



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning, Operation and calibration of Electronic Balance (Capacity 220 g) Make: Sartorius (Model No- MSE225-100-DU)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

- 1.1 To lay down a procedure for cleaning, operation and calibration of electronic weighing balance (Capacity 220 g), Make: Sartorius (Model No-MSE225P-100-DU).

2.0 SCOPE:

- 2.1 This procedure is applicable to the Cleaning, Operation and Calibration of Electronic Weighing balance (Capacity 220 g), Make: Sartorius (Model No-MSE225P-100-DU) in Production area.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate: Cleaning, Operation and Calibration of Electronic balance
- 3.2 Production Officer/Executive: Checking Cleaning, Operation and Calibration of Electronic balance.
- 3.3 Head Production: SOP Compliance of Cleaning, Operation and Calibration of Electronic balance
- 3.4 IPQA Person: Line Clearance and verification of Cleaning, Operation and Calibration of Electronic balance

4.0 DEFINITION (S):

- 4.1 NA

5.0 PROCEDURE:

5.1 "TYPE A" CLEANING:

Change over from one batch to next batch of the same product and same potency and of similar product with ascending potency.

- 5.1.1 Remove "EQUIPMENT STATUS" label and affix dully filled "UNDER CLEANING" label to the instrument
- 5.1.2 Ensure that the power supply is OFF and electric connection is disconnected to the balance.
- 5.1.3 Clean the inner and outer protective guard and clean with dry lint free cloth.
- 5.1.4 Clean the platform and weighing pan with dry lint free cloth.
- 5.1.5 Clean the bottom side of the balance and area with tissue paper taking care that no tablet/capsule should remain inside the narrow opening or edges of the balance.
- 5.1.6 Close all the protective guards.



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5.1.7 Clean the external surface of printer with wet lint free cloth and finally clean with dry lint free cloth.

5.1.8 Ensure that electronic weighing balance and printer are visually clean and dry.

5.1.9 Replace the “UNDER CLEANING” status label with “CLEANED” status label with batch details of next batch details, date and signature of production officer and verified by QA officer.

5.2 “TYPE B” CLEANING

This is a cleaning procedure for Changeover of product with different actives/Color/ descending potency/if the same product processed for more than a week or after maintenance of contact parts.

5.2.1 Remove “EQUIPMENT STATUS” label and affix dully filled “UNDER CLEANING” label to the instrument.

5.2.2 Cleaning of electronic balance to be done during product change over and record the cleaning activity in Annexure-I “Cleaning Checklist of Electronic Balance (Capacity 220 g)”.

5.2.3 Switch ‘OFF’ the main power supply of the electronic weighing balance.

5.2.4 Open all windows of protective guard and clean with wet lint free cloth and finally clean with lint free cloth.

5.2.5 Take out the weighing pan from center of the instrument and clean with wet lint free cloth and finally clean with dry lint free cloth.

5.2.6 Clean the bottom side of the balance and area with tissue paper taking care that no tablets /capsule should remain inside the narrow opening or edges of the balance.

5.2.7 Clean the external surface of the electronic weighing balance with wet lint free cloth and finally clean with lint free cloth.

5.2.8 Close all the protective guards.

5.2.9 Clean the external surface of printer with wet lint free cloth and finally clean with dry lint free cloth.

5.2.10 Ensure that electronic weighing balance and printer are visually clean and dry.

5.2.11 Replace the “UNDER CLEANING” status label with “CLEANED” status label with batch details of next batch details, date and signature of production officer and verified by QA officer.

5.3 Frequency:

5.3.1 Type ‘A’ cleaning is applicable after every batch to batch change over.

5.3.2 Type ‘B’ cleaning is applicable Daily start of the day or product change over which ever earlier.



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NOTE:

1. Electronic balance at IPQA UNDER CLEANING by type 'A' cleaning. Type 'B' cleaning is applicable only for balance present in the cubicles.
2. Calibration of electronic balance shall be performed after each Type B and at the start of the day as per 5.6.

5.4 OPERATION:

- 5.4.1 Ensure the cleanliness of the weighing balance.
- 5.4.2 Place the balance in area with minimum temperature fluctuation and on a solid support in order to avoid jerks or vibrations.
- 5.4.3 Ensure the calibration status of the instrument.
- 5.4.4 Switch on the power supply of electronic weighing balance by pressing wait for weighing mode, to display 0.00000 g on balance screen.
- 5.4.5 Ensure the level of the electronic weighing scale for correct results. Electronic weighing balance is equipped with auto level correction. An integrated sensor detected the level and trigger the warning message when the leveling is required with indication on display press the key and display will show AUT.LEV.
- 5.4.6 Place the disposable plate on the disc at center of the balance
- 5.4.7 Place empty container or butter paper on which sample weight is to be taken. Then process 'TARE' for tare and place the sample as required. Display will again show actual weight of sample. Note the weight.
- 5.4.8 After weighing is over, to turn of the balance press until a zero in the lower left-hand corner appears indicates that balance has been switched off and is in standby mode. Crush the disposable plate and put it in the waste Bin.

