



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

PROTOCOL No.:

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

EQUIPMENT ID. No.	
LOCATION	SYRUP MANUFACTURING ROOM
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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PROTOCOL No.:

PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	Protocol pre-approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment Detail	6
6.0	System Description	6
7.0	Pre Qualification Requirement	7
8.0	Critical Variables to be Met	8
9.0	Reference	17
10.0	Documents to be Attached	17
11.0	Deviation from pre-defined specification, if any	18
12.0	Change control, if any	18
13.0	Review (inclusive of follow up action, if any)	18
14.0	Conclusion	18
15.0	Recommendation	18
16.0	Abbreviations	19
17.0	Protocol post Approval	20



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**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
JACKETED 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)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



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

PROTOCOL No.:

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. (**Make:**) to be installed in Liquid Line.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of jacketed manufacturing vessel



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**INSTALLATION QUALIFICATION
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PROTOCOL No.:

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



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PROTOCOL No.:

5.0 EQUIPMENT DETAILS:

Equipment Name	SS Jacketed Manufacturing vessel
ID. Number	
Capacity	2000 lt.
Gross Capacity	2395 lt.
Manufacturer's Name	Pharmatech Process Equipment
Model	MFV-2000
Supplier's Name	Pharmatech Process Equipment
Location of Installation	Manufacturing Area

6.0 SYSTEM DESCRIPTION:

The Manufacturing Tank Comprises of Top & Bottom Torispherical Dish ends (10 %) Welded with Central cylindrical shell. It provide with limpet coil at shell for heating & cooling of vessel. It provided with glass wool insulation at shell. This is principally designed for the sugar syrup preparation and manufacturing of liquid syrup.

Bottom Entry Agitator of rating 5 HP, 960 RPM is provided at the bottom dish end of the tank with the help of specially designed lantern stool support. 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 dishend 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.



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

PROTOCOL No.:

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.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Physical Damage	Should be no Damage to the jacketed 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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PROTOCOL CUM REPORT
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PROTOCOL No.:

8.2 Utility Verification:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment	Manufacturing vessel 2000 ltr.		
Model	cGMP Model		
ELECTRICAL INSTALLATION:			
Electricity	Voltage	415±10% 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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Production
Sign & Date

Verified By
Quality Assurance
Sign & Date

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Reviewed By:
Manager QA
Sign & Date

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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 PROTOCOL CUM REPORT
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 JACKETED MANUFACTURING TANK**

PROTOCOL No.:

8.4 Verification of Technical Specification:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment Name	Jacketed Manufacturing Tank		
Make	Pharmatech Process Equipment		
Model	MFV-2000		
Gross Capacity	2395Ltr.		
Working Capacity	2000 Ltr.		
Contact Part	AISI 316 L		
Non Contact Part	AISI 304		
Main Shell	1350 x 6 mm thick		
Bottom Dish end	1350 x 6 mm (10 % Torispherical)		
Bottom Dish end	1350 x 6 mm (10 % Torispherical)		
Limpet coil	50NB x 3 mm thick		
Insulation cladding	OD 1500 x 2 mm thick		
Insulation at shell	45 mm thick		
Leg Pipe	140 x 3 mm thick		
Agitator shaft	38 mm		
Agitator blade	225 sweep x 4 mm thick		
Lifting hooks	12 mm thick		
Baffles	1050 x 150 x 6 mm thick		
Gasket for bottom Valve	4 mm thick		
Gasket for Manhole	10 mm sq.		



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PROTOCOL CUM REPORT
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PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Eye Bolt	M 12 x 65 long		
Davit arm assembly	Pipe and Elbow of 50 x 3 mm thick		
Davit arm Bearing housing	69 x 150 mm thick		
Davit arm swing shaft	55 x 150 mm thick		
Motor	5 hP , 960 RPM, 415 V, 50 Hz		
Mechanical Seal	Double Cartridge ; Water cooled Model : VT-9/VT-9 Seal Faces : TC/ TC & Carbon / satellite Size : 38 mm		
Safety Valve (For Impact coil)	Type : Spring Actuated Set Pressure : 4.0 kg/cm ² MOC : SS 304		
Safety Valve (For Vessel)	Type : Spring Actuated Set Pressure : 2.5 kg/cm ² MOC : SS 316 L		
Pressure Gauge	Type : 4 ” Dial Range : 0-7 kg/cm ² Accuracy : ± 1 %. MOC : AISI 304		
Compound Gauge	Type : 4 ” Dial Range : 0-760 mm Hg & 0-7 kg/cm ² glycerin filled Accuracy : ± 1 %. MOC : AISI 316 L		
Outlet Valve (vessel)	Type : Flush bottom valve Outlet Conn. : 2” Operation : Manual		
Butterfly Valve (For Process)	Conn. size : 38 mm Conn. Type : TC / TC Operation : Manual		



