PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Operation & Calibration of Weighing Balance (Semimicro)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE :

To lay down a procedure for Operation & calibration of Weighing Balance (Semimicro).

2.0 SCOPE :

This SOP is applicable for Operation & calibration of Weighing Balance (Semimicro) in the Quality control department.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control.

Head – Quality Control

4.0 PROCEDURE:

4.1 Operation :(Range: 0.02000 g to 200.00000 g)

4.1.1 Ensure the Calibration status of the instrument.

4.1.2 Ensure that instrument is clean and free from dust.

4.1.3 Switch ON the mains & level the balance (bubble position in center.)

4.1.4 Switch on the power supply of balance (Push I/Q key)

4.1.5 The display shows 88888888 and finally shows 0.00000g.

4.1.6 Allow the balance to stabilize for 10 minutes.

4.1.7 Take weight on balance as described in 4.1.

4.1.8 For Switching off the balance, press and hold the I/Q key. Release the key; switch off the main power supply.

4.2 Calibration:

4.2.1 Internal calibration:

4.2.1.1 Check the balance spirit level. (If the level is disturbed, correct it by adjusting the base screws). Record it on the Annexure - I as ok /not ok.

4.2.1.2 Press the arrow “CAL” corresponding to CAL.

4.2.1.3 Now the balance starts auto calibration and after some time when the auto calibration completes the display shows “0.00000 g”.

4.2.1.6 After internal calibration is over, the display will be shown 0.000 mg constantly. Record the zero display on the Annexure - I as ok /not ok.

4.2.2 Daily Verification:

4.2.2.1 After completion of the internal calibration press 'Tare' key to zero the display if necessary.

4.2.2.2 Place 20 mg standard weight on the pan with the help of forcep.

4.2.2.3 Press the print key after the display gets stable.

4.2.2.4 Repeat the operation with 100 mg, 1.0g 100 g and 200 g standard weights. Note the displayed weight after the display is stable & record in the format as per Annexure-I.

4.2.2.5 **Percentage variation**

± 0.10 % of actual weight.

4.2.3 Monthly Calibration:

4.2.3.1 Accuracy

4.2.3.1.1 Place 20 mg standard weight on the pan with the help of forcep.

4.2.3.1.2 Press the print key after the display gets stable.

4.2.3.1.3 Repeat the operation with 20 mg, 50 mg, 100 mg, 200 mg, 500mg, 1g, 2g, 5g, 10g, 20g, 50g, 100g and 200g standard weights and record the readings in the format as per Annexure-II.

4.2.3.1.4 Calculate the Percentage variation by using the following formula:

Observed Weight – Actual Weight (As per certificate) x 100 Actual Weight (As per certificate)

4.2.3.1.5 Acceptance Criteria: Percentage Variation shall not be more than ± 0.10 %.

4.2.4 Repeatability:

4.2.4.1 Place 100 mg standard weight on the pan.

4.2.4.2 Press the print key after the display gets stable.

4.2.4.3 Take atleast 10 replicate readings for the same weight on the balance.

4.2.4.4 If the repeatability obtained is smaller than 0.41 d, where d is the scale interval, replace the standard deviation with 0.41 d.

4.2.4.5 Calculate the repeatability by using the below mentioned

Formula:

$$\text{Repeatability} = \frac{2 \times \text{Standard deviation}}{\text{Actual weight}} \times 100$$

Where, Standard deviation = $\sqrt{\frac{\sum (x - \overline{x})^2}{n - 1}}$

Where, x = each observed weight

$\overline{x}$ = Mean observed weight.

n = No. of observations.

4.2.4.6 Acceptance Criteria: Uncertainty shall not be more than 0.10 %.

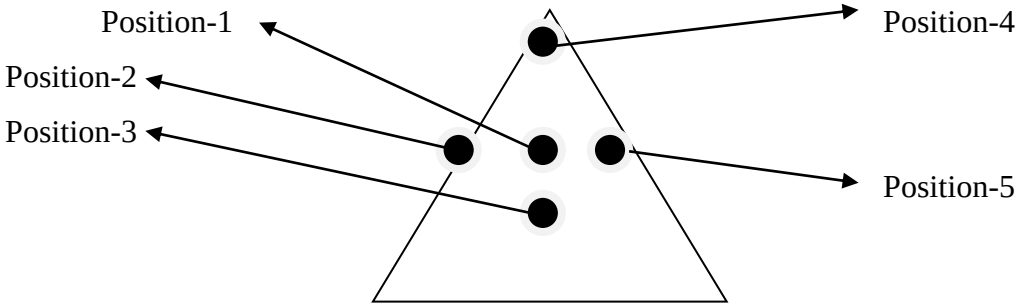
4.2.4.6 Record the readings and calculations in the format as per Annexure-II.

4.2.5 Eccentricity

4.2.5.1 Place 100 g standard weight on the pan.

4.2.5.2 Read the displayed weight after display is stable and take the print.

4.2.5.3 Repeat five times as per above procedure and calculate average display weight.



4.2.5.4 Record the readings in the format as per Annexure-II.

4.2.5.5 The average display weight shall be fixed as average actual weight.

4.2.5.6 Acceptance Criteria: The observed weight should not deviate by ± 0.10 % of actual weight and + 0.2 mg of the absolute mean weight.