5.5 Operation of Printer:

- 5.5.1 Check electric power supply connection and attachment with printer.
- 5.5.2 Ensure that the print roll is loaded. If print roll is over replace it with new one by pressing.
- 5.5.3 After each reading press the icon for print, repeat the process for completion of sample set.

5.6 Calibration:

- 5.6.1 Switch on the instrument, and wait till weighing mode appear.



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5.6.2 Press the 'CAL' key of the instrument than display will show CAL. RUN and instrument start auto calibration.

5.6.3 After completion of calibration display will show CAL. END.

5.7 Daily Calibration:

5.7.1 Daily calibration of balance should be performed at start of operation.

5.7.2 After completion the internal calibration press tare to zero display.

5.7.3 Place 20 mg standard weight in the center of the pan with help of forceps.

5.7.4 Note the displayed weight after the display is stable.

5.7.5 Repeat operation with 100 mg, 500 mg, 5 g and 50 g standard weights. Note the displayed weight after the display is stable & record in Annexure-II "Daily Calibration Record: Electronic Balance (Capacity 220 g)".

5.8 Full scale Calibration:

5.8.1 Calibration the balance with each individual standard weight in the center of the pan (200 g, 100 g, 50 g, 20 g, 10 g, 5 g, 2 g, 1 g, 500 mg, 200 mg, 50 mg, 20 mg, and 10 mg) and record the readings in Annexure-III "Full scale Calibration Electronic Balance (Capacity 220 g)".

5.8.2 And affix 'CALIBRATION TAG' as per SOP ("Status labeling").

5.9 Uncertainty:

5.9.1 Use 50 mg and 100 mg standard weight for measurement of uncertainty.

5.9.2 Place 50 mg standard calibrated weight in the center of the pan.

5.9.3 Wait for display to stabilize then note down the reading.

5.9.4 Take 10 replicate reading for same on the balance and note down.

5.9.5 Calculate the standard deviation of above 10 reading.

$$S = \sqrt{\frac{(x-x_1)^2 + (x-x_2)^2 + (x-x_3)^2 + (x-x_4)^2 + (x-x_5)^2 + (x-x_6)^2 + (x-x_7)^2 + (x-x_8)^2 + (x-x_9)^2 + (x-x_{10})^2}{(n-1)}}$$

Where, n = 10

X = Mean value of data

5.9.6 Now repeat the above procedure with 100 mg standard weight.

5.9.7 Calculate the uncertainty as follows.

3 x Standard deviation

Actual weight



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5.9.8 Uncertainty should not exceed 0.001 and record the same in Annexure-IV Uncertainty & Drift Checks of Electronic Balance (Capacity 220 g)".

5.9.9 Take 5 more reading.

5.9.10 Calculate the mean of 6 readings.

5.9.11 The average weight shall be fixed as average actual weight for the balance.

5.9.12 The observed weight should not exceed ± 0.2 mg of the average/ mean weight and record in Annexure-IV "Uncertainty & Drift Checks of Electronic Balance (Capacity 220 g)".

5.10 Tolerance:

5.10.1 Auto calibration test should pass for balance.

5.10.2 Daily Calibration record of balance $\pm 0.1\%$ of actual weight.

5.10.3 Full scale calibration $\pm 0.1\%$ of actual weight.

5.10.4 Uncertainty test should not exceed 0.001

5.10.5 Drift check ± 0.2 mg of the average weight of 20 g.

5.11 Frequency:

5.11.1 Auto calibration & daily calibration record – Daily

5.11.2 Full scale calibration – monthly.

5.11.3 Uncertainty & drift check – Every three month.

5.8.3 If instrument is out of calibration label of the instrument, record the calibration results in annexure-III "Full scale Calibration Electronic Balance (Capacity 220 g)", annexure-IV Uncertainty & Drift Checks of Electronic Balance (Capacity 220 g)".

