



PERFORMANCE QUALIFICATION PROTOCOL FOR AIR SAMPLER

Pre - Execution Approval

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



PERFORMANCE QUALIFICATION PROTOCOL FOR AIR SAMPLER

1.0 Objective:

- To establish documented evidence which will provide a High degree of assurance and reliability about the performance of the M Air T air sampler.
- To determine that the M Air T air sampler performs as intended by repeatedly running the system on its intended schedules and recording all relevant information and data. Results must demonstrate that performance consistently meets predefined specifications under normal conditions and where appropriate for worst case situations.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	M AIR T AIR SAMPLER
ID Number
Location	Incubator Room

3.0 Performance Verification Checklist:

Verify the performance of all the critical process/functions as per their respective procedure.
Refer Performance Verification Checklist as per Annexure - I.

4.0 Any Changes/Deviations identified during operating checks:

Refer Annexure – II.



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5.0 Recommendations and Conclusions:

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6.0 References:

- Installation Qualification
- Operational Qualification
- Standard Operating Procedure

7.0 Annexure

- Annexure - I : Performance Verification Checklist
- Annexure - II : List of Changes / Deviation.
- Annexure - III : Performance Qualification Report.

8.0 Abbreviations:

SOP : Standard Operating Procedure

Post execution approval:

	Name	Designation	Signature	Date
Compiled By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



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Annexure - I
Checklist for Performance Verification

S.No.	Critical variables to be met	Acceptance Criteria	Observation	Remarks	Verification done by
A.	Cassette Sterility verification				
1.	Cassette Catalogue Code	Not applicable			
2.	Incubation Time (hours)	Not applicable			
3.	Lot number of the cassette	Not applicable			
4.	Piece of cassette tested	Not applicable			
5.	M Air T Cassettes	Sterile/nonsterile at $32.5 \pm 2.5^{\circ}\text{C}$			
6.	M Air T Cassettes	Sterile/nonsterile at $22.5 \pm 2.5^{\circ}\text{C}$			
B.	Cassette Growth Promotion Verification				
1.	Incubation Temperature ($^{\circ}\text{C}$)	Not applicable			
2.	Incubation Time (Hours)	Not applicable			
3.	Cassette Catalogue Number	Not applicable			
4.	Cassette Lot Number	Not applicable			



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S.No.	Critical variables to be met	Acceptance Criteria	Observation	Remarks	Verification done by
5.	Name of the microorganisms use for Growth promotion test	Not applicable			
6.	<u>Cfu observed in Petriplates (90 mm)</u>	Not applicable			
	<u>Cfu observed in M Air T Cassettes</u>	Not applicable			
	Recovery	$\geq 70 \%$			
7.	<u>Cfu observed in Petriplates (90 mm)</u>	Not applicable			
	<u>Cfu observed in M Air T Cassettes</u>	Not applicable			
	Recovery	$\geq 70 \%$			
8.	<u>Cfu observed in Petriplates (90 mm)</u>	Not applicable			
	<u>Cfu observed in M Air T Cassettes</u>	Not applicable			
	Recovery	$\geq 70 \%$			



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S.No.	Critical variables to be met	Acceptance Criteria	Observation	Remarks	Verification done by
9.	Cfu observed in Petriplates (90 mm)	Not applicable			
	Cfu observed in M Air T Cassettes	Not applicable			
	Recovery	≥ 70 %			
10.	Cfu observed in Petriplates (90 mm)	Not applicable			
	Cfu observed in M Air T Cassettes	Not applicable			
	Recovery	≥ 70 %			
A.	Functional Testing Verification				
1.	Clean Room	Class 100.000 for USP (D for E.P.)			
2.	Clean Room Volume	> 10 m ³			
3.	Air born contamination	20 - 100 cfu (m ³)			
4.	Clean Room Temperature	4 ⁰ - 45 ⁰ C			
5.	Clean Room Pressure	Atmospheric			
6.	Clean Room Humidity	5 % 95 % non condensing			



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S.No.	Critical variables to be met	Acceptance Criteria	Observation	Remarks	Verification done by
7.	Cassette Catalogue Code	Not applicable			
8.	Cassette Lot Number	Not applicable			
9.	Incubation Temperature (°C)	Not applicable			
10.	Incubation Time (Hours)	Not applicable			
11.	Sampling Position	Not applicable			
12.	Cfu observed in M Air T under validation	Not applicable			
	Cfu observed in Qualified M Air T	Not applicable			
13.	Cfu observed in M Air T under validation	Not applicable			
	Cfu observed in Qualified M Air T	Not applicable			
14.	Cfu observed in M Air T under validation	Not applicable			
	Cfu observed in Qualified M Air T	Not applicable			

Note:

Remarks: - Performance Verification M Air T air sampler - Complies / Does not comply.



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Annexure - II

List of Changes / Deviations

S.No.	Description of Change / Deviations	Justification based on impact analysis

Verified By:

Approved By: