PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Procedure for Operation and Calibration of Micropipette	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Operation and Calibration of Micropipette.

2.0 SCOPE:

This SOP is applicable for Operation and Calibration of Micropipette in Microbiology Section of Quality Control Laboratory.

3.0 RESPONSIBILITY:

Officer / Executive - Microbiology

4.0 ACCOUNTABILITY:

Head – QC

5.0 ABBREVIATIONS:

µl	Micro liter
ml	Milliliter
No.	Number
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
RSD	Relative Standard Deviation

6.0 PROCEDURE:

6.1 Calibrate the Micropipettes for a volume of 20 to 200 µl 100 to 1000 µl and 1000 to 10000 µl.

6.2 Set the desired volume using the Volume-Setting Knob e.g. for 20 to 200 µl set 50 µl, 100 µl & 200 µl and for 100 µl to 1000 µl set 100 µl ,500 µl, 1000 µl and 1000 µl to 10000 µl set 1000 µl ,5000 µl, 10000 µl.

6.3 Carefully fit the tip into tip cone and pick up the Water for Injections.

6.4 Weigh the empty Vial (A).

6.5 Pick up the set water volume and add into the vial after weigh of empty vial (A) at temperature 25±2°C.

6.6 Observe the weight of vial with water (B).

6.7 Remove set tip with pipettes.

6.8 Calculate the exact weight of water M = B-A.

6.9 Divide the value of M with the D i.e. 0.997 gm/ml (D is specific density of water at 25 ± 2^0C) to obtain actual volume in ml /µL.

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6.10 Repeat the procedure for three times with high set volume and RSD should not be more than 2%.

6.11 Record the Calibration Details in **Annexure-I**, Titled **"Calibration of Micropipette (20-200 µl)"**.

6.12 Record the Calibration Details in **Annexure-II**, Titled **"Calibration of Micropipette (100-1000 µl)"**.

6.13 Record the Calibration Details in **Annexure-III**, Titled **"Calibration of Micropipette (1000-10000 µl)"**.

6.14 **Frequency:** Once in a 3 Months ± 7 Days.

Note: If any variation found in micropipette calibration set the micropipette with the help of micropipette key.

Acceptance Criteria:

VOLUME (IN µL)	TOLERANCE LIMIT IN µL	
	MINIMUM	MAXIMUM
50	49.5	50.5
100	99.0	101.0
200	198.0	202.0
500	495.0	505.0
1000	990.0	1010.0
5000	4950.0	5050.0
10000	9900.0	10100.0

In all above parameter % RSD not more than 2.0%

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Calibration of Micropipettes (20-200 µl)	
Annexure – II	Calibration of Micropipettes (100-1000 µl)	
Annexure – III	Calibration of Micropipettes (1000-10000 µl)	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 — Quality Assurance
- Controlled Copy No. 02 — Microbiology Laboratory
- Master Copy — Quality Assurance

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9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

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ANNEXURE – I
CALIBRATION OF MICROPIPETTE (20-200 µL)

Date of Calibration		**Next Due Date**	
Micropipette Make		**Micropipette ID**	
Volume Range			

OBSERVATION TABLE:

S.No.	Empty Vial wt. (A)	Volume Pipette in µl	Wt. of Vial & Water (B)	Wt. of Water (M=B-A)	Density of Water at 25°C	Actual Volume (V=M/D)
For 50 µl						
1.						
2.						
3.						
					Average	
					% RSD	
For 100 µl						
1.						
2.						
3.						
					Average	
					% RSD	
For 200 µl						
1.						
2.						
3.						
					Average	
					% RSD	

RSD should be not more then 2%.

LIMITS:

VOLUME IN µL	TOLERANCE LIMIT IN µL	
	MINIMUM	MAXIMUM
50	49.5	50.5
100	99.0	101.0
200	198.0	202.0

Remarks: The Calibration of Micropipettes Complies / Doesn't Comply as per requirement.

Done by: **Checked By:** **Approved By:**

Date: **Date:** **Date:**

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ANNEXURE – II
CALIBRATION OF MICROPIPETTE (100-1000 µL)

Date of Calibration		**Next Due Date**	
Micropipette Make		**Micropipette ID**	
Volume Range			

OBSERVATION TABLE:

S.No.	Empty Vial wt. (A)	Volume Pipette in µl	Wt. of Vial & Water (B)	Wt. of water (M=B-A)	Density of Water at 25°C	Actual Volume (V=M/D)
For 100 µl						
1.						
2.						
3.						
					Average	
					% RSD	
For 500µl						
1.						
2.						
3.						
					Average	
					% RSD	
For 1000µl						
1.						
2.						
3.						
					Average	
					% RSD	

RSD should be not more then 2%.

LIMITS:

VOLUME IN µL	TOLERANCE LIMIT IN µL	
	Minimum	Maximum
100	99.0	101.0
500	495.0	505.0
1000	990.0	1010.0

Remarks: The Calibration of Micropipettes Complies / Doesn't Comply as per requirement.

Done By: **Checked By:** **Approved By:**
Date: **Date:** **Date:**

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ANNEXURE – III
CALIBRATION OF MICROPIPETTE (1000-10000 µL)

Date of Calibration		**Next Due Date**	
Micropipette Make		**Micropipette ID**	
Volume Range			

OBSERVATION TABLE:

S.No.	Empty Vial wt. (A)	Volume Pipette in µl	Wt. of Vial & Water (B)	Wt. of water (M=B-A)	Density of Water at 25°C	Actual Volume IN µL (V=M/D)
For 1000 µl						
1.						
2.						
3.						
					Average	
					% RSD	
For 5000 µl						
1.						
2.						
3.						
					Average	
					% RSD	
For 10000 µl						
1.						
2.						
3.						
					Average	
					% RSD	

RSD should be not more than 2%.

LIMITS:

VOLUME IN µL	TOLERANCE LIMIT IN µL	
	Minimum	Maximum
1000	990.0	1010.0
5000	4950.0	5050.0
10000	9900.0	10100.0

Remarks: The Calibration of Micropipettes Complies / Doesn't Comply as per requirement.

Done By: **Checked By:** **Approved By:**
Date: **Date:** **Date:**