OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

MANUFACTURING TANK

CAPACITY: 2000 LITER

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

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MANUFACTURING TANK	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MANUFACTURING TANK	PROTOCOL No.:

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)			

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 Room.
- This Protocol Cum Report will define the methods and documentation used to perform Operational Qualification 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, and Authorization, 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 & 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	Manufacturing Tank
ID. Number	
Capacity	2000 ltr.
Gross Capacity	2395 ltr.
Manufacturer's Name	Pharmatech Process Equipment
Model	MFV-2000
Supplier's Name	Pharmatech Equipment
Location of Installation	Manufacturing Area

6.0 EQUIPEMENT DESCRIPTION:

Manufacturing Vessel Comprises of Top & Bottom Tori spherical Dish ends (10 %) Welded with Central cylindrical shell. This is principally designed for the preparation and manufacturing of liquid Preparation.

Bottom Entry Agitator of rating 5 HP, 950 RPM is provided at the bottom dish end of the tank. The bottom entry agitator is provided with mechanical seal to avoid the leakage during operation.

Top dish is provided with nozzles as per the service requirement and on the top dish end manhole with davit arm arrangement is provided for ease in cleaning the vessel. Top dish is provided with two nos. lifting hooks for ease at the time of installation.

Entire vessel is mounted on four legs support. Manufacturing tank is provided with all pipe fittings and valves with TC fittings and silicon gasket. A working platform made with S.S. Dimpled plates and SS 304 railing is also provided. The size of the working platform is 1600 mm L x 1175 mm W x1250 mm H. it will have a ladder on one side of 850 mm length.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- 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:

INSTRUMENTS NAME	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 MOTOR FUNCTIONALITY:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Switch ON the main Power Supply	Power flows in to the main panel this is indicating by the three light on the front panel having R Y B lamp indicator.		
Switch OFF the main Power Supply	Main power supply will be cut off and light on the operating panel will turn off.		
To Start Stirrer Press Green push Button	Motor should start and stirrer Start rotating		
To Stop Stirrer Press Red push Button	Motor should Stop and stirrer Stop rotating		
Pressing Emergency push button	Process Should Stop Immediately		
Releasing Emergency push button	Process should Start Immediately		
SPEED VARIATION			
To start stirrer of manufacturing vessel press start green push button.	Motor should start and stirrer should start rotating.		
Rotate the potentiometer clockwise	The speed of stirrer should increase.		
Rotate the potentiometer anti clockwise	The speed of stirrer should decrease.		

Checked By
Production
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date: _____

Inference:

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Reviewed By
Manager QA
Sign/Date: _____

8.4 LAMP FUNCTIONALITY:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Vessel Lamp On / Off turn toggle Key from off mode to on mode	Vessel Lamp Should On		
Vessel Lamp On / Off turn toggle Key from On mode to Off mode	Vessel Lamp Should Off		

Checked By
Production
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date: _____

Inference:

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Reviewed By
Manager QA
Sign/Date: _____

8.5 RPM Verification:

Set In HMI		Display In HMI	Observed By Tachometer (Id No.)	Observed by (Engineering) (Sign/date)
Minimum RPM				
Run-01	400 RPM			
Run-02	400 RPM			
Run-03	400 RPM			
Maximum RPM				
Run-01	950 RPM			
Run-02	950 RPM			
Run-03	950 RPM			

Checked By
Production
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date: _____

Inference:

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Reviewed By
Manager QA
Sign/Date: _____

8.6 Spray Ball Test :

8.6.1 Objective: To demonstrate that the spray ball of Vessel is Capable of Removing the Traces of 0.02 % of Riboflavin Solution & 0.2 % of Mannitol from the vessel Surface & to Check working of Spray ball during running trial.

8.6.2 Material: Water, Riboflavin Dye & Mannitol

8.6.3 Method :

- Connect the pump outlet to spray ball line and connect the vessel out let line to drain line.
- Prepared 0.02% Riboflavin solution (2 gm) & 0.2 % of Mannitol (20 gm) in one Bucket (10 Liter).
- Apply Riboflavin solution uniformly on the vessel and Nozzle through spray ball.
- Allow the vessel to dry about 20 Minute.
- After 20 minutes of drying, check the residue of Riboflavin through external light source.

Acceptance Criteria: All the internal surfaces of vessel should have significant residue of riboflavin and should glow prominently under light (Visually).

- Perform cleaning in place of vessels as per respective standard operating procedure.
- Record the pressure of line with the help of pressure gauges installed at frequency of Start, Middle and end of cycle.
- Collect 100 Sample from Sampling Valve and Sent to QC for Identification of Riboflavin

Acceptance Criteria: All the internal surfaces of vessel should be free from riboflavin residue and no traces of riboflavin should glow prominently under light (Visually) and spray pattern of water found all over 360 ° uniformly.

- All the surface of vessel internal should be free from riboflavin.

8.6.4 Observation and Results:

S. No.	Date of test	Observation			Complies / does not complies	Observed by Production (sign./date)
		After Spray of Riboflavin Solution (Visually)	After Cleaning as per SOP (Visually)	QC Results		
1.						

Checked By
Production
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date: _____

Inference:

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_____

Reviewed By
Manager QA
Sign/Date: _____

8.7 PASSIVATION TEST:

8.7.1 Objective: To Demonstrate that the Manufacturing Tank & connecting Loop system is free from any foreign Material and suitable to Deliver Desired Output.

Material: Nitric Acid, WFI or Purified Water.

Equipment: Weighing Machine, Tank, Connected Loop.

Method Applied:

- Calculate the quantity of Nitric Acid (AR Grade / Commercial Grade) for preparation of 2 % Nitric Acid solution for Tanks using the given below formula:
- For 2 % Solution:

$$\text{Required Nitric Acid (\%)} = \frac{100}{\text{\% Assay of Nitric Acid}} \times 2$$

- Total required Nitric Acid (v/v) = Total volume of water (liters.) x Required Nitric Acid (%)
- Fill the storage vessel with purified water or WFI up to 400 Ltr. and add required quantity of Nitric Acid.
- Re-circulate the 2 % Nitric Acid solution through pipelines for 120 minutes.
- After 120 minutes of Passivation, drain the water.
- Fill the tank with purified water or WFI, pipelines for 60 minutes and drain the Water from Tanks.
- The pH of recirculated water shall be between pH of purified water
- If pH value of recirculated water does not comply, repeat the Above Process till the pH of recirculated water comply.
- Take the sample of purified water for analysis from the last rinse.

8.7.2 Acceptance Criteria: The pH of Purified Water should 5-7 and Nitric acid Traces Should be absent.

8.7.3 Observation:

Date of Test	Specification	Observation	Checked By Engineering Sign/date
	pH: 5-7		
	Nitric acid Traces Should be absent.		

Checked By
Production
Sign/Date:…….

Verified By
Quality Assurance
Sign/Date:……

Inference:

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Reviewed By
Manager QA
Sign & Date:……

8.8 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:

- 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
DQ	:	Design Qualification
ID.	:	Identification
IQ	:	Installation Qualification
Lt.	:	Liters
LTD.	:	Limited
MFT	:	Manufacturing vessel
No.	:	Number
OQ	:	Operational Qualification
PVT.	:	Private
QA	:	Quality Assurance
RPM	:	Revolution per Minute
SOP	:	Standard operating procedure
WHO	:	World Health Organization

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)			