5.12 Precautionl

5.12.1 In case of any spillage of tablets/ capsules during in process shall be discarded

5.12.2 Balance should not be placed on stable, vibration free and leveled support.

5.12.3 Balance should not be placed in hazardous area.

5.12.4 Clean the pan properly before and after use.

5.12.5 Always keep the glass doors of the balance closed.

6.0 ABBREVIATION (S)I

6.1 g : Grams

6.2 Mg : Milligrams



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6.3 SOP : Standard Operating Procedure

6.4 NA : Not applicable

7.0 REFERENCE (S):

7.1 SOP: Status labeling.

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure - I	Cleaning Checklist of Electronic Balance (Capacity 220 g)		Logbook
Annexure-II	Daily Calibration Record: Electronic Balance (Capacity 220 g)		Logbook
Annexure-III	Full scale Calibration Electronic Balance (Capacity 220 g)		Logbook
Annexure-IV	Uncertainty & Drift Checks Of Electronic Balance (Capacity 220 g)		Logbook

9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled copy (S)** : Production department (02), Quality Assurance (01)

9.3 **Reference copy (S)** : Production department (04)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) For Revision	Details Of Revision	Effective Date
1	00		New SOP	NA	



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ANNEXURE I

Cleaning Checklist of Electronic Balance (Capacity 220 g) Make: Sartorius (Model No- SE225P-100-DU)

Name of the Equipment		Electronic Balance	
Equipment I.D. No.		Previous product	
Batch No.		Date	

S.No.	Activity	Activity Performed
1.	Windows of protective guard clean with wet lint free cloth and finally clean with lint free cloth.	
2.	Take out the weighing stainless steel disc from center of the instrument and clean with wet lint free cloth and finally clean with dry lint free cloth.	
3.	Clean the bottom side of the balance and area with tissue paper taking care that no tablet/capsule should remains inside the narrow opening or edges of the balance.	
4.	Clean the external surface of electronic weighing balance with wet lint free cloth and finally clean with lint free cloth.	
5.	Close all the protective guards.	
6.	Clean the external surface of printer with wet lint free cloth and finally clean with dry lint free cloth.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

Note: Put '√' mark if activity performed and put 'X' if activity not performed.



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ANNEXURE III

Full scale Calibration Electronic Balance (Capacity 220 g) Make: Sartorius (Model No- MSE225P-100-DU)

Location:	Balance ID No.:
Least Count: upto 60 g	0.01 mg / 0.00001 g
Least Count: 60 g to upto 120 g	0.02 mg / 0.00002 g
Least Count: \geq120 g	0.05 mg / 0.00005 g
Calibrated On	Next Calibration Due On

Capacity: 220 gm

Full Scale Calibration

Calibrated weight box Certificate No.: _____

Limit: ± 0.1 % of actual weight in mg/gm

*** Balance Spirit Level:** _____

Theoretical weight	Mass / Actual weight	Observed weight	Limit in mg / g	Remark
200 g				
100 g				
50 g				
20 g				
10 g				
5 g				
2 g				
1 g				
500 mg				
200 mg				
100 mg				
50 mg				
20 mg				
10 mg				

Opinion: The Instrument Calibration Complies / Does Not Comply.

Note: *Record the balance level as Ok / Not Ok (Bubble position in center)



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ANNEXURE IV

Uncertainty & Drift Checks of Electronic Balance (Capacity 220 g) Make: Sartorius (Model No-MSE225P-100-DU)

Location:	Balance ID No.:		
Least Count: upto 60 g	0.01 mg / 0.00001 g	Capacity: 220 gm	
Least Count: 60 g to upto 120 g	0.02 mg / 0.00002 g		
Least Count: ≥ 120 g	0.05 mg / 0.00005 g		
Calibrated On		Next Calibration Due On	

UNCERTAINTY

S.No.	50 mg	100 mg
x1		
x2		
x3		
x4		
x5		
x6		
x7		
x8		
x9		
x10		
Mean		

$$\text{Mean (x)} = \frac{(x1+x2+x3+x4+x5+x6+x7+x8+x9+x10)}{10}$$

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Standard Deviation

$$S = \sqrt{\frac{(x-x_1)^2 + (x-x_2)^2 + (x-x_3)^2 + (x-x_4)^2 + (x-x_5)^2 + (x-x_6)^2 + (x-x_7)^2 + (x-x_8)^2 + (x-x_9)^2 + (x-x_{10})^2}{(n-1)}}$$

Where, n = 10

x = Mean value of data

Standard Deviation for 50 mg weight =

Standard Deviation for 100 mg weight =

Calculate the uncertainty as follows:-

$$= \frac{3 \times \text{Standard deviation}}{\text{Actual weight}}$$

OBSERVED UNCERTAINTY:

For 50 mg –

For 100 mg –

Acceptance Limit: the Uncertainty test should not exceed 0.001.

Remarks: - The Instrument Calibration **Complies/ Does Not Comply**.



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DRIFT CHECK

Take 20 g weight:

01. _____ 02. _____ 03. _____

04. _____ 05. _____ 06. _____

Mean: _____

The observed Individual weight should not exceed ± 0.2 mg of the average/Mean weight.

Opinion: The Instrument Calibration is **Complies/ Does Not Comply**.