



**PERFORMANCE QUALIFICATION PROTOCOL  
FOR  
HOT AIR OVEN**

**PROTOCOL No.:**

**PERFORMANCE QUALIFICATION  
PROTOCOL  
FOR  
HOT AIR OVEN**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Cleaned Equipment Room</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



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**1.0 PROTOCOL APPROVAL:**

**INITIATED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (WAREHOUSE)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			



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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 Protocol covers all aspects of Performance Qualification for the **Hot Air Oven**.
- This Protocol 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 Protocol.

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Initiation, Approval and Compilation of the Performance Qualification Protocol.</li><li>• Co-ordination with Quality Control and Engineering to carryout Performance Qualification.</li><li>• Monitoring of Performance Qualification Activity.</li></ul>
<b>Warehouse</b>	<ul style="list-style-type: none"><li>• Review &amp; Approval of Protocol.</li><li>• To Co-ordinate and support for Execution of Performance Qualification study as per Protocol.</li></ul>
<b>External Agency (If Applicable)</b>	<ul style="list-style-type: none"><li>• Perform Performance Qualification activity as per protocol.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review &amp; Approval of Performance Qualification Protocol.</li><li>• Co-ordination, Execution and technical support in Hot Air Oven Performance Qualification Activity.</li><li>• Calibration of Process Instruments.</li><li>• Responsible for Trouble Shooting (if occurs during execution).</li></ul>



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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	HOT AIR OVEN
<b>Equipment</b>	
<b>Manufacturer's Name</b>	
<b>Supplier's Name</b>	
<b>Location of Performance</b>	Cleaned Equipments Room

**6.0 SYSTEM DESCRIPTION:**

- Standard Oven is a jacketed chamber containing heating coils and a fan inside the chamber to evenly distributing heat. The standard cycle is initiated by introducing heat through the heating coils.
- The temperature of the chamber increases and reaches to the set point temperature, the control system in place, controls this temperature.
- Oven is used for drying of Dispensing /Sampling tools.

**7.0 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**.
- Preparation of SOP for Preventive Maintenance of **Hot Air Oven**.

**7.1 TEST EQUIPMENT:**

S.No.	Test Instrument
1.	Duly Calibrated Data logger with calibrated sensors.
2.	Temperature sensors must be calibrated.

**7.2 CALIBRATION OF TEMPERATURE SENSORS:**

- **Pre & Post Calibration of Temperature Sensors**  
Pre & Post calibration shall be carried out before starting and after completion of Validation activity.  
Pre & Post calibration shall be done by External party.



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**8.0 REASON FOR QUALIFICATION:**

- New equipment in Cleaned Equipments Room.
- The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

**9.0 SITE OF STUDY:**

- Cleaned Equipments Room.

**10.0 FREQUENCY OF QUALIFICATION:**

- After any major breakdown or after major modification.
- After Change of Location.
- Once in a year  $\pm 1$  month.



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**11.0 TESTS AND CHECKS:**

**11.1 HEAT DISTRIBUTION STUDY(Empty Chamber):**

**11.1.1 Objective:**

- To ensure that the Hot Air Oven when operated with empty chamber is capable of producing the temperature profiles as per the temperature set points set in the equipment.
- Three run shall be performed to qualify the measurement of the temperature throughout the Chamber by 12 Nos. Temperature sensors.

**11.1.2 Equipment Required:**

- Calibrated Data Logger with 8 Temperature sensors

**11.1.3 Procedure:**

- Set the temperature 110°C for the heat distribution to be operated during the test.
- Suspend the probe in the chamber in different position in such a way that probes don't touch any metallic surface. Record the position of the probe in a representative schematic manner.
- Connect the probes to suitable data logger, which can scan and print the actual temperature observed at different locations with respect to time.
- Operate the oven as per operating procedure. Also start the data logger to record the actual temperatures with respect to time.
- After completion of cycle "Switch OFF" the data logger.
- Download the data from the data logger in the computer for the data analysis and printing enclosed the printout obtained from the data logger.
- Location of temperature sensors is given in the Table-1 & Figure-1.



