



**OPERATIONAL QUALIFICATION PROTOCOL FOR COLONY COUNTER**

**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				



**OPERATIONAL QUALIFICATION PROTOCOL FOR COLONY COUNTER**

**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**

<b>Equipment / System Name</b>	<b>Colony Counter</b>
<b>ID Number</b>	.....
<b>Location</b>	<b>Incubation Room</b>

**3.0 Checklist for Operational verification:**

Operation of Colony counter 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 Colony counter 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.

<u>S. No.</u>	<u>SOP Title</u>	<u>SOP Number</u>
1.	Cleaning, Calibration and Operation of Colony Counter	



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### 6.0 Training

The List of QC (Microbiology) person trained during the operation qualification of Colony Counter is listed as per Annexure - III.

### 7.0 Recommendations and Conclusions:

### 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				
Reviewed By				
Reviewed By				
Approved By				



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**Annexure - I**

**Checklist for Operational Verification**

S.No.	Operating Parameters	Function	Observation	Remarks
A.	<b>Control Panel Testing</b>			
1.	Mains key	To start the main Power supply		
2.	POWER button	To start the Machine and it will illuminate wolffhuegel glass		
3.	Magnifying Lens	For accurate counting of small or closely spaced colonies without straining the eye		
4.	Graduated Wolffhuegel glass Plate	For keeping the Petriplates		
5.	Reset Button	For reset the automatic counter (00000)		
6.	Auto marker pen	For register the count of Petriplates on the colony counter display		



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**Annexure - II**

**List of Changes / Deviations**

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

**Verified By:**

**Approved By:**



**OPERATIONAL QUALIFICATION PROTOCOL FOR COLONY COUNTER**

**Annexure - III**

**Training Detail**

S.No.	Name of Trainee	Name of Trainer

**Verified By:**

**Approved By:**