



**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
PASTE KETTLE
(CAPACITY- 200 LITRES)**

EQUIPMENT ID. No.	
LOCATION	Solution Preparation Room , Coating Area
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

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 provide documented evidence for the Installation Qualification of Paste Kettle for
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Paste Kettle (Make- Bectochem, Capacity- 200 liter)** to be installed in **Solution Preparation Room of Coating Area**.
- Said Equipment was in Granulation, earlier now .it has been shifted in Coating Solution Preparation area, Refer more details by respective change control.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required for installation qualification activity.



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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">• Initiation, Approval, Compilation and Authorization of the Installation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Qualification Activity.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Qualification Protocol cum report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• Co-ordination, Execution and technical support in Installation Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Qualification Protocol cum report after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Paste Kettle
Equipment ID.	
Manufacturer's Name	Bectochem
Supplier's Name	Bectochem
Location of Installation	Solution Preparation Room, Coating Area

6.0 SYSTEM DESCRIPTION:

Paste kettle is designed as per good manufacturing practice in terms of clean ability of components, surface finish, absence of sharp corners, assembling and de-assembling of components and control devices. Machine should be designed to be of jacketed type, electrically or steam heated, thermostatic control with the unit, safety valve, insulated with suitable insulating material, tilting with hand wheel. Easy transfer of paste while tilting, unit should be provided with suitable lid to discharge. Bottom valve for steam water, which should be easily removable and easily cleanable.

MAIN FEATURES

- All contact part made of SS 316 as per GMP standard
- Hemispherical design for proper mixing of paste.
- Jacket provided with Steam/Electrical heating arrangement.
- Tilting arrangement for kettle is provided for discharge for starch paste.
- Anchor type impeller design for proper mixing of paste.
- Safe earthing system.



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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents :

- Executed and approved design qualification document.
- Piping and Instrumentation Diagram (P& ID).
- Electrical Circuits Diagram.
- Technical Specification of Equipment.
- Calibration Certificate of Components.
- 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.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks & Checklist:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Grouting And Mounting	Should be grouted and mounted properly.		
Leveling	Should be properly balanced and leveled		
Edges of Parts	Metal edges should be properly Rounded off without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Solution Preparation Room, Coating Area , 'G' Block		
Illumination in area	NLT 300 Lux.		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		
Machine Inspection	Ensure that all parts are present and not damaged.		
Electrical component verification	Ensure that the electrical components match to the descriptions in D.Q		

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Sign/Date:**



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8.2 Utilities Provided:

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Utility connections should be available as per the manufacturer's specification.			
Electrical Supply	3 Phase Voltage – 415 ± 10% Frequency – 50 Hz ± 5%		
Compress Air Supply			
Flow Pressure	6 bar (kg/cm ²)		
Main Cable specification	50 mm ² copper, 4 core		
Total Load	39.375 KW (52.5 HP)		
Quality	Oil, Water & Dust Free		

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8.3 MOC Verification List:

S.No.	Component	MOC	Observation	Observed by (Engineering) Sign/Date
1.	Bowl	SS 316		
2.	Top Dish	SS 316		
3.	Impeller	SS 316		
4.	Discharge Assembly	SS 316		
5.	Safety Railing	SS 304		
6.	Ladder	SS 304		
7.	V belt	STD		
8.	Gasket For Top Lid	Food grade silicon		
9.	Operating Panel	SS 304		
10.	pipe line RMG to FBD	SS 316		
11.	Main Shaft	SS 316L		
12.	Chopper Shaft	SS 316L		
13.	Frame structure Cladding and Covers	SS 304		

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8.4 Drawing Verification:

Reference Engineering Drawings	Available (Yes/No)	Observed By (Engineering) Sign/Date
General arrangement Diagram		
Power Circuit Diagram		
Pneumatic Connections Diagram		
Pneumatic Diagram for Solenoid valve		
Panel Physical Layout		
Circuit Diagram for PLC Controls		

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8.5 Equipment Verification:

8.5.1 Technical Specifications:

Name of Components	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Capacity	Working : 200 Ltr Gross : 160 Ltr		
Dimension	1275L x 1000 W x 1880 H in mm		
All Contact Parts	SS316		
Non Contact Parts	SS304		
Motor	<ul style="list-style-type: none">• Make: REMI• HP: 3 HP• RPM: 1440• VOLT: 415 ± 10%• PHASE: 3PH		
Gear Box	<ul style="list-style-type: none">• Make: "SUDARSHAN GEARS"• Type: Worm Reduction Type• Ratio: 30:1		
Agitator	<ul style="list-style-type: none">• Shape: Anchor Type• RPM: 30-200• Shaft: SS 304• Coupling: fanner type• Sealing: single dry mechanical seal		
Bowl Dimension	<ul style="list-style-type: none">• Shell : 700 mm ID x 540 mm HT x 4 thk• Jacket : 850 mm ID x 380 mm HT x 2mm thk• Cladding: 16 SWG fully covering the jacket. Welding type• Locking: 2 Nos. locking pins with top cover to align bowl in position		



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Name of Components	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Tilting Arrangement	<ul style="list-style-type: none">Type : mechanicalHand wheel with bevel gear arrangement		
Nozzle Schedule	<ul style="list-style-type: none">Jacket inlet with QRC- 25 BSPSafety valve : 15 BSPJacket Outlet With QRC : 20 BSPJacket Drain : 20 BSP- with blindThermo well: 20 BSP- PT-100 SensorJacket Vent: 15 BSP- with needle valveBottom Outlet: 100 With Flush Type Valve Manually OperatedSteam inlet: 20 NB		
Finish	<ul style="list-style-type: none">Internal : 240 Grit mirrorExternal: 180 Grit matt		
Main Bowl & shell	Make: BLPTPL MOC: 10 SWG (SS 316)		
Jacket Bowl	Make: BLPTPL MOC: 10 SWG(SS 304)		
Insulation Bowl	Make: BLPTPL MOC: 14 SWG(SS 304)		
Stand	Make: BLPTPL MOC: 10 SWG(SS 304) Dimension: 80 x 80 x10		
Plummer Block	Make: ZKL MODEL: UCP-211		
Top Lid	Make: BLPTPL MOC: 14 SWG(SS 316)		
VFD For geared	Make: ABB		



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Name of Components	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
motor	Volt: 3 HP		
Anchor blade & shaft	Make: BLPTPL MOC: (SS 316) Dimension: 50x10 Thk Dia: 55 Dia		
Operating Panel	Make: BLPTPL Type: Non FLP, push button type		
Safety Valve At Steam Line	Make: Spirex MOC: Gun metal 15 B		
Electric Actuated Solenoid Valve At Steam Line	Make: Aira MOC: ½ “BSP Volt : 230 V AC		
Gate Valve At Steam Line	Make: HVI MOC: gun metal, ½ “ NB		
Gate Valve at condensate line	Make: HVI MOC: gun metal, ½ “ NB		
Steam Trap At Condensate Line	Make: HVI MOC: ½ “ NB		

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8.6 Installation Checks:

S.No.	Specification	Observation	Observed By (Engineering) Sign/Date
1.	Identification and verification of major and sub components of Paste Kettle.		
2.	Verification of system utility requirements.		
3.	Check that all bolts are properly tightened.		
4.	Ensure all Electric connections done properly.		
5.	Ensure all mechanical adjustment.		
6.	Check that all Pneumatic connections are properly fitted.		

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8.7 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 motors) and operator should be provided.		
MCB for overload Trip	Should be provided for equipment safety.		
Emergency off: To stop the process immediately	Should be provided For equipment and operator safety		

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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.

The following references are used for addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition/March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, Beta. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission’s working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC
- Calibration certificates
- Operation and Maintenance Manual



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

16.0 ABBREVIATIONS:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
EU	:	European Union
SS	:	Stainless Steel
Kg	:	Kilogram
mm	:	Millimeter
HP	:	Horse Power
V	:	Volt
Hz	:	Hertz
QA	:	Quality Assurance
IQ	:	Installation Qualification
CFM	:	Cubic Feet per Minute
RMG	:	Rapid mixer granulator
MOC	:	Material of construction
NLT	:	Not less than
HP	:	Horse power
KW	:	Kilo watt
SS	:	Stainless steel
PLC	:	Programmable logical control
Kg	:	Kilo gram
MCB	:	Miniature circuit break
PTS	:	Powder transfer system
HMI	:	Human machine interface
FBD	:	Fluid bed dryer
Id	:	Inner diameter



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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:

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HEAD (QUALITY ASSURANCE)			