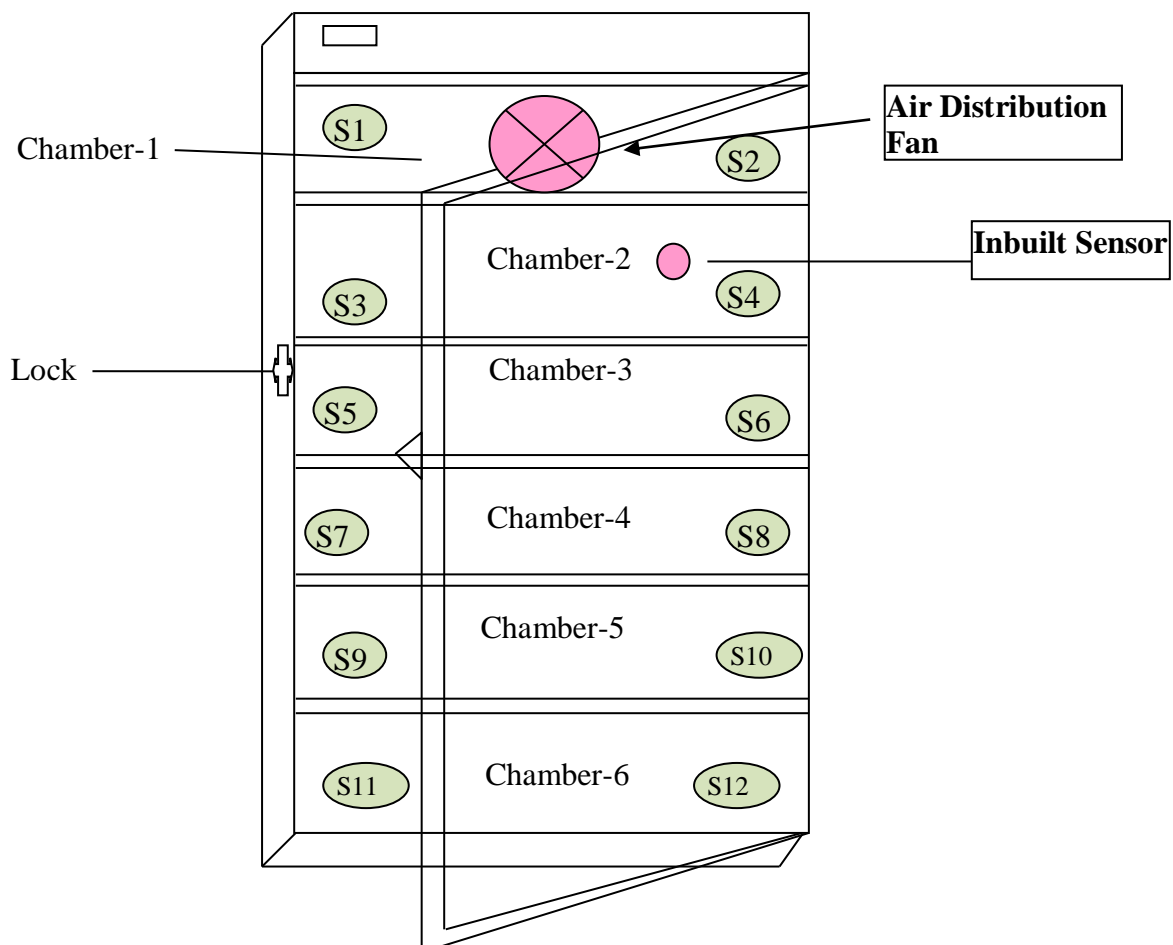


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**Table 1: Location of Temperature Sensors inside the Chamber**

Sensor No.	Location in the Chamber
S1	Left side of Chamber-01
S2	Right side of the Chamber-01
S3	Left side of Chamber-02
S4	Right side of the Chamber-02
S5	Left side of Chamber-03
S6	Right side of the Chamber-03
S7	Left side of Chamber-04
S8	Right side of the Chamber-04
S9	Left side of Chamber-05
S10	Right side of the Chamber-05
S11	Left side of Chamber-06
S12	Right side of the Chamber-06





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**11.1.4 Acceptance criteria:**

- Throughout the dwell time, all temperature measured in the chamber should be  $110 \pm 5^{\circ}\text{C}$ .

**11.1.5 Observations And Results:**

- Record the temperature at various locations.

**11.2 HEAT DISTRIBUTION STUDY(Loaded Chamber):**

**11.2.1 Objective:**

- To ensure that the Hot Air Oven when operated with loaded chamber is capable of producing the temperature profiles as per the temperature set points set in the equipment.
- Three run shall be performed to qualify the measurement of the temperature throughout the Chamber by 12 Temperature sensors.

**11.2.2 Equipment Required:**

- Calibrated Data Logger with 12 Temperature sensors

**11.2.3 Procedure:**

- Set the temperature  $110^{\circ}\text{C}$  of the heat distribution to be operated during the test.
- Suspend the probe in the chamber in different position in such a way that probes don't touch any metallic surface. Record the position of the probe in a representative schematic manner.
- Connect the probes to suitable data logger, which can scan and print the actual temperature observed at different locations with respect to time.
- Operate the oven as per operating procedure. Also start the data logger to record the actual temperatures with respect to time.
- After completion of cycle "Switch OFF" the data logger.
- Download the data from the data logger in the computer for the data analysis and printing enclosed the printout obtained from the data logger.
- Location of temperature sensors is given in the Table-1 & Figure-1

**11.2.4 Acceptance Criteria:**

- Throughout the dwell time, all temperature measured in the chamber should be  $110 \pm 5^{\circ}\text{C}$

**11.2.5 Observations And Results:**

- Record the temperature at various locations.



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**12.0 CHECKLIST OF ALL TESTS & 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:

- Throughout the dwell time (Empty Chamber), all temperature measured in the chamber should be  $110 \pm 5^{\circ}\text{C}$ .
- Throughout the dwell time (Loaded Chamber), all temperature measured in the chamber should be  $110 \pm 5^{\circ}\text{C}$ .

**13.0 REFERENCES:**

- 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.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.

**14.0 DOCUMENTS TO BE ATTACHED:**

- Calibration Certificates for Data Logger.
- Calibration Certificates of Sensors.
- Endotoxin vial Challenge Study Reports.

**15.0 NON COMPLIANCE:**

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

**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.



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**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.

**18.0 ABBREVIATIONS:**

+ve	:	Positive
C	:	Container
cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate Quality Assurance
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
Sr.	:	Senior
SS	:	Stainless Steel
Temp.	:	Temperature
-ve	:	Negative
WHO	:	World Health Organization