Magnetic Stirrer.	Speed of Magnetic Stirrer should change as per the speed entered in HMI.		
Pressing Selector Switch	HMI & load cell indicator should be powered on.		
Pressing Emergency push button	Process Stop Immediate with message on HMI.		
Releasing Emergency push button	Process Start Immediate with message on HMI.		

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8.2 Verification of Control Valve Function With Symbol in Maintenance Mode :

Control Valve Name	Valve Symbol	Operation (Satisfactory /Not Satisfactory)	Observed by (Engineering) (Sign/Date)
Air Vent Filter Inlet Valve	CV1		
Air Vent Filter Outlet Valve	CV2		
Air vent Filter SIP Control Valve	CV3		
SIP for Tank Valve	CV4		
Jacketed Air Vent Valve	CV5		
Jacket Steam Inlet Valve	CV6		
Jacket Chilled Water Return Valve	CV7		
Jacket Compressed Air Inlet Valve	CV8		
Jacket Chilled Water Inlet Valve	CV9		
Jacket Drain Valve	CV10		
Jacket Condensate Outlet Valve	CV11		
Tank Outlet Valve	CV12		
Sampling Valve SIP Inlet Valve	CV13		
Sampling Valve Condensate Valve	CV14		
Vent Filter Outlet Sensor	TS1		
Tank Sensor	TS2		
Tank Drain Sensor	TS3		
Sampling Valve SIP Sensor	TS4		
Pressure Transmitter	PT		
Conductivity Sensor	CT		

Note : During Operation all symbol Converted into Green

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8.3 FUNCTIONAL & OPERATIONAL CHECKS:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION (Complies/Not Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Control Panel's Operational Verification			
Main Switch 'ON'	R Y B three phase lamp should be glow on.		
Pressing Emergency Button	Hooter should be activated with alarm message on HMI		
On Acknowledge alarm message.	Hooter should be Silent		
Releasing Emergency push button	Alarm should be disappeared		
Instrument's Operational Verification			
Product temperature sensor immersing in known temperature bath	The same Temperature valve should be display on HMI with ± 0.1 to 0.2 °C tolerance & 0.1 °C incremental		
Vent Housing drain temperature sensor immersing in known temperature bath	The same Temperature valve should be display on HMI with ± 0.1 to 0.2 °C tolerance & 0.1 °C incremental		
Load Cell Keeping Standard weight	The load cell indicator should display the same weight with incremental of 0.1 kg.the same valve should be display on HMI		
Load Cell Filling Known qty of water	The load cell indicator should display the same weight with incremental of 0.1 kg.the same valve should be display on HMI		
ON /OFF Operational Verification of all output in maintenance Mode			



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CHECKS	ACCEPTANCE CRITERIA	OBSERVATION (Complies/Not Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Steam Inlet Valve			
Pressing Steam inlet Valve Symbol	Steam inlet Valve Should be open.		
	Red Symbol Converted into green		
Pressing again after opening	Steam inlet Valve Should be Close.		
	Green Symbol Converted into Red		
Cooling outlet valve			
Pressing cooling outlet valve symbol	Cooling Outlet valve should be opened.		
	Red Symbol Converted into green		
Pressing again after opening	Cooling inlet valve should be closed		
	Green Symbol Converted into Red		
Jacket Vent valve			
Pressing cooling inlet valve symbol	Jacket drain valve should be opened		
	Red Symbol Converted into green		
Pressing again after opening	Jacket drain valve should be closed.		
	Green Symbol Converted into Red		
Condensate out valve			
Pressing Condensate outlet valve symbol	Condensate out let valve should be open.		
	Red Symbol Converted into green		
Pressing again after opening	Condensate out let valve should be closed.		
	Green Symbol Converted into Red		
Jacket Drain Valve			
Pressing Cooling inlet valve symbol	Jacket drain valve should be opened.		
	Red Symbol Converted into green		



