



DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Operation, Cleaning, Calibration and Verification of Weighing Balances	Effective Date:
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1.0 OBJECTIVE:

To lay down a Procedure for Operation, Cleaning, Calibration and Verification of Weighing Balances.

2.0 SCOPE:

This SOP is applicable to Operation, Cleaning, Calibration and Verification of Weighing Balances used in various Departments, except Analytical Balance used in Quality Control Laboratory at

3.0 RESPONSIBILITY:

Concerned Department Officer /Executive

4.0 ACCOUNTABILITY:

Head QA

5.0 DEFINITION:

5.1 Cleaning:

5.1.1 Cleaning is the process of removing unwanted substances, such as dirt, infectious agents, and other impurities, from an object or environment. Cleaning occurs in many different contexts, and uses many different methods. Several occupations are devoted to cleaning.

5.2 Calibration:

5.2.1 The set of operation that establish, under specified condition, the relationship between values indicated by an instrument or system for measuring, recording and controlling , or the values represented by a material measure ,and the corresponding known value of a reference standard limits for acceptance of measuring should be established. Always remember any reference standard in always used in calibration.

5.3 Verification:



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5.3.1 Comparison of two or more items, or the use of supplementary tests, to ensure the accuracy, correctness, or truth of the information.

6.0 PROCEDURE:

6.1 OPERATION:

6.1.1 Check the cleanliness of the area.

6.1.2 Check the Pan or Platform and exposed parts of the Balance for cleaning and dryness.

6.1.3 Switch 'ON' the main power supply of the Balance.

6.1.4 Switch 'ON' the Balance and check that zero is displayed on the screen.

6.1.5 Check the level of the Balance with the help of Spirit Level. If required, Adjust the level with the help of the level screw provided at the bottom of balance & bring the bubble in the center of the circle of the level indicator.

6.1.6 Place the material/item to be weighed in the center of the weighing pan of the Balance.

6.1.7 Record the weight displayed.

6.1.8 Remove the material from the Balance.

6.1.9 Switch 'OFF' the Balance and main power supply at the end of the day.

6.1.10 Clean the Pan or Platform and exposed parts of the Balance.

6.2 VERIFICATION:

6.2.1 Verification Frequency: Daily before use/immediately after maintenance work/Power Failure /Relocation of Balance.

6.2.2 Verify the Balance using two Standard Weights certified by Weights and Measures Department.

6.2.3 Verify the Balance using Standard Weights as per **Annexure-VI**, Titled "**Balance Verification and Calibration Checkpoints**".

6.2.4 Place the Standard Weights one by one in the center of the Platform of the Balance and record the observations in **Annexure-II**, Titled "**Balance Verification Record**".



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6.2.5 Tolerance Limit:

6.2.5.1 Tolerance limit for the individual Balance is mentioned in **Annexure–VI**, Titled “**Balance Verification and Calibration Checkpoints**”.

6.2.5.2 If observations are out of Tolerance Limit, affix “**UNDER MAINTENANCE**” tag, sign & date and discontinue use of Balance.

6.2.5.3 Inform to Engineering department for corrective action.

6.2.5.4 Verify the Balance after corrective action as per procedure for verification described above.

6.2.6 OPERATING RANGE:

- **Minimum:** Least Count x 20
- **Maximum:** 80% of Balance Capacity

➤ During Calibration/Verification of weighing balances standard weight to be used for less suitable of minimum capacity and more suitable for maximum capacity as per standard weight availability, “Preferably uses of single standard weight”.

6.3 CALIBRATION OF BALANCE:

6.3.1 **Calibration Frequency:** First working day of every month before use.

6.3.2 Check the cleanliness of the area.

6.3.3 Check that the Pan or Platform and exposed parts of the Balance are clean and dry.

6.3.4 Check the level of the Balance with the help of Spirit Level. Adjust the level, if not leveled.

6.3.5 Switch ‘ON’ the main power supply of the Balance.

6.3.6 Switch ‘ON’ the Balance and check that zero is displayed on the screen.

6.3.7 Calibrate the Balance using Standard Weights as per **Annexure–VI**, Titled “**Balance Verification and Calibration Checkpoints**”.

6.3.8 Place the Standard Weights one by one in the center of the pan of the Balance and note down the reading in the **Annexure-I**, Titled “**Balance Calibration Record**”.

6.3.9 Following parameters to be checked while performing Calibration



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- Accuracy
- Linearity
- Precision
- Corner Load Test

6.3.10 ACCEPTANCE LIMIT:

- **Minimum:** Min Operating Range - Least Count to Min Operating Range + Least Count
- **Maximum:** Max Operating Range - Least Count to Max Operating Range + Least Count

6.4 CLEANING OF BALANCE :

- 6.4.1 Switch off the balance and disconnect the main switch before cleaning activity.
- 6.4.2 Remove the weight pan from support (if available).
- 6.4.3 Wipe the weight pan and surface of balance with cotton cloth or brush.
- 6.4.4 Clean the weighing pan and surface of balance with 70% IPA solution.
- 6.4.5 Take precaution while cleaning do not disturbed spirit level of balance.
- 6.4.6 Place the balance on its position and adjust the spirit level of balance (if available).
- 6.4.7 Place the weighing pan in its place.
- 6.4.8 Make the electrical connection and check its display.
- 6.4.9 After cleaning verify the balance and used.

6.5 ACCURACY:

- 6.5.1 Check the accuracy of the Balance using Standard Weights mentioned against the Capacity of the Balance in **Annexure–VI**, Titled “**Balance Verification and Calibration Checkpoints**”.
- 6.5.2 Place the Standard Weights one by one in the center of the Platform of the Balance and record the observations in the Balance Calibration Record.
- 6.5.3 **Acceptance Criteria:** Standard Weight more than $\pm 2 X$ of least count or $\pm 0.10\%$ of the Standard Weight (whichever is higher)



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6.6 LINEARITY:

6.6.1 Draw the Linearity Curve as per **Annexure-V**, Titled “**Linearity of Balance**” for the readings of Accuracy and find out the Correlation Factor. Record the observations in the Balance Calibration Record. (**Limit:** NLT 0.9999).

6.7 PRECISION:

6.7.1 Check the Precision of the Balance by using two Standard Weights mentioned in Balance Calibration Record.

6.7.2 Repeat the procedure 9 times for both the Standard Weight and one time randomly check after record the readings.

6.7.3 Calculate % RSD for both the Standard Weights. Record the observation in the Balance Calibration Record.

6.7.4 Acceptance Criteria: % RSD: NMT 0.10%.

6.8 CORNER LOAD TEST:

6.8.1 Place the Weights as mentioned in the Balance Calibration Record in the four corners & center of the Balance and note down the readings in the Balance Calibration Record. Calculate % RSD.

Note: While positioning the weights on corner it should touch the lips of the pan

6.8.2 Acceptance Criteria:

Deviation: Actual weight $\pm 2 \times$ least count or $\pm 0.10\%$ of the actual weight (whichever is higher) % RSD: NMT 0.10%

6.8.3 If all the parameters fall within the acceptance criteria limit, affix the Calibration Status label on the Balance.

6.9 If any observation is out of limit, affix “**UNDER MAINTENANCE**” tag and discontinue use of Balance. Inform to engineering department for corrective action.

6.10 Calibrate the Balance after corrective action has taken place.



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6.11 Switch off the Balance at the end of the day.

6.12 No repairs should be made to any balance by anyone other than a concerned engineering person.

Note: If Balance is not calibrated on or before due date, stop using the Balance till satisfactory Calibration is done.

7.0 ABBREVIATIONS:

Ltd.	Limited
SOP	Standard Operating Procedure
No.	Number
QA	Quality Assurance
QC	Quality Control
NLT	Not Less Than
NMT	Not More Than
RSD	Relative Standard Deviation
gm	gram
kg	kilogram

8.0 ANNEXURES:

Annexure No.	Title of Annexure	Format No.
Annexure – I	Balance Calibration Record	
Annexure – II	Balance Verification Record	
Annexure –III	Weighing Balance Calibration Status	
Annexure –IV	Weighing Balance Verification Status	
Annexure – V	Linearity of Balance	
Annexure – VI	Balance Verification and Calibration Checkpoints	

ENCLOSURES: SOP Training Record



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9.0 DISTRIBUTION:

- Controlled Copy No. 1 Quality Assurance Department
- Controlled Copy No. 2 Production Department
- Controlled Copy No. 3 Warehouse Department
- Controlled Copy No. 4 Engineering Department
- Master Copy Quality Assurance Department

10.0 REFERENCES:

USP-39

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		



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ANNEXURE-I BALANCE CALIBRATION RECORD

Month		Year	
Department		Location	
Balance ID. No.		Balance Capacity	
Least Count		Operating Range	
Calibration date		Next Calibration due Date	
Std. Wt. Certified On		Next Due Date	
Weight Box ID No.			

1. Accuracy by Using Standard Weight:

Standard Weight	Observed Weight	Difference	Limit*

*Standard Weight $\pm 2 \times$ least count of the Balance

2. Linearity: Attach the graph with this record. (Take actual standard weight on X-axis and observed weight on Y-axis)

Correlation Factor: (Limit: NLT 0.9999)

3. Precision:

Standard Weight	1	2	3	4	5	6	7	8	9	10	Mean	%RSD	Limit
													RSD NMT 0.10%

4. Corner Load Test:

Standard Weight	Left	Right	Front	Back	Middle	Mean	%RSD	Limit
								RSD NMT 0.10%

Calibration Done By:
Sign & Date

Checked By:
Sign & Date



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ANNEXURE-II BALANCE VERIFICATION RECORD

Month		Year	
Department		Least Count	
Location		Operating Range	
Balance ID NO.		Balance Capacity	
Min Standard Weight		Acceptance Limit	
Max Standard Weight			

S.No.	Date	Spirit Level Ok/Not Ok	Standard Weight (A)	Displayed Weight (B)	Difference (A-B)	Done By Sign & Date	Checked By Sign & Date	Remarks
			Min					
			Max					
			Min					
			Max					
			Min					
			Max					
			Min					
			Max					
			Min					
			Max					



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ANNEXURE-III

WEIGHING BALANCE CALIBRATION STATUS	
Capacity	:
Balance ID No.	:
Least Count	:
Calibration Weight Range	:
Permissible Weighing	:
Minimum Weighing	:
Maximum Weighing	:
Calibration Frequency	: Monthly
Verified By (QA Officer / Executive)	
Sign / Date :	

ANNEXURE-IV

WEIGHING BALANCE VERIFICATION STATUS	
Capacity	:
Balance ID No.	:
Least Count	:
Permissible Weighing	:
Minimum Weighing	:
Maximum Weighing	:
Verification Frequency	: Daily
Verified By (QA Officer/Executive)	
Sign/Date:	
FORMAT No.:	



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ANNEXURE-V LINEARITY OF BALANCE

Section/area:

Weighing Balance ID No.:

Calibration Date:

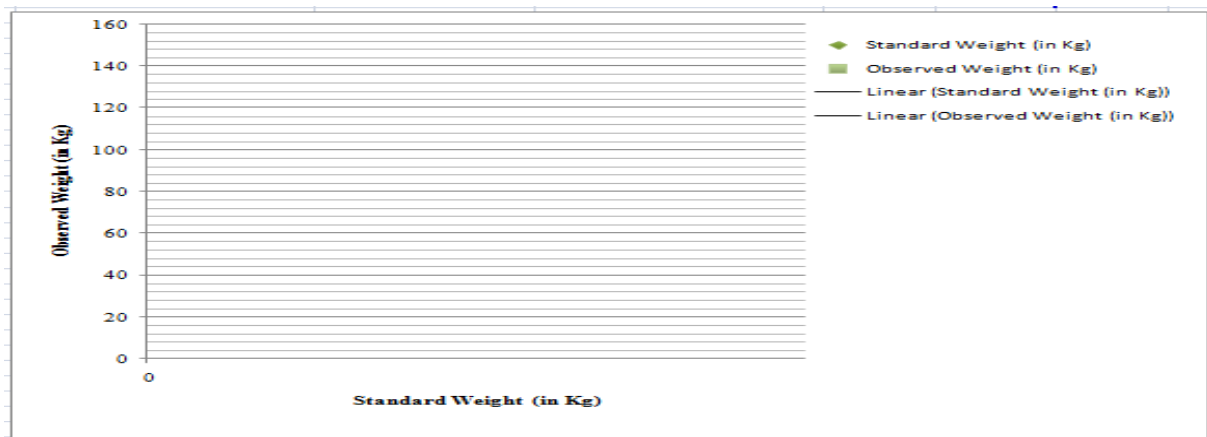
Calibration Due Date:

LINEARITY TABLE:

Standard Weight (in kg/gm/mg)	Observed Weight (in kg/gm/mg)

Correlation Factor: _____ (Limit: NLT 0.9999)

LINEARITY GRAPH:



Done By
Sign & Date

Checked By:
Sign & Date



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ANNEXURE-VI BALANCE VERIFICATION AND CALIBRATION CHECKPOINTS

S.No.	Verification				Calibration	
	Weighing Balances Capacity	Least Count	Operating Range	Accuracy By Using Standard Weight	Acceptance Limit	
1.	200 gm	0.001			Min	
					Max	
2.					Min	
					Max	

Note: Only format shall be revised in case any new additions of weighing balance with different Capacity/Least Count/Accuracy Limit.