OPERATIONAL 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**

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

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OPERATIONAL 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)			

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and comply with cGMP Requirements.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To verify the operational features of Paste kettle and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user friendly point of view of the Machine, Cleaning Procedure and 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 **Paste kettle (Make- Bectochem, Capacity- 200 liter)** installed in the **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 Protocol will define the methods and documentation used to perform OQ activity the Paste kettle Granulator for OQ. Successful completion of this Protocol will verify that Paste kettle 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	• Initiation, Approval Compilation and Authorization of the Operation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operation Qualification. • Monitoring of Operation Process.
Production	• Review of Operation Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operation Qualification study as per Protocol. • Post Approval of Operation Qualification Protocol cum report after Execution.
Engineering	• Review of Operation Qualification. • To co-ordinate and support Operation Qualification Activity. • Calibration of Process Instruments.

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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	Granulation

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.

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

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.

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Documents Verification:

S.No.	Document Name	Document /SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	Draft SOP for operating & Cleaning of Paste Kettle.				
4.	Draft SOP for Preventive Maintenance of Paste Kettle.				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system will be in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All equipment/instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment/ Instruments Name	Equipment/ Instrument Id	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 Operational And Functional Checks:

Operate the Paste Kettle as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

Objective:

To verify that all the components on the control panel of machine provides the proper functioning as specified by the manufacturer.

Testing procedure:

1. Check all the components on the control panel are properly labeled /identified.
2. Turn 'ON' the power to the control panel.
3. Set the required "controls" on the panel
4. Verify the functioning of each key/component on the panel against its specified function.
5. Observe and record the response on each component on the panel.

8.1 Main Power Supply checks:

Objective:

To ensure correct operation of the machine

Method:

Connect operation of the machine.

Acceptance criteria:

Checks that there is no power supply to the machine when M.C.B is off and vice versa. Check that the main motor of the Paste Kettle -200L. Rotate In The clockwise direction by provides the required input supply of suitable frequency of motor as per the utility mentioned in the utility list/cable schedule.

8.2 Operating panel function test

Objective:

Confirm that all the wires are connected to the electrical switchgears tightly. Continuity of electrical switch gears is verified for proper connection with respect to the equipment.

Method:

Lightly pull all the wires connected to the electrical switchgears one by one testing for any loose connections. Redo the connection, if any is found loose. Any discrepancies and deviations are to be noted in this document in the deviation report. Check the operation of unit as per the start sequence detailed in the manual. Any discrepancies and deviations are to be noted in this document in the deviation report.

Acceptance criteria:

Smooth function of operating panel carried out and achieved as per required parameter.

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

Function	Acceptance criteria	Observation
Main Power Supply	there is no power supply to the machine when M.C.B is off and vice versa	
Main Motor	Rotate In The clockwise direction by provides the required input supply of suitable frequency of motor	
Operating panel function	Smooth function of operating panel carried out and achieved as per required parameter.	

8.3 Equipment operation verification

Objective:

To verify the operation of the machine as per manual/FDS & process requirements

Method:

Check the operation of unit as per the start sequence detailed in the manual. Fill out the table as per attachment. Any discrepancies and deviations are to be noted in this document in the deviation report.

Acceptance criteria

The equipment parameter without load should confirm to the rated capacities of the components and the process needs should be full filled.

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GEARED MOTOR CHECKS WITHOUT LOAD						
Operations	**Speed**	**Time s/m/h**	**Temp °C**	**Vibration**	**Sound level**	**Geared motor current(amps)**
Geared Motor Performance						**R:** **Y:** **B**:

Instruments Operation Verification			
	Fitment rigidity	**Functional performance**	**Accepted (Yes/No)**
Temperature controller + indicator			
temperature sensor			
process timer			
pressure gauge on steam line			

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.4 Safety Testing/Interlocks:

Description of "Safety Feature"	Functioning as Specified (Yes/No)	Deviation	Observed By (Engineering) Sign/Date
Main switch			
Temperature gauge			
M.C.B for electrical overload			
Machine overload mechanism			

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

8.5 Power Failure Verification:

Operational Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment should be stopped in a safe and secure condition.		
Restore electrical power to the system	The system should not be automatically restart whenever start through PLC.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.6 Emergency Operation Verification:

Operational Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Emergency STOP: • Press Emergency Stop Push Button. • Release Emergency Stop Push Button & Start the M/C through PLC.	Operation of Equipment should be stopped.		
	Operation of Equipment should be started.		
With the Emergency Stop Pressed in, try to cause movement of an Operating function.	The Equipment should be inoperative.		

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.

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.

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:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
OQ	:	Operational Qualification
Ltd.	:	Limited
DQ	:	Design Qualification
IQ	:	Installation Qualification
No.	:	Number
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
ID.	:	Identification
Kg	:	Kilo gram
Ltrs	:	Liters
Mm	:	Millimeter
MCB	:	Miniature Circuit Break

17.0 PROTOCOL 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)			