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CHECKS	ACCEPTANCE CRITERIA	OBSERVATION (Complies/Not Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Pressing again after opening	Jacket drain valve should be Closed.		
	Green Symbol Converted into Red		
BAGI 1K Stirrer			
Pressing BAGI 1K stirrer symbol	BAGI Stirrer should be turned on.		
	Red Symbol Converted into green		
Pressing again after opening	BAGI Stirrer should be turned off.		
	Green Symbol Converted into Red.		
ON /OFF Operational Verification of all Output in Maintenance Mode			
Vessel Lamp			
Pressing Vessel Lamp switch from lamp.	Vessel lamp should be glow on.		
“BAGI Stirring” Operation			
BAGI Stirring start for entire set time	BAGI stirrer should be turned on to run at set speed.		
	set time over BAGI stirrer should be turned off.		
	Hooter should be activated with BAGI stirrer over Message.		
	On Acknowledging message, hooter should be silent		
BAGI Stirring with intermediate stop	BAGI Stirrer should be Turned off.		
	Hooter should be activated with BAGI stirring stopped message.		
	On Acknowledging message, hooter should be silent		
Heating Operation in Semi Auto Mode			
Heating for entire set time	Boiler steam inlet valve & condensate out valve should be opened		



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CHECKS	ACCEPTANCE CRITERIA	OBSERVATION (Complies/Not Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
	BAGI Stirrer should be Turned on to run at set speed.		
	As Product Temperature reach the set point heating maintain time should be started.		
	Steam inlet valve should be opened & closed to maintain heating temp.		
	On Heating maintain the time over, steam inlet valve condensate outlet valve is closed & BAGI stirrer should be turned off.		
	Hooter should be activated with Heating over message		
	On acknowledge message hooter should be silent		

Heating Operation in Semi Auto Mode

Heating for entire set time	Boiler steam inlet valve & condensate outlet valve should be opened.		
	BAGI stirrer should be turned on to run at set speed.		
	As product temp. reaches the set point heating maintain time should be started.		
	Steam inlet valve should be opened & closed to maintain the over, steam inlet valve		



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CHECKS	ACCEPTANCE CRITERIA	OBSERVATION (Complies/Not Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
	should be closed & BAGI stirrer should be turned off.		
	Hooter should be activated with Heating over Message.		
	On Acknowledging message, hooter should be silent.		
Heating with intermediate stop	Boiler steam inlet valve & condensate outlet valve should be Closed.		
	BAGI stirrer should be turned off.		
	Hooter should be activated with Heating stopped message.		
	On Acknowledging message hooter should be silent.		
Semi Auto Mode Mixing process verification			
Set The Mixing Time in HMI	Desired Time Setting Should be Accepted		
Set The RPM in HMI	Required RPM Setting Accepted		
		Printing should be Take Place	
Semi Auto Mode Addition process verification			
Ingredient Addition	Add Ingredient message should be display.		
	On Acknowledging & pressing back, process should move ahead further.		
	BAGI stirrer should be turned on to run at set speed.		



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CHECKS	ACCEPTANCE CRITERIA	OBSERVATION (Complies/Not Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
	On set process time over BAGI stirrer should on to run at set speed.		
Semi Auto Mode Addition process verification			
	BAGI stirrer should be turned on to run at set speed.		
	Boiler steam inlet valve & condensate outlet valve should be opened.		
Semi Auto Mode Heating process verification			
Heating with BAGI Run	BAGI stirrer should be turned on to run at set speed.		
	Boiler steam inlet valve & condensate outlet valve should be opened.		
	As product temp. reaches the set		
	point, heating maintenance time should be started.		
	On Heating maintain the time over steam inlet valve condensate outlet valve should be closed.		
	BAGI stirrer should be turned off.		
Semi Auto Mode Cooling process verification			
Cooling with BAGI Run	BAGI stirrer should be turned on to run at set speed.		
	Cooling water inlet valve & cooling water outlet valve should be opened.		



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CHECKS	ACCEPTANCE CRITERIA	OBSERVATION (Complies/Not Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
	As Product temp. reaches the set point Cooling maintain time should be started.		
	On Cooling maintain time over cooling water inlet valve cooling water outlet valve should be closed.		
	BAGI stirrer should be turned off.		
Alarm & Interlocks Verification			
Air Pressure low			
Disconnection / Interruption Plant Compressed air Supply to air pressure Switch	Running process should be tripped & Air pressure low alarm should be HMI hooter activation.		
	Alarm should be printed once and printed should be held.		
On acknowledge alarm	Hooter should be silent		
Connecting / Continuing plant compressed air supply to air pressure switch	Alarm should be disappeared		
Pressing Restart from HMI	Process should be resumed.		
	Printing should be continued with process restarted message Printing.		
Emergency Pressed			
Pressing Emergency Push button from control panel.	Running process should be tripped & Emergency pressed alarm should be displayed on		



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CHECKS	ACCEPTANCE CRITERIA	OBSERVATION (Complies/Not Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
	HMI with hooter activation.		
	Alarm should be Printed once and printing should be held.		
On acknowledging alarm	Hooter should be silent.		
Releasing Emergency pressed	Alarm should be disappeared		
Pressing Restart from HMI	Process should be resumed		
	Printing should be continued with process restarted message printing.		
BAGI Stirrer over Load			
Making terminal short at BAGI stirrer VFD in control Panel	Running process should be tripped & BAGI stirrer overload'' alarm should be displayed on HMI with hooter activation.		
	Alarm should be printed once and printed should be held.		
On acknowledging alarm	Hooter should be silent.		
Pressing Restart from HMI	Process should be resumed.		
	Printing should be continued with process restarted message printing.		
Phage Fail or Change			
Disconnecting or reversing one phase from main supply terminal	Running Process should be tripped & Phase Fail alarm should be displayed on HMI with hooter activation.		
	Alarm should be printed once and printing should be held.		



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CHECKS	ACCEPTANCE CRITERIA	OBSERVATION (Complies/Not Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
On acknowledging alarm	Hooter should be silent.		
Reconnecting phase in proper order as earlier	Alarm should be silent.		
Pressing Restart from HMI	Process should be resumed.		
	Printing should be continued with Process restarted message Printing.		
Mixing Process Alarm & Interlock Verification			
No Safe Level to run BAGI			
In manual mode ,keep content level below safe load & try to start BAGI stirrer	BAGI Stirrer should not be started & no safe load to run BAGI Stirrer alarm should be display on HMI with hooter activation.		
	Alarm should be printed once if Printed once if printing is enabled.		
On acknowledging alarm	Hooter should be silent & alarm should be disappeared.		
Note : All Trail Print Should be attached.			

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8.4 RPM Verification :

Set In HMI	Display In HMI	Observed By Tachometer (Id No.)	Observed by (Engineering) (Sign/date)
Minimum RPM			
Maximum RPM			

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Sign/Date:**

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8.5 Minimum Volumetric Capacity Verification with Maximum RPM : Minimum Capacity of Tank with Stirrer RPM are Physically Verified, observation Recorded, Because Load Cell Required Minimum quantity of Water for Dipping the Stirrer.

Weight of Water	RPM of Stirrer	OBSERVATION (Satisfactory /Not Satisfactory)	Observed by (Engineering) (Sign/Date)
Minimum Weight			
Maximum Weight			

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8.6 Spray Ball Test :

8.6.1 Objective : To Demonstrate that the spray ball of Vessel is Capable of Removing the Traces of 1-5 % of Riboflavin Solution & 0.2 % of Mannitol solution from the vessel Surface & to Check working of Spray ball during running trial.

8.6.2 Material : Water, Riboflavin Dye, Manitol, Bucket

8.6.3 Utilities :

Pump, Hosepipe, U.V. Light, painting brush, Pressure gauge

8.6.4 Method :

- Fit the Spray ball & its line on Vessel.
- Connect the pump outlet to spary ball line and connect the vessel out let line to drain line.
- Prepare 1-5% Riboflavin solution & 0.2 % of Mannitol solution in one Bucket.
- Apply Riboflavin solution uniformly on the vessel and Nozzle through Painting brush.
- Allow the vessel to dry about 5-10 Minute.
- Close the open Connection provide on vessel.
- Open the vessel outlet valve & operate the pump with water 1-2 bar pressure for 30 minute . and that time stirrer should be on position
- Collect 100 ml Sample from Sampling Valve and Sent to QC for Identification of Riboflavin
- Riboflavin detection test are inspected for remaining riboflavin using a UV lamp at either 365 or 254nm wavelength for riboflavin detection.



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8.6.5 Result :

TEST	ACCEPTANCE CRITERIA	OBSERVATION (Complies /Non Complies)	VERIFIED BY
Spray Ball Test	Spray pattern of water found all over 360° uniformly & all the surface of vessel internal should be free from riboflavin dye, Detected by UV lamp and QC Result.		

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8.7 Load Cell Verification:

8.7.1 Load Cell Verification by Using Standard Weight :

TEST	LOAD (in kg)	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Load 1 st			
Load 2 nd			
Load 3 rd			
Load 4 rd			
Load 5 rd			

Acceptance Criteria : ± 0.1 %

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8.7.2 Load Cell Verification by Using WFI Water: Measured Sufficient Quantity of Purified Water and added in a Manufacturing Tank, Observation Recorded.

