OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

SS JACKETED MANUFACTURING VESSEL

CAPACITY: 2000 LITER

(FFS LINE)

EQUIPMENT ID. No.	
LOCATION	**MANUFACTURING AREA, FFS LINE**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (2000 LITER)	PROTOCOL No.:

PROTOCOL CONTENTS

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PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (2000 LITER)	PROTOCOL No.:

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)			

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 2000 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.

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, 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	• 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	• 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.

5.0 EQUIPMENT DETAILS:

Equipment Name	SS Jacketed Manufacturing vessel
ID Number	
Capacity	2000 ltr.
Gross Capacity	2400 ltr.
Manufacturer's Name	Pharmatech Process Equipment
Sr. No.	
Model	cGMP Model.
Supplier's Name	Pharmatech Process Equipment
Location of Installation	Manufacturing Area, FFS Line

6.0 EQUIPEMENT DESCRIPTION:

The Manufacturing Vessel is the Jacketed, Insulated & Cladding vessel having Bottom entry low shear magnetic mixer to perform heating & cooling with stirring operations respectively during the mixing Process .the vessel is incorporated with high shear mixer tank plate for future installation of mixer, if required .the respective electrical components have been organized in the control panel except VFD .it's also designed of having compatible with clean in process and steam in process with in-built facilities of the same .some process valves are manually operated & some are pneumatically operated as per process Requirements. All utility valve are pneumatically operated to perform the heating & cooling operation automatically & control the same.

- Shell
- Jacket
- Insulation &cladding
- Stirrer
- SS panel
- Legs
- Rotating spray ball
- Compound gauge
- Sterile safety valve

- 0.2 micron plain vent filter
- Manual operated diaphragm valve
- Rupture disc
- Temperature sensor with transmitter
- Manual operated flush bottom diaphragm valve with sampling valve arrangement.
- Safety valve for jacket.
- PG For Jacket
- Manual ball valve
- Auto steam trap unit
- Variable frequency drive
- Load cell
- SS304 PLC panel

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Verification of certificate of Measuring Instrument Associated with the Vessel and MOC
- SOP for Operation & Cleaning of manufacturing vessel
- SOP for Preventive Maintenance of manufacturing vessel.

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 OQ Protocol cum Report.

7.1.2 Acceptance Criteria:

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

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S. NO.	DOCUMENT NAME	COMPLETED (YES/NO)	VERIFIED BY (QA) 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		

Inference:

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

8.2 Test / Measuring Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

EQUIPMENT/ INSTRUMENTS NAME	EQUIPMENT/ INSTRUMENT I.D.	CALIBRATION ON	DUE ON	OBSERVED BY SIGN/DATE

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.3 EQUIPMENT START-UP VERIFICATION

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Selector Switch ON ,	The light on the front panel should glow.		
Selector Switch OFF ,	The light on the front panel should not 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.		
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 Emergency push button	Process Stop Immediate with message on HMI.		
Releasing Emergency push button	Process Start Immediate with message on HMI. .		
Noise Level	Below 80 db.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.4 FUNCTIONAL & OPERATIONAL VERIFICATION

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
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		
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		
Pressing cooling Supply & Return valve symbol	Cooling inlet valve should be opened.		
	Red Symbol Converted into green		
Pressing again after opening	Cooling inlet valve should be closed		
	Green Symbol Converted into Red		
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		
Pressing Drain valve symbol	Drain valve should be open.		
	Red Symbol Converted into green		

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (2000 LITER)	PROTOCOL No.:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Pressing again after opening	Drain valve should be closed..		
	Green Symbol Converted into Red		
	Green Symbol Converted into Red		
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 .		
Pressing Vessel Lamp Switch Manually	Vessel lamp should be glow on.		
Overloading	Hooter should be activated with BAGI stirrer over Message .		
	On Acknowledging message , hooter should be silent		
Heating for entire set time	Boiler steam inlet valve & condensate out valve should be opened		
	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		

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
	be turned off.		
	Hooter should be activated with Heating over message		
	On acknowledge message hooter should be silent		
	On Acknowledging message hooter should be silent.		
Cooling for entire set time	Cooling inlet valve & cooling outlet valve should be opened.		
	BAGI stirrer should be turned on to run at set speed.		
	As product temp. reaches the set point Cooling maintain time should be started.		
	Cooling inlet valve should be opened & Closed to maintain cooling temp.		
	On Cooling maintain time over, cooling inlet valve, cooling outlet valve should be closed & BAGI stirrer should be turned off.		
	Hooter should be activated with Cooling over message		
	On acknowledge message hooter should be silent.		
Jacket Drain start	Jacket Compressed air valve should be opened.		
Jacket Drain stop	Jacket Compressed air valve should be Closed.		

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CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Stirring with BAGI	BAGI Stirrer should be turned on to run at set speed.		
	On set process time over BAGI stirrer should be turned off.		
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 by Acknowledge		
Pressing Restart from HMI	Process should be resumed.		
	Printing should be continued with process restarted message Printing .and Last Cycle again Start.		
Pressing Emergency Push button from control panel.	Running process should be tripped & Emergency pressed alarm should be displayed on 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		

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (2000 LITER)	PROTOCOL No.:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Pressing Restart from HMI	Process should be resumed		
	Printing should be continued with process restarted message printing and Last Cycle again Start.		
Pressing O/L reset tab on VFD to reset overload	Alarm should be Appeared then Disappeared after Resetting.		
Pressing Restart from HMI	Process should be resumed.		
	Printing should be continued with process restarted message printing.		
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.		
On acknowledging alarm	Hooter should be silent.		
Reconnecting phase in proper order as earlier	Alarm should be silent by Manually acknowledging than Silent		
Pressing Restart from HMI	Process should be resumed.		
	Printing should be continued with Process restarted message Printing.		
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.		

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
	Alarm should be printed once if Printed once if printing is enabled.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.1 Hydro Test:

8.1.1 Objective: To qualify the Welding Quality in View of Leak of Tightness under Hydraulic Pressured Condition as per ASME Sec. VIII Div. I (2001) code and qualifying the vessel to operate at Specified Design Condition.

8.1.2 Material: water

8.1.3 Utility: Water Supply ,Compressed Air

8.1.4 Instrument: Air Vent Valve

8.1.5 Method:

- Fill the Tank with Water
- Blind of all Nozzle ,Except bottom Connection & Top Connection
- Connect water pump to Bottom Connection
- When Water Flow out vent, Close the vent Valve
- Pressurize the shell side up to Hydro test Pressure
- Mark the Pressure on Pressure gauge.
- Check the Same after 30 minute
- Check all weld joint & Temporary Joint for leakage.
- Record all the data on Hydro test in Report.

8.1.6 Hydro Test Observation:

HYDRO TEST	START TIME OF THE TEST	END TIME OF THE TEST	OBSERVATION
Main Shell			
Jacket Shell			
Acceptance Criteria: No Leakage Observed with in 30 min.			

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.2 Spray Ball Test :

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

8.2.2 Material: Water, Riboflavin Dye. Hose pipe, Painting Brush, Bucket,

8.2.3 Method :

- Fit the Spray ball & its line on Vessel.
- Connect the pump outlet to Spray ball line and connect the vessel out let line to drain line.
- Prepared 1-5% Riboflavin solution in one Bucket.
- Apply Riboflavin solution uniformly on the vessel and Nozzle through Painting brush.
- Allow the vessel to dry (5-10 Minute)
- Close the open Connection provide on vessel .
- Open the vessel out let valve and operate the pump with Fresh water at 1-2 Bar for specified time and that time Stirrer should be in ON position.
- Collect 100 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.
- At the same time perform blank for the riboflavin detection test also

8.2.4 Operating Parameter

PARAMETER	OPERATING PARAMETER	OBSERVATION	OBSERVED BY
Pressure	**1.5 to 2.o Bar**		
Flow rate	**73 LPM**		
Time	**10 Min**		

8.2.5 Result :

TEST	ACCEPTANCE CRITERIA	OBSERVATION	VERIFIED BY
Spray Ball Test	Run the Spray ball smoothly and clean the Surface Areas. Riboflavin dye not Detected UV lamp		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date:……

8.3 Load Cell Verification:

8.3.1 Load Cell Verification by Using Standard Weight :

TEST	LOAD (IN KG)	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Load Ist	10 Kg		
	10 kg		
	10 kg		
Load 2nd	20 kg		
	20 Kg		
	20 kg		
Load 3rd	50 kg		
	50 kg		
	50 kg		
Load 3rd	80 Kg		
	80 Kg		
	80 Kg		
Acceptance Criteria : ± 1 %			

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

S.No.	QUANTITY OF WATER (IN KG)	OBSERVATION BY LOAD CELL DISPLAY	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Total Weight			
Acceptance Criteria : ± 1 %			

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.4 Security Levels Verification.

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	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.		
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.		
Manager Level	Manager level should excess to Supervisory level all menu and in additional to that should have excess to change the Password,		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.5 Power Failure Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	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 Again Login and cycle restart.		

Checked By
(Production)
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:

- 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:

- Operation and Maintenance Manual.
- Any other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED 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:

°C	:	Degree centigrade
cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate Quality Assurance
DQ	:	Design Qualification
HMI	:	Human machine interface
ID.	:	Identification
IQ	:	Installation Qualification
Lt.	:	Liters
LTD.	:	Limited
MFT	:	Manufacturing vessel
No.	:	Number
OQ	:	Operational Qualification
PDV	:	Pneumatic Diagram Valve
PLC	:	Programmable Logic Control
PVT.	:	Private
QA	:	Quality Assurance
RPM	:	Revolution per Minute
SIP	:	Sterilization in place
SOP	:	Standard operating procedure
VFD	:	Variable Frequency Drive
WHO	:	World Health Organization

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)			