DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Servicing & Calibration of Balance (Half Yearly)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

OBJECTIVE

To lay down a procedure to describe the steps to be followed while servicing and calibration of balance.

SCOPE

Applicable to all balances except analytical balances.

RESPONSIBILITY

Trained person of External agency: To do servicing and calibration.

Concerned department Executives : To check and ensure the Calibration

ACCOUNTABILITY

Department Head

REFERENCES

In- House

ATTACHMENTS

Attachment I: Balance Calibration Record

PROCEDURE

1.0 Check the cleanliness of the area.

2.0 Check that platform and exposed parts of the balance are clean and dry

3.0 Check the level of the balance with the help of spirit level. Adjust level, if not leveled.

4.0 Switch on the main power supply of the balance.

5.0 Following parameters to be checked while performing calibration.

- Accuracy
- Linearity
- Precision
- Corner Load Test

FREQUENCY: Every 6 months

Note: If balance is not calibrated on or before due date, stop using the balance till Satisfactory calibration is done.

6.0 Accuracy

6.1 Check the accuracy of the balance by using 5 standard stamped weight.

6.2 Place standard weight one by one in the center of the platform and record the observations in the balance calibration record.

6.3 Acceptance Criteria : Standard Weight ± 2 x Least Count

7.0 **Linearity**

7.1 Draw the linearity curve for the above readings and find out the correlation factor. Record the observations in the balance calibration record.(Limit: NLT 0.9999)

8.0 Precision

8.1 Check the Precision of the balance by using standard weight equivalent to 5 % of maximum capacity.

8.2 Repeat the procedure for 5 time and record the readings.

8.3 Repeat 8.1 to 8.2 using standard weight equivalent to 50 % of maximum capacity.

8.4 Calculate % RSD for both the standard weights. Record the observations in the balance calibration record.

8.5 Acceptance Criteria :

% RSD NMT 0.5 %

9.0 Corner Load test

9.1 Place standard weight equivalent to 30 % of maximum capacity in four corners and center of the balance and note down the readings in record. Calculate % RSD. Record the observations in the balance calibration record.

9.2 Acceptance Criteria:

Deviation : Standard Weight ± 2 x Least Count

% RSD : NMT 0.5 %

10.0 If all the parameters fall with the acceptance criteria limit, affix the calibration tag as per SOP. .

11.0 If any of the observation is out of limit, correct and reset the balance

12.0 After resetting, Calibrate again all the parameters as mentioned in point 6.0 to 8.0

13.0 Switch off the balance at the end of day.

Note : No repairs should be made to any balance by anyone other than a qualified maintenance person.

14.0 ABBREVIATIONS

QA : Quality Assurance

CC No. : Change Control number

NMT : Not More Than

RSD : Relative Standard deviation

SOP : Standard Operating Procedure

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ATTACHMENT I
BALANCE CALIBRATION RECORD

Balance			Location	Calibration date	Next Calibration due Date
ID. No	**Sr. No.**	**Capacity**			

Standard weights Certified On	Next Due Date

1.0 Accuracy by using standard weight.

Standard weight	Observed weight	Limit*

* Standard weight ± 2 x Least Count of the balance

2.0 Linearity +

Correlation factor: (Limit: Not less than 0.9999)

+Attach Graph with this record

3.0 Precision:

Standard weight	1	2	3	4	5	Mean	%RSD	Limit
								NMT 0.5 %

4.0 Corner load test: (Weight equivalent to 30 % of the balance capacity)

Standard weight	Left	Right	Front	Back	Center	Mean	%RSD	Limit
								NMT 0.5 %

Done by :
Date :

Checked by:
Date :

	Prepared By	Checked By	Approved By	Authorised By
Sign				
Date				
Designation	**QA Officer**	**QA Executive**	**QA Head**	**Plant Head**