



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Control	<b>SOP No.:</b>
<b>Title:</b> Cleaning, Calibration and Operation of Analytical Balance (XP 205)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

#### 1.0 OBJECTIVE:

To lay down procedure for cleaning, calibration and operation of Analytical balance.

#### 2.0 SCOPE:

This SOP is applicable at .....

#### 3.0 RESPONSIBILITY- Execution - Executives QC

Checking - Assistant Manager QC

#### 4.0 ACCOUNTABILITY - Manager Quality Control

#### 5.0 PROCEDURE:

##### 5.1 Operation

- 5.1.1 Connect the plug of the AC adapter into the AC adapter socket of the balance and connect to the power supply.
- 5.1.2 The balance must be connected to power supply for 30 minute in order to reach the operating temperature.
- 5.1.3 Ensure that anti vibration table / working bench and balance is clean.
- 5.1.4 Ensure that the position of the bubble is exactly at the center of the circle.
- 5.1.5 If not leveled turn the leveling screw of the balance clock wise or anti clock wise to get the bubble exactly at the central position of the circle.
- 5.1.6 Switch on the balance by pressing 'ON' once, and wait till the figure 0.00000 gm gets display.
- 5.1.7 Press "Adjust. Int" for internal calibration.
- 5.1.8 During internal calibration, display indicates "INTERNAL ADJUSTMENT, Please Wait"
- 5.1.9 After completion of internal calibration, display indicates "ADJUSTMENT DONE, Press Ok"
- 5.1.10 Place the butter paper over the pan; ensure that all the windows are closed properly.
- 5.1.11 Tare the weight of the paper by pressing the Tare key.
- 5.1.12 Weigh the require quantity of sample by closing the window.
- 5.1.13 Wait till the weight gets stabilized as the bubble get disappear from the display.
- 5.1.14 Record the weight or take printout.

##### 5.2 Calibration



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<b>Issue Date:</b>	<b>Page No.:</b>

#### 5.2.1 Auto calibration

5.2.1.1 Before carrying out calibration ensure that the weighing pan must be clean, empty and all windows are closed.

5.2.1.2 Press and “Adjust. Int” for internal calibration.

5.2.1.3 During internal calibration, display indicates “INTERNAL ADJUSTMENT, Please Wait”

5.2.1.4 After completion of internal calibration, display indicates “ADJUSTMENT DONE, Press Ok”

5.2.1.5 During calibration the weighing pan must be clean, empty and all windows are closed.

#### 5.2.2 Daily calibration

5.2.2.1 Before carrying out internal calibration ensure that the weighing pan must be clean empty and all windows are closed.

5.2.2.2 Place the 20 mg standard weight with the help of forceps over the pan.

5.2.2.3 Note the displayed weight after its stabilization.

5.2.2.4 Repeat the operation with 50 mg. Record the displayed weight.

5.2.2.5 The difference in the observed and actual values shall not be more than  $\pm 0.2$  mg from the actual value (Refer to the calibration certificate of the weight box).

#### 5.2.3 Monthly calibration

##### 5.2.3.1 Uncertainty test

5.2.3.1.1 Weigh the certified fractional weights of capacity 50,100, 200 & 500 mg and 1, 2 & 5 gms with the help of a clean forceps.

5.2.3.1.2 The difference in the observed and actual values shall not be more than 0.1% from the actual value (Refer to the calibration certificate of the weight box).

##### 5.2.3.2 Measurement Uncertainty

5.2.3.2.1 Weigh specified weight 50 & 100 mg 10 times each, record the readings and determine the standard deviation (D).

5.2.3.2.2 Calculate the measurement uncertainty as given below :

$$\text{Measurement Uncertainty} = \frac{\text{Random error} + \text{Systematic error}}{\text{-----}} \times 100$$



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Actual weight

Random error =  $3 \times$  Standard Deviation (n=10)

Systematic error = Observed weight(Average) - Actual weight

5.2.3.2.2 The measurement uncertainty shall not be more than 0.1%.

5.2.3.3 Eccentricity / off center accuracy

5.2.3.3.1 Place 100gm standard weight on centre, left corner, right corner, top corner, bottom corner of the pan.

5.2.3.2.2 Note down the stable weight.

5.2.3.2.2 The variation it should not exceed  $\pm 0.1\%$  of actual value.

5.2.4 Frequency

5.2.4.1 Daily calibration - Daily once

5.2.4.2 Monthly calibration – monthly once

5.2.5 Acceptance criteria

5.2.5.1 Auto calibration - Should pass

5.2.5.2 Daily calibration - Should pass

### 5.3 Cleaning

Cleaning should be done daily with lint free cloth along with 70% IPA.

### 6.0 SAFETY & PRECAUTIONS:

6.1 Ensure that at the time of weighing the window of the balance are closed.

6.2 Always keep the balance on plane surface.

6.3 Before and after weighing, always clean the pan & balance with 70% IPA.

### 7.0 REVISION HISTORY

Revision No.	Reason for Revision	Superseded from & date



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#### 8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/Date	By	Sign/Date

#### 9.0 REFERENCES:

Not applicable

#### 10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

IPA : Iso Propyl Alcohol

% : Percentage

gm : Gram

mg : Milligram

**Annexure I: Monthly Calibration Record Of Analytical Balance**

**Annexure II: Daily Calibration Record Of Analytical Balance**



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**ANNEXURE – I**  
**MONTHLY CALIBRATION RECORD OF ANALYTICAL BALANCE**  
**Uncertainty test**

Make: \_\_\_\_\_ Location : \_\_\_\_\_  
Serial / Model No.: \_\_\_\_\_ ID No. : \_\_\_\_\_  
Calibration on : \_\_\_\_\_ Next due on : \_\_\_\_\_

Standard weight	Certified value	Observed value	Percentage difference	Acceptance criteria
50 mg				± 0.1%
100 mg				± 0.1%
200 mg				± 0.1%
500 mg				± 0.1%
1 gm				± 0.1%
2 gm				± 0.1%
5 gm				± 0.1%



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### MONTHLY CALIBRATION RECORD OF ANALYTICAL BALANCE

#### Measurement Uncertainty test

Make: \_\_\_\_\_ Location : \_\_\_\_\_  
Serial / Model No.: \_\_\_\_\_ ID No. : \_\_\_\_\_  
Calibration on : \_\_\_\_\_ Next due on : \_\_\_\_\_

Standard weight : <u>50 mg</u>		Standard weight : <u>100 mg</u>	
Certified weight : _____		Certified weight : _____	
Sr. No.	Observed value	Sr. No.	Observed value
1		1	
2		2	
3		3	
4		4	
5		5	
6		6	
7		7	
8		8	
9		9	
10		10	
Average		Average	
Standard deviation		Standard deviation	
%RSD		%RSD	

Random error:	Random error:
Systematic error:	Systematic error:
Measurement uncertainty:	Measurement uncertainty:

Acceptance criteria : NMT 0.1%



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### MONTHLY CALIBRATION RECORD OF ANALYTICAL BALANCE

#### Eccentricity / Off center accuracy

Make: \_\_\_\_\_ Location : \_\_\_\_\_  
Serial / Model No.: \_\_\_\_\_ ID No. : \_\_\_\_\_  
Calibration on : \_\_\_\_\_ Next due on : \_\_\_\_\_

Sr. No	Certified value	Observed value	Percentage difference	Acceptance criteria
Centre				± 0.1%
Right corner				± 0.1%
Left corner				± 0.1%
Top corner				± 0.1%
Bottom corner				± 0.1%

Balance performance : complies / does not comply

Remark :

Done by:

Date:

Checked by:

Date:

