



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

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
JACKETED MANUFACTURING TANK
MANUFACTURING LINE
(LOTION LINE)**

EQUIPMENT ID. No.	
LOCATION	Manufacturing Line (Lotion)
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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PROTOCOL No.:

1.0 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)			



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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 SS jacketed Mfg tank 1000 ltr.) Procured from Punchtab solution at the site.
- 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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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 Approval 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 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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5.0 EQUIPMENT DETAILS:

Equipment Name	Manufacturing Tank
Equipment	
Manufacturer's Name	Punchtab
Model	cGMP
Supplier's Name	Punchtab
Location of Installation	Manufacturing Line (Lotion)

6.0 SYSTEM DESCRIPTION:

SS jacketed Mfg. tank and its components are designed to process pharmaceutical products in accordance with cGMP principles. Manufacturing Vessel is used for mixing of Pharmaceuticals product with bottom entry magnetic stirrer.

- Shell
- Jacket
- Insulation & cladding
- Stirrer
- Legs
- safety valve
- Manual operated flush bottom diaphragm valve with sampling valve arrangement.
- Safety valve for jacket.
- PG For Jacket
- Variable frequency drive



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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document
- Certificate of material of construction of components.

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	Manufacturing Line-03 (Lotion) Q-Block		
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:

Installation Checks	Acceptance Criteria	Observation	Observed By Engineering Sign/Date
Equipment	Manufacturing Tank		
Model	cGMP Model		

ELECTRICAL INSTALLATION:

Electricity	Voltage	415±10% V		
	Phases	3 Phase		
	Frequency	50 Hz		
	Motor	2 HP		
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.			

UTILITY INSTALLATION FOR MANUFACTURING VESSEL

Cooling Water	20 BSP Header at 100 lt./Hr			
Compressed Air Supply	5-6 kg/cm ²			
Room Condition	Should be able to meet the requirement of Clean Environment.			
Steam	2-2.5 kg/cm ²			

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Installation Checks	Acceptance Criteria	Observation	Observed By Engineering Sign/Date
Service Water	20 BSP line at 2 kg/cm ²		

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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8.1 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		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Manager QA
Sign/Date:



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8.2 Verification of Technical Specification:

Critical Variables	Acceptance Criteria	Observation	Observed By Engineering Sign/Date
Jacketed Manufacturing Tank With Stirrer	Working capacity : 750 ltr. Gross Capacity : 1000 ltr. Minimum Capacity :60 ltr Shell Thickness : 5mm dish type Vessel top : 5mm dish type Insulation : 2mm Legs : 3 Nos. Jacket Thickness : 4 mm Vessel Inside Finish : Mirror Polish Out Side Finish : mat finish		
'O' Ring	MOC : silicon food Grade		
Vessel Safety Valve	Make : Inoxpa Diameter : 38.1 mm MOC : SS316L		
Jacked Safety Valve	Make : Inoxpa Diameter : 38.1 mm MOC : SS304		
Pressure Gauge	Make : Baumer MOC : SS304 Range : 0-10 kg/cm ² Size : 2.5 '' Type : End Conn-1/4'' BSP		
Air Pressure Switch	Type : 1/4''BSP end Conn MOC : SS304 Make : SMC		
VFD	Make : Allen Bradley HP : 1 HP Volt : 415 V		



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Critical Variables	Acceptance Criteria	Observation	Observed By Engineering Sign/Date
Condensate inlet / Cooling Inlet	Make : Spirex Diameter : 25mm Type : Pneumatic operated Piston Valve		
Steam Inlet /Cooling Outlet Valve	Make : Spirex Diameter : 25 mm Type : With pneumatic operated Piston operated Valve		

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Production
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Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:

8.3 MATERIAL OF CONSTRUCTION:

S.No.	COMPONENTS	MOC	OBSERVATIONS
1	Vessel shell	SS316L	
2	Jacket shell	SS 304	
3	legs	SS 304	
4	Lid	SS 304	
5	Insulation	SS 304	
6	Safety valve	SS 304	
7	Pressure gauge for jacket	SS304	
8	Manual Ball Valve	SS304	
9	Contact part	SS316 L	
10	Non Contact part	SS304	

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8.4 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		
Operation	Manufacturing vessel should be in working condition, and it		
Variable Frequency Drive	Motor safety from overload		
Main Supply	Main power supply should be always switched off when not in		
Safety valve	Safety against over pressure		
Insulation	For operator safety & Heat loss prevention		
Emergency Button	Protection against abnormal condition		

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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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
- 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:

AC	:	Alternate current
AISI	:	American Iron & Steel Institute
BSP	:	British Standard Pipe
cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate Quality Assurance
db	:	Decibel
DQ	:	Design Qualification
HP	:	Horse Power
Hz	:	Hertz
IQ	:	Installation Qualification
Kg	:	Kilograms
Ltd.	:	limited
MFT	:	Manufacturing Vessel
mm	:	Millimeter
MOC	:	Material of Construction
NO	:	Number
Ø	:	Diameter
PLC	:	Programmable Logic Controller
PVT.	:	Private
QA	:	Quality Assurance
SS	:	Stainless Steel
V	:	Volt
WHO	:	World Health Organization



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17.0 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)			