



**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
MANUFACTURING TANK**

**PROTOCOL No.:**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
MANUFACTURING TANK  
CAPACITY: 2000 LITER**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>MANUFACTURING AREA</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



**PHARMA DEVILS**

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**1.0 PROTOCOL PRE- APPROVAL:**

**PREPARED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			
<b>HEAD (ENGINEERING)</b>			
<b>HEAD (PRODUCTION)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			



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**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 Mfg. tank. (**Make:** Pharmatech Equipment, **Model:** MFV 2000) to be installed in Manufacturing Area.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of manufacturing vessel



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**4.0 RESPONSIBILITY:**

The Validation Group, comprising of a representative from each of the following Departments, shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review and Authorization of Installation Qualification Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.</li><li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li><li>• Monitoring of Design Qualification activity.</li><li>• Post Approval of Installation Qualification Protocol cum Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review and Approval of Installation Qualification Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.</li><li>• Post Approval of Installation Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Installation Qualification Protocol cum Report.</li><li>• To co-ordinate and support the Activity.</li><li>• To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e.<ul style="list-style-type: none"><li>• Specification of the sub-components / bought out items, their Make, Model, Quantity and Backup Records / Brochures.</li><li>• Details of Utilities</li><li>• Material of Construction of all components</li><li>• Brief Equipment Description</li><li>• Safety Features and Alarms</li></ul></li><li>• Post Approval of Installation Qualification Protocol cum Report after Execution.</li></ul>



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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Manufacturing vessel
<b>ID. Number</b>	
<b>Capacity</b>	2000 lt.
<b>Gross Capacity</b>	2395 lt.
<b>Manufacturer's Name</b>	Pharmatech Equipment
<b>Model</b>	MFV-2000
<b>Supplier's Name</b>	Pharmatech Equipment
<b>Location of Installation</b>	Manufacturing Area

**6.0 SYSTEM 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 1600mm L x 1175 mm W x 1250 mm H. it will have a ladder on one side of 850mm length.

**7.0 PRE – QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

- Executed and approved Design Qualification document
- Verification of Certificate of material of construction of components.
- Verification of Calibration Certificate of test Instrument.

**7.1.1 Procedure:**

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

**7.1.2 Acceptance Criteria:**

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



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**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 General Checks and Location Suitability:**

<b>Installation Checks</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign/Date</b>
Physical Damage	Should be no Damage to the mfg. tank with stirrer		
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Syrup Manufacturing		
Room Condition	General working condition		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

**Checked By**  
**Production**  
**Sign/Date:** \_\_\_\_\_

**Verified By**  
**Quality Assurance**  
**Sign/Date:** \_\_\_\_\_

**Inference:**

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**Reviewed By**  
**Manager QA**  
**Sign/Date:** \_\_\_\_\_



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**8.2 Utility Verification:**

<b>INSTALLATION CHECKS</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
Equipment	Manufacturing vessel 2000 lt		
Model	cGMP Model		

**ELECTRICAL INSTALLATION:**

Electricity	Voltage	415± 5% V		
	Phases	3 Phase		
	Frequency	50 Hz		
Electrical connections have been provided and secured.	Should be provided & secured			
All components in the panel are properly secured	Should be properly secured			
Earthing connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.			

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**8.3 Installation Checks:**

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Verify that the "As built" drawings are complete and represent the design concept		
2.	Check the proper mechanical installation		
3.	Check the proper electrical installation of		
4.	Check the equipment is free from any defects		
5.	Check the finishing of product contact parts		
6.	Verify that major components are securely anchored and protected from shock		
7.	Verify that there is no observable physical damage		
8.	Verify that "Room layout" drawing is OK and sufficient space for servicing is provided		

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**Production**  
**Sign & Date** \_\_\_\_\_

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**8.4 Verification of Technical Specification:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
<b>Equipment Name</b>	Manufacturing Tank		
<b>Make</b>	Pharmatech Equipment Pvt. Ltd.		
<b>Model</b>	MFV-2000		
<b>Working Capacity</b>	2000 Ltr.		
<b>Gross Capacity</b>	2395 Ltr.		
<b>Contact Part</b>	SS 316 L		
<b>Non- Contact Part</b>	SS 304		
<b>Main Shell</b>	Ø 1350 x 4 mm thick MOC:SS 316 L		
<b>Bottom Dish end</b>	Ø 1350 x 4 mm ( 10 % Torispherical) MOC:SS 316 L		
<b>Bottom Dish end</b>	Ø 1350 x 4 mm ( 10 % Torispherical) MOC:SS 316 L		
<b>Leg Pipe</b>	Ø 140 x 3 mm thick MOC:SS 316 L		
<b>Agitator shaft</b>	Ø 38 mm MOC:SS 316 L		
<b>Agitator blade</b>	Ø 225 sweep x 4 mm thick MOC:SS 316 L		
<b>Lifting hooks</b>	12 mm thick MOC:SS 316 L		
<b>Baffles</b>	1050 x 150 x 6 mm thick MOC:SS 316 L		



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<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
<b>Monkey ladder</b>	Ø 19 mm rod x 300 mm x 100 mm		
<b>Gasket for bottom Valve</b>	4 mm thick		
<b>Gasket for Manhole</b>	10 mm <sup>2</sup>		
<b>Eye Bolt</b>	M 12 x 65 long		
<b>Davit arm assembly</b>	Pipe and Elbow of Ø 50 x 3 mm thick		
<b>Davit arm Bearing housing</b>	Ø 69 x 150 mm thick		
<b>Davit arm swing shaft</b>	Ø 55 x 150 mm thick		
<b>Motor</b>	5 HP , 950 RPM, 415 V, 50 Hz, Make: Hindustan motors Sr. no. 80301875		
<b>VFD</b>	Rating : 3.7 kw, 415 V AC 3Ph, Ph : Delta , E-series		
<b>Mechanical Seal</b>	Type: Single Cartridge dry seal Seal Faces : Car-Sic Size : 38 mm Make : Sigma Seal		
<b>Outlet Valve (vessel)</b>	Type : Flush bottom ball valve Outlet Conn. : 38mm Operation : Manual Conne. Size : 38 mm , 1 nos MAC : Quality flow		



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<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
<b>Butterfly Valve (For Process)</b>	Operation : Manual MOC : SS 316 L Conn. Type : TC / TC Conn. size : 38 mm (4 nos)/50 mm(1 nos) Make : Cipriani Harrison Sr. no. 2203/19 , 2210/19, 2215/19 , 2219/19		
<b>Spray Ball</b>	Type : Dynamic self-rotating with 360° water flow : 89 LPM at 2 Bar MOC : SS 316 L Conn. size : 3/4" BSP Spray : Jet spray		
<b>Temperature Sensor</b>	Type : PT 100, 3 wire, simplex Shed dia. : 6 mm Range : 0-150 °C MOC : AISI 316 L Make : Radix Sr. no. 219024314		
<b>Temperature Indicator</b>	Mounting : Panel door Mode : TC 513 AX Make : Selec Sr. no. 1802 p01-1982		
<b>Speed Indicator</b>	Mounting: Panel Door, Mode: PIC101 N Make: Selec Sr. no. 1905 T 04 -N-295		
<b>Flow switch</b>	Model: WFS-06-S1 Max, Temp.-100 °C Line Size-1/4" B.S.P Minimum flow setting- 2 Ltrs/Min Make: Multi tech Devices Sr. No. 21804345		



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**Quality Assurance**  
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**Manager QA**  
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**8.5 MATERIAL OF CONSTRUCTION:**

S.No.	COMPONENTS	MOC	OBSERVATIONS
1	Main Shell	SS316L	
2	Bottom Dishend	SS 304	
3	Top Dishend	SS 316L	
4	Leg Pipe	SS316 L	
5	Agitator shaft	SS316 L	
6	Agitator Blade	SS316 L	
7	Lifting Hooks	SS316 L	
8	Baffles	SS316 L	
9	Gasket for Bottom Valve	Silicon	
10	Gasket for manhole	Silicon	
11	Eye Bolt	SS 304	
12	Davit arm Assembly	SS 304	
13	Davit arm Bearing Housing	SS 304	
14	Davit arm swing shaft	SS 304	
15	Spray ball	SS 316 L	
16	Agitator	SS 316 L	

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**8.6 Safety:**

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN/DATE
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine, Panel and operator should be provided		
Variable Frequency Drive	Motor safety from overload		
Main Supply	Main power supply should be always switched off when not in use.		
Safety valve	Safety against over pressure		
Rupture Disc	Safety against Over pressure		
Emergency Button	Protection against abnormal condition		

**Checked By**  
**Production**  
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**Quality Assurance**  
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**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:**

- MOC & Calibration certificate
- P & ID
- Any other relevant Documents

**11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:**

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**12.0 CHANGE CONTROL, IF ANY:**

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

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**14.0 CONCLUSION:**

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**15.0 RECOMMENDATION:**

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**16.0 ABBREVIATIONS:**

BSP	:	British Standard Pipe
cGMP	:	Current Good Manufacturing Practices
D	:	Depth
DQ	:	Design Qualification
GA	:	General Arrangement
HMI	:	Human Machine Interface
HP	:	Horse Power
Hz	:	Hertz
Kg	:	Kilograms
kW	:	Kilo Watt
LPH	:	Liter per Hours
LPM	:	liter per Minute
MFT	:	Manufacturing Vessel
mm	:	Millimeter
MOC	:	Material of Construction
OD	:	Outer Diameter
PO	:	Purchase Order
PT-100	:	Platinum-100
RPM	:	Revolution per Minute
SS	:	Stainless Steel
Temp.	:	Temperature
V	:	Volt
VFD	:	Variable Frequency Drive



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**17.0 PROTOCOL POST APPROVAL:**

**PREPARED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			
<b>HEAD (ENGINEERING)</b>			
<b>HEAD (PRODUCTION)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			