



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation, Calibration and maintenance of Digital Colony Counter

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 5

- 1. Purpose:** The purpose of this SOP (Standard Operating Procedure) is to describe Operation, calibration and maintenance of Digital Colony Counter procedure for Colony counter.
- 2. Scope:** This SOP is applicable to Colony counter kept in the Microbiology section.

Model	Make	Sr. No.	In-House ID
Lapiz	Medica Instrument		
DBK	DBK Instruments		

3. References, Attachments & Annexures:

3.1 References:

- 3.1.1 Instruction Manual supplied by manufacturer
- 3.1.2 SOP "Maintenance of Laboratory Instruments"

3.2 Attachments:

- 3.2.1 Attachment-1: Calibration record of colony counter
- 3.2.2 Attachment-2 :Calibration Status Label

3.3 Annexures: None

4. Responsibilities:

4.1 Microbiologist:

- 4.1.1. To perform the activity as per SOP
- 4.1.2. To maintain the records as per SOP

4.2 QC Head or designee:

- 4.2.1 To check the SOP
- 4.2.2 To give the training to all concern persons

4.3 Quality Assurance:

- 4.3.1 To check the SOP
- 4.3.2 To ensure proper implementation of SOP

4.4 Regulatory Affairs, Quality Head , Plant Head:

- 4.4.1 To review and approve the SOP



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5. Distribution:

- 5.1 Quality Assurance
- 5.2 Microbiological section.

6. Abbreviations & Definition of Terms :

6.1 Abbreviations:

- 6.1.1 **SOP:** Standard Operating Procedure
- 6.1.2 **SS:** Stainless Steel

6.2 Definition of Terms :None

7. Procedure:

7.1 Operational Procedure:

- 7.1.1 Clean the instrument with tissue paper.
- 7.1.2 Keep the instrument on working bench base and connect the unit to mains power supply.
- 7.1.3 Switch "ON" the power supply and switch "ON" the mains of the instrument for illumination of instrument.
- 7.1.4 Connect plug of the "AUTO MARKER PEN" to the provided probe socket.
- 7.1.5 Instrument is ready for use / calibration.
- 7.1.6 In case of any malfunctioning of instrument inform to maintenance department and Quality Head.
- 7.1.7 Ensure the display of the colony counter to read "0".
- 7.1.8 Clean the wolffhuegel glass with clean cloth/tissue paper.
- 7.1.9 Keep petridish on the wolffhuegel glass in inverted position.
- 7.1.10 Turn the magnifier lens for accurate counting of small or closely spaced colonies.
- 7.1.11 Put the nib of "AUTO MARKER PEN" on the identified colony. At the time of nib pressing "BEEP" sound indicates that the count has been made. At the same time display will show the no. of colony counted.
- 7.1.12 Whenever required to start with another plate observation press the "RESET" key to start count from the "0".
- 7.1.13 Switch off the colony counter when not in use.

7.2 Calibration Procedure:

- 7.2.1 Clean the instrument with tissue paper.
- 7.2.2 Ensure the display of colony counter to read "0".
- 7.2.3 Put the nib of "AUTO MARKER PEN" on the empty petri dish.
- 7.2.4 At the time of nib pressing "BEEP" sound indicates that the count has been made.



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7.2.5 Press 10 times the nib and check the display for numbers and record in calibration log (Attachment-1).

7.2.6 Press 50 times the nib and check the display for numbers and record in calibration log (Attachment-1).

7.2.7 Press 150 times the nib and check the display for numbers and record in calibration log (Attachment-1).

7.2.8 Press 300 times the nib and check the display for numbers and record in calibration log (Attachment 1)

7.3 **Frequency:** Quarterly +/- one week

7.4 **Maintenance :**

7.4.1 In case of noticing any malfunctioning inform to Quality Head and follow the SOP "Maintenance of Laboratory instruments"

7.5 **In case of Relocation of instrument :**

7.5.1 Instrument shall be relocated in presence of Quality Head or designee.

7.5.2 Quality Head or designee shall ensure the instrument operation .

7.5.3 Quality Head or designee shall ask analyst to carry out calibration of instrument as per the SOP.

7.5.4 After satisfactory calibration, Quality Head shall allow the instrument for the further use.



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Attachment – 1 Calibration record of Colony Counter

Instrument Name	Digital Colony Counter	Instrument Code no		Frequency	Quarterly
Date of Calibration :		Due date of calibration			

S.No	Number of Beeps	Display Reading	Remarks

Remarks : The instrument is **Satisfactory/Unsatisfactory.**

Calibration Done By:	Checked By:	Approved By:
Date:	Date:	Date:



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Attachment-2

	Quality Control-Microbiology	
	Calibration Status Label	
Instrument :		
Make :	Model :	
ID No. :		
Calibrated On :	By :	
Next Calibration Due On :		

8. History:

Version No.		Effective Date	