PERFORMANCE QUALIFICATION PROTOCOL FOR ISOLATOR SYSTEM

Pre - Execution Approval

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

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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 Isolator.
- To determine that the M Air T Isolator 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 ISOLATOR SYSTEM**
ID Number	**……..**
Location	**Incubator Room**

3.0 Performance Verification Checklist:

Verify the performance of all the critical process/functions as per their respective procedure defined in SOP and ensure the reproducibility. Record the raw data as per Annexure - I.

4.0 Any Changes/Deviations identified during operating checks:

Refer Annexure – II.

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				
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Approved By				

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Annexure - I
Checklist for Performance Verification

S.No.	Critical variables to be met	Acceptance Criteria	Observation	Remarks
A.	**Cassette Sterility verification**			
1.	Incubation Time (hours)	Not applicable		
2.	Lot number of the cassette	Not applicable		
3.	Piece of cassette tested	Not applicable		
4.	M Air T Cassettes	Sterile/nonsterile at 32.5 ± 2.5^{0}C		
5.	M Air T Cassettes	Sterile/nonsterile at 22.5 ± 2.5^{0}C		
B.	**Cassette Growth Promotion Verification**			
1.	Cassette Catalogue Number	Not applicable		
2.	Cassette Lot Number	Not applicable		
3.	Reference Pharmacopoeia	Not applicable		

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S.No.	Critical variables to be met	Acceptance Criteria	Observation	Remarks
4.	Name of the microorganisms use for spiking	Not applicable		
5.	Concentration of the microorganisms use for spiking (cfu)	Not applicable		
6.	Incubation Temperature (^{0}C)	Not applicable		
7.	Incubation Time (Hours)	Not applicable		
8.	$\frac{\text{Cfu observed in Petriplates (90 mm)}}{}$	Not applicable		
	$\frac{\text{Cfu observed in M Air T Cassettes}}{}$	Not applicable		
	Recovery	$\geq$ 70 %		
9.	$\frac{\text{Cfu observed in Petriplates (90 mm)}}{}$	Not applicable		
	$\frac{\text{Cfu observed in M Air T Cassettes}}{}$	Not applicable		
	Recovery	$\geq$ 70 %		

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S.No.	Critical variables to be met	Acceptance Criteria	Observation	Remarks
10.	$\frac{\text{Cfu observed in Petriplates}}{(90\ mm)}$	Not applicable		
	$\frac{\text{Cfu observed in M Air T}}{\text{Cassettes}}$	Not applicable		
	Recovery	$\geq$ 70 %		
11.	$\frac{\text{Cfu observed in Petriplates}}{(90\ mm)}$	Not applicable		
	$\frac{\text{Cfu observed in M Air T}}{\text{Cassettes}}$	Not applicable		
	Recovery	$\geq$ 70 %		
12.	$\frac{\text{Cfu observed in Petriplates}}{(90\ mm)}$	Not applicable		
	$\frac{\text{Cfu observed in M Air T}}{\text{Cassettes}}$	Not applicable		
	Recovery	$\geq$ 70 %		

Note:

Remarks: Performance verification of M Air T Isolator - Complies / Does not comply.

Verification Done By: -

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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: