



QUALIFICATION OF BOILER

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QUALIFICATION OF BOILER
(Eq. ID:)



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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DOCUMENT PREPARATION AND APPROVAL:

Preparation and Approval of this Requalification document will be joint responsibility of the following functional area. Any modification in this document shall be documented and approved.

Prepared By

Name	Designation	Department	Signature	Date

Reviewed By

Name	Designation	Department	Signature	Date

Approved By

Name	Designation	Department	Signature	Date



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2.0 OBJECTIVE:

The objective of developing and executing this protocol is to

- Document the verification of all aspects of the equipment that can affect product quality.
- To make an impact assessment of the critical components of the equipment's on the material
- To establish, check and document the performance of equipment in the established / predetermined operating ranges.

3.0 PURPOSE & SCOPE:

The purpose of this protocol is to verify Installation Qualification, OQ dry run and to perform Performance qualification.

The protocol will define the IQ check list, OQ check list, PQ procedures, documentation, references and acceptance criteria.

At the end of the requalification, to derive Boiler capability.

4.0 RESPONSIBILITY:

Quality assurance officer/Executive – Preparation of Protocol

Engineering manager or designee – Execution of re-qualification activities.

Quality Head or designee –Approval of Protocol and review of summary of re-qualification activity.

5.0 REASON FOR REQUALIFICATION:

To study and verify the equipment (Boiler) that meets the production need and to establish the operating range.



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6.0 VALIDATION TEAM:

Team member: Validation team is formed under the guidance of Head Quality having qualified and trained persons from Quality Assurance, Quality Control, Production and Engineering.

Name	Department	Responsibility
	Quality Assurance	Preparation of protocol and execution of the qualification activity.
	Engineering	Ensure to provide the utility during qualification activity.
	Engineering	Ensure to provide the utility during qualification activity.
	Quality Assurance	To Check the protocol and monitor the qualification activity.
	Quality Assurance	To approve the protocol & to review the summary of activity..

7.0 TRAINING:

Training is required for all the personnel, who are directly or indirectly involved in the overall requalification operations.

8.0 GENERAL CONSIDERATION / PREREQUISITE:

- 8.1 Approved Standard operating procedure of the Boiler shall be available.
- 8.2 Duly signed & approved qualification protocol shall be available.
- 8.3 The installation and operational qualification verification of the equipment shall be successfully completed before the execution of the performance qualification.
- 8.4 All the deficiencies and discrepancies related to the equipment which affect the product quality and corrective action taken shall be recorded in the appropriate section of the protocol.
- 8.5 After the successfully completion of PQ activities, equipment shall be cleaned as per respective cleaning SOP's and released for Operation.



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9.0 INSTALLATION QUALIFICATION CHECK LIST:

S.No.	DESCRIPTION	OBSERVATION (Yes/No)	CHECKED BY
1.	Make: Forbes Marshall Model No.: Serial No.: Capacity: 1120 Kg/Hr.		
2.	Verify that the “As built” drawings are complete and represent the design concept.		
3.	Verify that major components are securely anchored and protected from shock.		
4.	Verify that there is sufficient room for servicing provided.		
5.	Verify that all piping and electrical connections have been done according to the drawings.		
6.	All access ports are examined and cleared of any.		
7.	Walking access to roof mounted equipment provided.		
8.	Required electric connectors are light, weather proofed and grounded.		
9.	All require certificate should be verified.		
10.	All top up part verified.		
11.	Equipment identification name plate visible.		



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10.0 OPERATIONAL QUALIFICATION CHECK LIST:

10.1 VERIFICATION FUNCTIONALITY OF BOILER:

S.No.	TEST OBJECT
1.	Check all the documents on the panel are properly labeled/ Identified.
2.	Turn on the power with electrical panel.
3.	Set the control on the panel.
4.	Verify functionality of each component on the panel against its specified functions.
5.	Observe and record the responses of the control panel.

S.No.	Component of the control panel	Specified function	Compliance or Variance	Checked by
1.	Sequence controller	For control Function		
2.	Operation switch	Starting		
3.	Indicator	Indication		
4.	MCB	Protection		
5.	Contractor	Operation		
6.	Over Load relay	Protection		

10.2 SAFETY FEATURES TEST:

Presser switch

Hooter

PRV

Temp. Thermostat

Water level controller

Oil level controller



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S.No.	Features description	Function	Working Yes/No	Checked by
1.	Presser switch	Maintain switch		
2.	Hooter	Indicator		
3.	PRV	Reduce pressure		
4.	Temp. Thermostat	Maintain temperature		
5.	Water level controller	Controlled water level		
6.	Oil level controller	Controlled Oil level		

11.0 PERFORMANCE QUALIFICATION PROCEDURE:

S.No.	Items	Requirement	Actual Observation	Checked by
1.	Steam generation requirement	Steam generated shall be approx.. 1120 kg of steam per hour.		
2.	Line pressure after PRV	Pressure developed shall be 2.5-3.5 kg/cm ² of steam after PRV valve.		
3.	FO Consumption	FO consumption shall be 15-18 Liter./hr.		
4.	RO Water Consumption	RO water consumed shall be approx. 100-140 liter/hr.		
5.	Blow Down Time	Blow down time shall be less than 20 sec.		



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11.2 AVAILABILITY OF STEAM AT USERS' POINT:

S.No.	Items	Requirement	Actual observation	Checked by
1.	Steam at FBD heat exchanger	2.5-3.5 kg/cm ² of steam.		
2.	Steam at paste making kettle	2.5-3.5 kg/cm ² of steam.		
3.	Steam at hot air system for Coating	2.5-3.5 kg/cm ² of steam.		
4.	Steam at Purified water storage tank	2.5-3.5 kg/cm ² of steams		

12.0 ACCEPTANCE CRITERIA:

All parameter should be complies as per design.

15.0 RE QUALIFICATION CRITERIA:

Re-qualification shall be considered in the case of:

- Change in manufacturing site or location.
- Change in location of the equipment.
- In case of any major maintenance or modification, this affects performance of the equipment.
- Periodic re-qualification as per VMP or company policy.

16.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:

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16.1 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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16.2 RECOMMENDATIONS:

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16.3 CERTIFICATION:

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17.0 DOCUMENT CHECK – LIST:

Following documents related to Boiler are reviewed and listed below.

S.No.	Document Name	Checked By	Date

Comments:

Inspected & Reviewed By:

Date:



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18.0 CHANGE CONTROL PROCEDURE:

Change in the agreed design shall be addressed through the well-defined change control procedure.

19.0 DEFICIENCY AND CORRECTIVE ACTION REPORT:

Following deficiency is observed and corrective action work allotted to responsible person.

20.1 Description of Deficiency and Date of Observation:

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20.2 Person responsible for corrective action and Date Assigned:

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20.3 Corrective action taken and Date Conducted:

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Comments:

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Reviewed By:

Date:



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21.0 CONCLUSION:

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22.0 SUMMARY:

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23.0 ABBREVIATIONS:

PQ: Performance Qualification

BOI: Boiler

24.0 REFERENCES:

Equipment Manual

25.0 ANNEXURES:

26.0 REPORT APPROVAL:

Name	Designation	Department	Signature	Date