4.2.6 **Drift check**

4.2.6.1 Place 1.0 g standard weight in the centre of the pan 10 times and record the observation as per Annexure-II.

4.2.6.2 Calculate the Average of the ten observations.

4.2.6.3 Report the difference between average and minimum / maximum weight observed and record the observations in Annexure-II

4.2.6.4 Acceptance Criteria : Minimum and maximum weight shall not deviate from average by more

than 0.2 mg

4.2.6.5 Attach all the prints of the weights to the calibration format.

4.2.7 Frequency:

4.2.7.1 Internal calibration & Daily verification : Daily

4.2.7.2 Monthly calibration

4.2.8 If instrument is out of calibration, put an "OUT OF CALIBRATION" tag, and proceed as per SOP.

4.3 Cleaning :

4.3.1 Carefully remove any sample residue/ spilled powder using a brush.

4.3.2 Use blotting paper to remove liquid spills.

4.3.3 Clean the balance using a piece of cloth which has been wet with a mild detergent. Do not use any aggressive cleaning agents (solvents or similar agents).

4.3.4 Use commercially available glass cleaning agent to clean the draft shield doors.

4.3.5 After cleaning, wipe down the balance with a soft, dry cloth.

4.4 Precaution :

4.4.1 Ensure the balance is placed on a stable, vibration free and leveled support and in a non-hazardous area.

4.4.2 Do not use forceps or similar utensils behind the platen of the draft shield.

4.4.3 Always keep the draft shield closed.

5.0 ANNEXURE (S) :

Annexure – I: Daily Verification Weighing Balance (Semimicro).

Annexure – II: Monthly Calibration Weighing Balance (Semimicro).

6.0 REFERENCE (S):

SOP: Handling of out of calibration of Instruments.

SOP: Preparation, Approval, Distribution control, revision and destruction of Standard operating Procedure (SOP).

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7.0 ABBREVIATION (S)/DEFINITION (S):

SOP : Standard operating Procedure

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	----	New SOP	-

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ANNEXURE I

DAILY VERIFICATION WEIGHING BALANCE (SEMIMICRO)

Reference SOP

Location		**Model No.**	
Manufacturer		**Capacity**	
Instrument ID No.		**Least Count**	
Month & Year			

Calibrated weight box Certificate No.: _____ **Validity:** _____

Tolerance: + 0.10 % of actual weight

Standard Weight	**20 mg**	**100 mg**	**1.0g**	**100 gm**	**200 g**	**Done by**	**Checked by**
Actual Weight							
Limits (mg)							

Date	***Balance Level**	***Zero display**	**Observed Weight (mg)**						

Note:*Record the balance level (Bubble position in centre) and zero display as OK/Not OK.

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ANNEXURE II
MONTHLY CALIBRATION WEIGHING BALANCE (SEMIMICRO)

MONTHLY CALIBRATION WEIGHING BALANCE (SEMIMICRO). Reference SOP			
Location		**Model No.**	
Manufacturer		**Capacity**	
Instrument ID No.		**Least Count**	
Date of Calibration		**Next Calibration Due on**	

Calibrated weight box Certificate No.: _____ Validity: _____

1.0) Accuracy

Theoretical weight (mg/gm)	Actual weight (mg)	Observed weight (mg)	Percentage variation	Limit ± 0.10 % of actual weight	Remarks

Calculate the Percentage variation by using the following

Formula: Observed Weight – Actual Weight (As per certificate) x 100 Actual Weight (As per certificate)

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2.0) REPEATABILITY:

Standard weight: 100 mg

Actual weight : _____ mg (Limit: _____ to _____ mg)

S.No.	Observed Weight
01	
02	
03	
04	
05	
06	
07	
08	
09	
10	
Mean	
Standard deviation	

If the repeatability obtained is smaller than 0.41 d, where d is the scale interval, replace the standard deviation with 0.41 d.

$$\text{Repeatability} = \frac{2 \times \text{Standard deviation}}{\text{Actual weight}} \times 100$$

$$= \frac{2 \times \_\_\_\_\_}{\_\_\_\_\_} \times 100 =$$

Acceptance Criteria: Repeatability shall not be more than 0.10 %.

3.0 ECCENTRICITY

Used in weight: _____ Actual Certificate Weight _____

S.No.	Position	Observed Weight	Difference between Position	Percentage variation
1				
2				
3				
4				
5				

Acceptance Criteria: Not more than0.2 mg difference from the position-1
Acceptance Criteria: Shall not be more than 0.10 %.

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4.0) DRIFT CHECK

Used in weight: _____ Actual Certificate Weight _____

S.No.	Observed Weight
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
Average	
Max	
Min Weight	

Acceptance Criteria: Minimum and maximum weight shall not deviate from average by more than 0.2 mg

The instrument calibration is OK / Not OK		
Calibrated By: **Date :**	**Checked By :** **Date :**	**Approved By :** **Date :**