



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

PERFORMANCE QUALIFICATION PROTOCOL FOR COLONY COUNTER

Pre - Execution Approval

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



PERFORMANCE QUALIFICATION PROTOCOL FOR COLONY COUNTER

1.0 Objective:

- To establish documented evidence which will provide a High degree of assurance and reliability about the performance of the Colony Counter.
- To determine that the Colony Counter 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	Colony Counter
ID Number
Location	Incubation 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.

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.	No. of time pressed on the Petriplates	Reading Display on Digital Display	Sr. No.	No. of time pressed on the Petriplates	Reading Display on Digital Display
	1			26	
	2			27	
	3			28	
	4			29	
	5			30	
	6			31	
	7			32	
	8			33	
	9			34	
	10			35	
	11			36	
	12			37	
	13			38	
	14			39	
	15			40	
	16			41	
	17			42	
	18			43	
	19			44	
	20			45	
	21			46	
	22			47	
	23			48	
	24			49	
	25			50	

Remarks: - Performance Verification of Colony Counter - 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: