OPERATIONAL QUALIFICATION PROTOCOL FOR ISOLATOR SYSTEM

Pre - Execution Approval

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

OPERATIONAL QUALIFICATION PROTOCOL FOR ISOLATOR SYSTEM

1.0 Objective:

- To determine that the equipment operates according to specifications, and to record all relevant information's and data to demonstrate its functions as intended for.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	**M AIR T ISOLATOR SYSTEM**
ID Number	**……..**
Location	**Incubator Room**

3.0 Checklist for Operational verification:

Operation of M Air T Isolator is verified for the compliance with the critical parameters mentioned in the Functional Specification. Sequentially prepare the list of operating checks specifying critical parameters, perform them as per operating procedure as mentioned in the vender operating manual & document the same in the attached check list (Annexure - I).

4.0 Any Changes/Deviations identified during operating checks:

Refer Annexure – II

5.0 Identification & preparation of Standard Operating Procedures:

Prepared the SOP for cleaning, calibration and operation of M Air T Isolator using the actual feedback from the operation checks and vendor-operating manual. The preventive maintenance procedure and schedule shall be applicable as per Annual Maintenance Contract of QC Instrument.

S. No.	**SOP Title**	**SOP Number**
1.	Cleaning, Calibration and Operation of M Air T Isolator System	……

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6.0 Training

The List of QC (Microbiology) person trained during the operation qualification of M Air T Isolator is listed as per Annexure - III.

7.0 Recommendations and Conclusions:

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8.0 References:

Installation Qualification

Operating Manual submitted by the Vendor.

9.0 Annexure

Annexure - I : Checklist for Operational Verification.

Annexure - II : List of Changes / Deviation.

Annexure - III : Training Detail

10.0 Abbreviations:

SOP : Standard Operating Procedure

QC : Quality Control

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 Operational Verification

S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
A.	**Verification of Cassette Sterility Qualification**			
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 ± 2.5^0C		
5.	M Air T Cassettes	Sterile/nonsterile at 22.5 ± 2.5^0C		
B.	**Verification of Cassette Growth Promotion Qualification**			
1.	Cassette Catalogue Number	Not applicable		
2.	Cassette Lot Number	Not applicable		
3.	Reference Pharmacopoeia	Not applicable		
4.	Name of the microorganisms use for spiking	Not applicable		

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S.No.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
B.	**Verification of Cassette Growth Promotion Qualification**			
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.	Operating Parameters	Function /Acceptance criteria	Observation	Remarks
B.	**Verification of Cassette Growth Promotion Qualification**			
10.	$\frac{\text{Cfu observed in}}{\text{Petriplates (90 mm)}}$	Not applicable		
	$\frac{\text{Cfu observed in M}}{\text{Air T Cassettes}}$	Not applicable		
	Recovery	$\geq$ 70 %		
11.	$\frac{\text{Cfu observed in}}{\text{Petriplates (90 mm)}}$	Not applicable		
	$\frac{\text{Cfu observed in M}}{\text{Air T Cassettes}}$	Not applicable		
	Recovery	$\geq$ 70 %		
12.	$\frac{\text{Cfu observed in}}{\text{Petriplates (90 mm)}}$	Not applicable		
	$\frac{\text{Cfu observed in M}}{\text{Air T Cassettes}}$	Not applicable		
	Recovery	$\geq$ 70 %		

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Annexure - II

List of Changes / Deviations

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

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Annexure - III

Training Detail

S.No.	Name of Trainee	Name of Trainer

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