



**PERFORMANCE QUALIFICATION REPORT
FOR
HOT AIR OVEN**

PROTOCOL No.:

**PERFORMANCE QUALIFICATION
REPORT
FOR
HOT AIR OVEN**

EQUIPMENT ID. No.	
LOCATION	Cleaned Equipments Room
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	NIL



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1.0 REPORT PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (WAREHOUSE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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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.

3.0 SCOPE:

- The report covers all aspects of Performance Qualification for the **Hot Air Oven**, installed in **Cleaned Equipments Room**.
- This report will define the methods and documentation used to qualify **Hot Air Oven** for Performance Qualification.



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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 Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Approval and Compilation of the Performance Qualification Report.• Co-ordination with Quality Control and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.• Post Approval of Performance Qualification Report after Execution.
Warehouse	<ul style="list-style-type: none">• Review of Performance Qualification Report.• Post Approval of Performance Qualification Report after Execution.
Engineering	<ul style="list-style-type: none">• Reviewing of Performance Qualification Report for correctness, completeness and technical excellence.• Responsible for trouble shooting (if occurred during execution).• Maintenance & Preventive Maintenance as per schedule.• Post Approval of Performance Qualification Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	HOT AIR OVEN
Equipment	
Manufacturer's Name	
Supplier's Name	
Location of Performance	Cleaned Equipments Room

6.0 PRE – QUALIFICATION REQUIREMENTS:

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

- Calibration of all critical Components of Equipment.
- Preparation of SOP for Operation & Cleaning of **Hot Air Oven**.

6.1 Test Instruments Calibration:

S.No.	Instruments Name	Calibration done on	Calibration due on	Verified by QA Sign & Date

Checked By
Engineering
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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7.0 TESTS AND CHECKS:

7.1 HEAT DISTRIBUTION STUDY (Empty Chamber):

Test Instrument Name		Model No		Calibration done Date	
Sensors type & Qty.		Make		Calibration due Date	

Name of Cycle	Empty Chamber Heat Distribution Study	Cycle No.	
Equipment Name		Equipment I.D.	
Equipment Make		Equipment Location	

Cycle Observation

Parameter	Observed Value
Cycle Start Date / Time	
No. of Temperature Sensor	
Minimum Temperature	
Maximum Temperature	
Hold Start Time	
Hold Completion Time	
Total Hold Time	
Results	
Cycle End Date / Time	
Cold Spot	
Hot Spot	

Checked By
Engineering
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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7.2 HEAT DISTRIBUTION STUDY (Loaded Chamber):

Test Instrument Name		Model No		Calibration done Date	
Sensors type & Qty.		Make		Calibration due Date	

Name of Cycle	Empty Chamber Heat Distribution Study	Cycle No.	
Equipment Name		Equipment I.D.	
Equipment Make		Equipment Location	

Cycle Observation

Parameter	Observed Value
Cycle Start Date / Time	
No. of Temperature Sensor	
Minimum Temperature	
Maximum Temperature	
Hold Start Time	
Hold Completion Time	
Total Hold Time	
Results	
Cycle End Date / Time	
Cold Spot	
Hot Spot	

Checked By
Engineering
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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8.0 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Tests or Checks	Executed (Yes/No)	Remarks
Heat Distribution Study for empty chamber		
Heat Distribution Study for loaded chamber		

Checked By
Engineering
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:

9.0 DOCUMENTS TO BE ATTACHED:

- Calibration Certificates for Data Logger.
- Calibration Certificates of Sensors.

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PREDEFINED 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:

cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate Quality Assurance
DQ	:	Design Qualification
HAO	:	Hot Air Oven
ID.	:	Identification
mm	:	Mili meter
MOC	:	Material of Construction
NLT	:	Not Less Than
Nos.	:	Numbers
PQ	:	Performance Qualification
S	:	Sensor
Sec.	:	Seconds
SOP	:	Standard Operating Procedure
Temp.	:	Temperature
WHO	:	World Health Organization



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17.0 REPORT POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (WAREHOUSE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			