



**PHARMA DEVILS**

MICROBIOLOGY DEPARTMENT

**INSTALLATION QUALIFICATION PROTOCOL FOR AIR SAMPLER**

**Pre - Execution Approval**

	<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



## **INSTALLATION QUALIFICATION PROTOCOL FOR AIR SAMPLER**

### **1.0 Objective:**

The purpose of installation qualification is as follows

- To provide documented evidence that the mentioned M Air T air sampler is installed as per design.
- To ensure that the M Air T air sampler installed confirms to purchase specifications and manufacturer literature, and to document the information that the M Air T air sampler meets the specification.

### **2.0 Scope:**

**Scope is limited to the following**

<b>Equipment / System Name</b>	<b>M AIR T AIR SAMPLER</b>
<b>ID Number</b>	.....
<b>Location</b>	<b>Incubator Room</b>

### **3.0 Equipment / System Description:**

M Air T air sampler is a portable instrument designed to detect airborne contamination in clean rooms from clean room class 10000 to clean room class 100. M Air T air sampler uses a uniquely designed agar cassette that ensures consistent nutrition across the surface of the agar while minimizing colony overlapping. The microorganisms collect on the cassette media surface, and then grow during incubation at the required temperature.

### **4.0 Checklist for Preinstallation verification:**

The purpose of the checklist is to confirm the availability of required documents for installation and to verify the availability of components and parts as per the approved purchase order in presence of the technical personnel of the vendor.

Preinstallation verification checklist is enclosed as Annexure - I.

### **5.0 Checklist for Installation verification:**

Installation verification checklist is enclosed as Annexure - II.



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### **6.0 Any Changes identified towards equipment design / lay out.**

Refer Annexure - III.

### **7.0 Recommendations and Conclusions:**

### **8.0 References:**

Copy of Purchase order

Packing list supplied by vendor (Not applicable).

List of spares (Not applicable).

Installation Qualification submitted by vendor.

Impact Assessment analysis.

### **9.0 Annexure**

Annexure - I : Check list for Preinstallation Verification.

Annexure - II : Check list for Installation Verification.

Annexure - III : List of Changes / Deviation.

Annexure - IV : Installation Qualification Submitted by the vendor.

Annexure - V : Impact Assessment Analysis.

Annexure - VI : Summary Report of Installation Qualification

Annexure - VII : Copy of Purchase order

### **10.0 Abbreviations:**

IQ : Installation Qualification



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**Post execution approval:**

	<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Compiled By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



**INSTALLATION QUALIFICATION PROTOCOL FOR AIR SAMPLER**

**Annexure - I**

**Checklist for Preinstallation Verification**

S.No.	Main Components Accessories / Documents	Code / Doc No.	Actual	Remarks
1.	Purchase Order No.	.....		
2.	Vendor's Name	M/s Millipore		
3.	Instrument Make	Millipore		
4.	Instrument Model No.	M Air T™		
5.	Instrument Manual	Instrument Manual submitted by the vendor		



**INSTALLATION QUALIFICATION PROTOCOL FOR AIR SAMPLER**

**Annexure - II**

**Checklist for Installation Verification**

S.No.	System Data	Acceptance Criteria	Actual	Remarks
<b>A.</b>	<b>Equipment /Instrument specific details</b>			
<b>a.</b>	<b>Verification of the Documents</b>			
1.	Millipore air Tester User Guide	Issue: ....., Revision - .....		
2.	Certificate of Calibration	Issue: .....		
<b>b.</b>	<b>Verification of the Equipment List</b>			
1.	M Air T Catalogue	Catalogue No.: ..... Serial No: .....		
2.	Sieve Catalogue	Catalogue No.: ..... Serial No: .....		
3.	Sieve Catalogue	Catalogue No.: ..... Serial No: .....		
4.	Battery Charger	Catalogue No.: .....		
5.	Micro-perforated sieve with cover	Catalogue No.: .....		
6.	Allen Key	Catalogue No.: .....		
7.	Tripod, including fixation screw	Catalogue No.: .....		
8.	Battery (Inside the tester)	Catalogue No.: .....		



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S.No.	System Data	Acceptance Criteria	Actual	Remarks
<b>c.</b>	<b>Verification of the Critical Reference Instruments</b>			
1.	Reference M Air T	Catalogue No.: .....		
<b>d.</b>	<b>Verification of the utilities and operating environment Requirements</b>			
1.	Electrical Requirements	230 V $\pm$ 10 % - 50 Hz		
2.	Temperature	4 <sup>0</sup> C to 45 <sup>0</sup> C		
3.	Humidity	5 % to 95 % non condensing		
<b>e.</b>	<b>Verification of the Instrument Start - up</b>			
1.	AT1 Connecting the power to the instrument	Charger logo "AC" Display		
		Battery Logo Display		
		Display show the last sampling volume		



## INSTALLATION QUALIFICATION PROTOCOL FOR AIR SAMPLER

S.No.	System Data	Acceptance Criteria	Actual	Remarks
<b>e.</b>	<b>Verification of the Instrument Start - up</b>			
2.	AT2 Charge the battery overnight	Display show the battery logo disappears after a overnight charge		
3.	AT3 Disconnect the charger	Display show the logo AC disappear		
4.	AT4 Press the ON/OFF button	Display show the instrument is switch off		
5.	AT5 Switch On the instrument	The display Show the last sampling volume		
6.	AT6 Test run	Display show at the end of a test the logo "EOC" appears		
<b>f.</b>	<b>Verification of the software release</b>			
1.	Software release	Software version display after removing the battery cover and putting it back in place		
<b>g.</b>	<b>Verification of the Setting parameter</b>			
1.	Preset volumes	Pre - set sampling volume and delay time should be available		





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S.No.	System Data	Acceptance Criteria	Actual	Remarks
<b>h.</b>	<b>Verification of the sampling time</b>			
1.	Sampling time when selecting 25 L	(Time at speed 1 + speed 2) 11 second		
2.	Sampling time when selecting 50 L	(Time at speed 1 + speed 2) 22 second		
3.	Sampling time when selecting 100	(Time at speed 1 + speed 2) 43 second		
4.	Sampling time when selecting 250 L	(Time at speed 1 + speed 2) 108 second		
5.	Sampling time when selecting 500 L	(Time at speed 1 + speed 2) 215 second		
6.	Sampling time when selecting 750 L	(Time at speed 1 + speed 2) 215 + 86 second		
7.	Sampling time when selecting 1000 L	(Time at speed 1 + speed 2) 215 + 165 second		



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S.No.	System Data	Acceptance Criteria	Actual	Remarks
<b>i.</b>	<b>Verification of the test condition</b>			
1.	Atmospheric pressure	Not applicable		
2.	Room Temperature	Not applicable		
3.	Test processed before logo battery appears	$\geq 40$ test		
4.	Test processed after the battery logo appears	5 test then ER1 appears		
5.	Signal ER1 appears	No more test		
6.	Sampling time when selecting 1000 liter of sampling volume	380 seconds ( $\pm 5\%$ )		



## INSTALLATION QUALIFICATION PROTOCOL FOR AIR SAMPLER

S.No.	System Data	Acceptance Criteria	Actual	Remarks
<b>B.</b>	<b>Location suitability</b>			
1.	Location	Should be place in Incubator Room		
<b>C.</b>	<b>Utilities</b>			
1.	Electrical Supply	230 V $\pm$ 10 % - 50 Hz, supply should be provided		
<b>D.</b>	<b>Safety</b>			
1.	Not Applicable	Not Applicable		
<b>E.</b>	<b>MOC Certificates</b>			
1.	Not Applicable	Not Applicable		
<b>F.</b>	<b>Calibration Certificates</b>			
1.	Calibration Certificates	Should be provided		
<b>G.</b>	<b>Testing Certificates</b>			
1.	Not Applicable	Not Applicable		
<b>H.</b>	<b>Drawing Details</b>	<b>Drawing No.</b>		
1.	Not Applicable	Not Applicable		



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**Annexure - III**

**List of changes / Deviations**

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

**Verified By:**

**Approved By:**



**INSTALLATION QUALIFICATION PROTOCOL FOR AIR SAMPLER**

**Annexure - VI**

**Summary Report of Installation Qualification**

<b>Checks</b>	<b>Observations (Yes / No)</b>	<b>Reviewed By Sign / Date</b>
All test procedures executed and verified as per the protocol.		
All criteria set forth in the installation qualification were met.		
Deviation if any		

**Summary:**

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**Summary Report Prepared By:**

**Date & Sign**