PHARMA DEVILS

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

PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Angle Seated Valve (For Steam and Cooling Water)	Conn. size : 25 mm Conn. Type : TC / TC Operation : Pneumatic MOC : SS 304		
Ball Valve (Jacket vent & bypass)	Conn. size : 38 mm Conn. Type : TC / TC Operation : Manual MOC : SS 304		
Temperature controller	Mounting : Panel door Input : RTD Model : EC 48 Accuracy : 0.1 % of span		
Temperature Sensor	Type : PT 100, 3 wire , simplex Shed dia. : 6 mm Range : 0-150 °C MOC : AISI 316 L		
Spray Ball	Type : Dynamic self rotating with 360° water flow : 159 LPM at 2 Bar Conn. size : 1 ¼” BSP Range : 0-150 °C MOC : SS 316 L		
Steam Trap	Type : Ball Float Model : SOFT 31 Conn. size : 1” BSP MOC : SS 304		
Strainer	Type : Y type Model : FMSTR 31 Conn. size : 1” BSP MOC : SS 304		
Thermosyphon	With seal inlet and outlet , cooling water inlet and outlet fitted with cooling coil, level switch filling connection ,		
VFD	Rating 3.7 kw, 12 A , 480 V AC 3Ph Model : FMSTR 31 Conn. size : 1” BSP MOC : SS 304		



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Sign/Date:



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

PROTOCOL No.:

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	Limpet Coil	SS 316L	
5	Insulation Cladding	SS 304	
6	Insulation shell	Glass Wool / equivalent	
7	Leg Pipe	SS316 L	
8	Agitator shaft	SS316 L	
9	Agitator Blade	SS316 L	
10	Lifting Hooks	SS316 L	
11	Baffles	SS316 L	
12	Gasket for Bottom Valve	Silicon	
13	Gasket for manhole	Silicon	
14	Eye Bolt	SS 304	
15	Davit arm Assembly	SS 304	
16	Davit arm Bearing Housing	SS 304	
17	Davit arm swing shaft	SS 304	
18	Spray ball	SS 316 L	
19	Agitator	SS 316 L	

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

PROTOCOL No.:

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		
Noise Level	Below 80 db		
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		
Air pressure switch	Protection for low air pressure for pneumatic valves		
Rupture Disc	Safety against Over pressure		
Insulation	For operator safety & Heat loss prevention		
Emergency Button	Protection against abnormal condition		
Instrument air pressure	Low air pressure protection		
Overload Relay	For motor & equipment protection		
Temperature Controller	To Control the temperature of vessel		
Steam Control Valve	For Controlling On / Off Action of Steam Depending on the set		

 PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR JACKETED MANUFACTURING TANK	PROTOCOL No.:
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CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN/DATE
	point.		

**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:

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



**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
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PROTOCOL No.:

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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PROTOCOL No.:

16.0 ABBREVIATIONS:

AISI	:	American Iron & Steel Institute
BSP	:	British Standard Pipe
cGMP	:	Current Good Manufacturing Practices
D	:	Depth
db	:	Decible
DQ	:	Design Qualification
GA	:	General Arrangement
HMI	:	Humen Machine Interface
HP	:	Horse Power
Hz	:	Hertz
Kg	:	Kilograms
KW	:	Kilo Watt
LPH	:	Liter per Hours
LPM	:	liter per Minute
Ltd.	:	limited
MFT	:	Manufacturing Vessel
mm	:	Millimeter
MOC	:	Material of Construction
NO	:	Number
OD	:	outer Diameter
PLC	:	Programmable Logic Controller
PO	:	Purchase Order
PT-100	:	Platinum-100
PVT.	:	Private
RPM	:	Revolution per Minute
SS	:	Stainless Steel
TC	:	Triclover
Temp.	:	Temperature
V	:	Volt
VFD	:	Variable Frequency Drive



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**INSTALLATION QUALIFICATION
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PROTOCOL No.:

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)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			