S.No.	Quantity of Water (In Kg)	Observation by Load Cell Display (Total Cumulative)	Sr. No.	Quantity of Water (In Kg)	Observation by Load Cell Display (Total Cumulative)	Observed By (Engineering) (Sign/Date)
1			71			
2			72			
3			73			
4			74			
5			75			
6			76			
7			77			
8			78			
9			79			
10			80			
11			81			
12			82			
13			83			
14			84			
15			85			
16			86			
17			87			
18			88			
19			89			
20			90			
21			91			
22			92			
23			93			
24			94			
25			95			
26			96			
27			97			



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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

S.No.	Quantity of Water (In Kg)	Observation by Load Cell Display (Total Cumulative)	Sr. No.	Quantity of Water (In Kg)	Observation by Load Cell Display (Total Cumulative)	Observed By (Engineering) (Sign/Date)
28			98			
29			99			
30			100			
31			101			
32			102			
33			103			
34			104			
35			105			
36			106			
37			107			
38			108			
39			109			
40			110			
41			111			
42			112			
43			113			
44			114			
45			115			
46			116			
47			117			
48			118			
49			119			
50			120			
51			121			
52			122			
53			123			
54			124			
55			125			
56			126			



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

S.No.	Quantity of Water (In Kg)	Observation by Load Cell Display (Total Cumulative)	Sr. No.	Quantity of Water (In Kg)	Observation by Load Cell Display (Total Cumulative)	Observed By (Engineering) (Sign/Date)
57			127			
58			128			
59			129			
60			130			
61			131			
62			132			
63			133			
64			134			
65			135			
66			136			
67			137			
68			138			
69			139			
70			140			

Total Weight

Acceptance Criteria : $\pm 0.1 \%$

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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QUALITY ASSURANCE DEPARTMENT

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

8.8 SIP Verification in Semi Auto Mode :

Parameter	Acceptance Criteria	OBSERVATION (Complies/Not Complies)	Observed by (Engineering) (Sign/Date)
Purging Time	060 Sec		
Sterilization Pressure	1.90 Bar		
Pressure Dead Band	00.02 Bar		
Sterilization Temperature	121.4 °C		
Heating on Temperature	122.2 °C		
Heating off Temperature	122.7 °C		
Sterilization hold Time	30 Min		
Sterilization Fail Temperature	119.0 °C		
Overshoot Temperature	130 .0 °C		
Cooling Temperature	80.0 °C		
TS1	Vent Filter Condensed Drain Temperature		
TS2	Tank Temperature		
TS3	Tank Condensed Drain Temperature		
TS4	Sampling Valve Condensed Drain Temperature		
PT	Tank Pressure		

Note :Trail Print attached

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

8.9 Verification of CIP Function :

Parameter	Acceptance Criteria	OBSERVATION (Complies/Not Complies)	Observed by (Engineering) (Sign/Date)
CIP	Contaminate the Manufacturing Tank with 15 % Sodium Hydroxide Solution , Start the Pre wash & Final Wash until Conductivity Not achieved Less then 1.2 $\mu\text{s}/\text{Cm}$		

Note :Trail Print attached

**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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MANUFACTURING VESSEL (4000 LITER)**

8.10 Security Levels Verification:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION (Complies/Not Complies)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Operator Level	Operator level should have access to process selection, Process start & stop in auto manual mode, Print start & stop, alarm, I/O & MIMIC Visualization. it should have access to acknowledge the alarm & reset the Process.	Password :.....	
Supervisory Level	Supervisory level should have access to operator level all menu and in addition to that should have excess to set the process parameter ,batch information, recipe preparation & Recipe upload.	Password :.....	
Manager Level	Manager level should excess to Supervisory level all menu and in additional to that should have excess to change the Password,	Password :.....	

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

8.11 Power Failure Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION (Complies/Not Complies)	OBSERVED BY (ENGINEERING) SIGN/DATE
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions. Press Continue Button Equipment Start.		

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

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

Inference:

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



**OPERATIONAL 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.
- Raw Data Generate During Operational Qualification

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
HMI	:	Human machine interface
ID.	:	Identification
MFT	:	Manufacturing vessel
OQ	:	Operational Qualification
PLC	:	Programmable Logic Control
RPM	:	Revolution per Minute
SIP	:	Sterilization in place
CIP	:	Clean in Place
SOP	:	Standard operating procedure
VFD	:	Variable Frequency Drive
WHO	:	World Health Organization



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**OPERATIONAL 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)			