



**PERFORMANCE QUALIFICATION PROTOCOL FOR PASTE KETTLE**

**PERFORMANCE QUALIFICATION  
PROTOCOL  
FOR  
PASTE KETTLE  
(CAPACITY - 200 LITRES)**

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



**PERFORMANCE QUALIFICATION PROTOCOL FOR PASTE KETTLE**

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# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## PERFORMANCE QUALIFICATION PROTOCOL FOR PASTE KETTLE

**1.0 APPROVAL:**  
**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



## **PERFORMANCE QUALIFICATION PROTOCOL FOR PASTE KETTLE**

### **2.0 OBJECTIVE:**

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

### **3.0 SCOPE:**

- The Protocol covers all aspects of Performance Qualification for the **Paste kettle (Make-Bectochem, Capacity- 200 liter)** 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 Protocol will define the methods and documentation used to qualify the Paste Kettle for PQ.



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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:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Initiation, Authorization, Approval and Compilation of the Performance Qualification.</li><li>• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.</li><li>• Monitoring of Performance Qualification.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of Protocol.</li><li>• To co-ordinate and support Performance Qualification Activity.</li></ul>
	<ul style="list-style-type: none"><li>• Review of Protocol.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Reviewing of qualification protocol for correctness, completeness and technical excellence.</li><li>• Responsible for trouble shooting (if occurred during execution).</li><li>• Maintenance &amp; preventive maintenance as per schedule.</li></ul>



**PERFORMANCE QUALIFICATION PROTOCOL FOR PASTE KETTLE**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Paste Kettle
<b>Equipment</b>	
<b>Manufacturer's Name</b>	Bectochem
<b>Model</b>	cGMP Model
<b>Supplier's Name</b>	Bectochem
<b>Location of Installation</b>	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.

**7.0 REASON FOR QUALIFICATION:**

- Equipment transferred from Granulation to Solution Preparation Room, Coating Area.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

**8.0 SITE OF STUDY:**

Solution Preparation Room, Coating Area.



**PERFORMANCE QUALIFICATION PROTOCOL FOR PASTE KETTLE**

**9.0 FREQUENCY OF QUALIFICATION:**

- Once in every two years time period.
- After any major breakdown or after major modification.
- After Change of Location.

**10.0 PRE – QUALIFICATION REQUIREMENTS:**

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Calibration of all critical Components of Equipment.
- Preparation of SOP for Operation & Cleaning of Paste Kettle.
- Preparation of SOP for Preventive Maintenance Paste Kettle.



## **PERFORMANCE QUALIFICATION PROTOCOL FOR PASTE KETTLE**

### **11.0 TESTS AND CHECKS:**

#### **11.1 Verification of Documents:**

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Paste Kettle.
- SOP for Preventive Maintenance Paste Kettle.

#### **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.
- Supporting documents would form a part of the PQ report.

#### **Acceptance Criteria:**

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





**PERFORMANCE QUALIFICATION PROTOCOL FOR PASTE KETTLE**

**11.2 Qualification of Jacketed Vessel for Heating Efficiency:**

**Objective:**

- The purpose of this test is to check the performance of jacketed vessel to heat the purified water and to determine the required time to attain the desired temperature in the paste kettle.

**Procedure:**

- Take the approximately 40 liters Purified Water in Paste Kettle.
- Supply the steam of 1-2 Kg/cm<sup>2</sup> at a constant pressure.
- Heat the Purified Water to boil up to 80° C±5°C.
- Record the total time required to attain the required temperature of Purified Water.

**Acceptance Criteria:**

- Heating should be sufficient to raise the temperature of the Purified Water up to 80° C.
- Required time to achieve the temperature should be acceptable with respect to the quantity of Purified Water.



## **PERFORMANCE QUALIFICATION PROTOCOL FOR PASTE KETTLE**

### **11.3 Qualification of Paste Kettle for Paste Preparation Efficiency:**

#### **Objective:**

- The purpose of this test is to generate documented evidences that the Paste Kettle is Capable of efficiently producing paste consistently and formed paste is not affected adversely during the process.

#### **Procedure:**

- The qualification study shall be carried out on 3 lots or 3 batches of same or different products.
- Take the required quantity of Purified Water as mentioned in the BMR and transfer to Paste Kettle.
- Supply the steam of 1-2 Kg/cm<sup>2</sup> at a constant pressure.
- Heat the Purified Water to reach the required temperature.
- Add starch slurry to paste following the instructions as mentioned in the BMR.
- Perform mixing and other activities mentioned for the process.
- Record the total time required to complete the process.

#### **Acceptance Criteria:**

- Heating should be sufficient to raise the temperature of the entire content of vessel and no agglomerate of poorly cooked starch lump should appear in any location of the entire vessel.
- Discoloration of formed paste due to local overheating should not be found on any location of entire vessel.
- Paste of all locations should have uniform consistency.
- Required time to achieve the temperature should be acceptable with respect to the quantity of Formed Paste.



## **PERFORMANCE QUALIFICATION PROTOCOL FOR PASTE KETTLE**

### **12.0 CHECKLIST OF ALL TESTS AND CHECKS:**

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of DQ, IQ & OQ & other documents.
- Qualification of Jacketed Vessel for Heating Efficiency.
- Qualification of Paste Kettle for Paste Preparation Efficiency.

### **13.0 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 to give addition guidance:**

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition/March 2001.
- 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.

### **14.0 DOCUMENTS TO BE ATTACHED:**

- Calibration Certificate.
- Operation and Maintenance Manual.

### **15.0 NON COMPLIANCE:**

- All the Non-compliances of procedure, specifications, sampling, analysis and documentation activities shall be monitored & recorded.



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

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

**17.0 CHANGE CONTROL, IF ANY:**

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.



**PERFORMANCE QUALIFICATION PROTOCOL FOR PASTE KETTLE**

**18.0 ABBREVIATIONS:**

URS	:	User requirement specification.
cGMP	:	Current Good Manufacturing Practice
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
OD	:	Oral Solid Dosage
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
NLT	:	Not Less Than
KW	:	Kilo watt
SS	:	Stainless Steel
MCB	:	Miniature circuit breaker
db	:	Decibel
RH	:	Relative Humidity
RPM	:	Revolution per Minute
HP	:	Horse Power
AMP	:	Ampere
STD	:	Standard
BMR	:	Batch Manufacturing Record