

	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT		
SOP Title :	SOP for Cleaning, Operation and Calibration of Analytical and Weighing Balances.		
SOP No.:	SOP/QA/062	Effective Date:	01/06/2025
Revision No.:	00	Issued Date:	19/05/2025
Supersedes:	NA	Review Month:	May' 2028
Page No.:	1 of 13		

1. OBJECTIVE:

1.1 To provide guidelines for Cleaning, Operation and Calibration of Analytical balance and Weighing balance.

2. SCOPE:

This procedure is applicable to the Analytical balance and Weighing balance located at NOVO EXCIPIENTS PVT. LTD. NAVI MUMBAI.

3. RESPONSIBILITY:

3.1 User Department:

3.1.1 To follow the SOP.

3.1.2 To maintain the record as suggested in SOP.

3.2 User Department Manager/Designee:

3.2.1 To ensure the implementation of SOP.

3.3 Maintenance Officer/Designee:

3.3.1 To rectify the Analytical and Weighing balance in case of an error or breakdown.

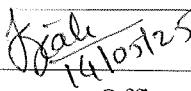
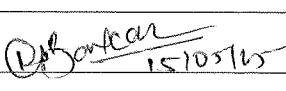
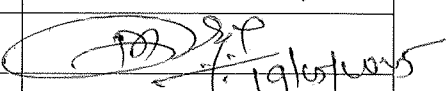
3.4 QA Officer / Designee:

3.4.1 To verify the Daily Verification and Monthly calibration of Weighing Balances.

3.5 QA Manager / Designee:

3.5.1 To Approve the SOP.

3.5.2 To ensure the compliance of SOP.

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/2025
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

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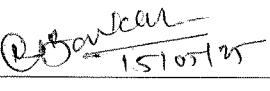
4. ABBREVIATIONS:

SOP	Standard operating Procedure
QA	Quality Assurance
PR	Production
WR	Warehouse
FD	Formulation and Development
QM	Microbiology
QC	Quality Control
Pvt.	Private
Ltd.	Limited
IPA	Isopropyl alcohol
g/gm	Gram
mg	Milligram
Kg	Kilogram
Max	Maximum
Min	Minimum
Wt.	Weight
OOC	Out of Calibration

5. PROCEDURE:

5.1 Definition:

- 5.1.1 **Calibration:** Calibration is the process of establishing the relationship between the values indicated by an instrument or system and the corresponding known values of a reference standard, ensuring accurate measurements.

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- 5.1.2 **Verification:** Verification is the process of confirming that a balance is functioning correctly and providing accurate measurements after calibration or over a period of usage. This involves checking the balance's performance against known weight standards at regular intervals.
- 5.1.3 **Eccentricity:** Deviation in the measurement value caused by eccentric loading in other words, the asymmetrical placement of the center of gravity of the load relative to the load receiver. Eccentricity usually is expressed as the largest magnitude of any of the deviations between an off-center reading and the center reading for a given test load.
- 5.1.4 **Repeatability:** Ability of a weighing instrument to display identical measurement values for repeated weighing's of the same objects under the same conditions. It is usually expressed as the standard deviation of multiple weighing's.
- 5.1.5 **Accuracy:** Accuracy of a balance is the closeness of the displayed weighing result to the **true value** of the weight placed on the balance. In other words, it's how correct the balance's reading is when you put a known standard weight on it.

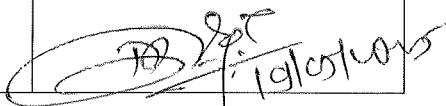
5.2 Precautions, Cleaning, Operations and Calibration of Weighing and Analytical Balance:

5.2.1 Precaution:

- 5.2.1.1 Keep the balance always clean.
- 5.2.1.2 Do not leave anything on the weighing pan.
- 5.2.1.3 Keep the balance on the vibration free surface.
- 5.2.1.4 Do not exceed the maximum limit.
- 5.2.1.5 Check zero reading before starting the weighing.
- 5.2.1.6 Keep the balance away from exhaust fan or direct air.
- 5.2.1.7 Check spirit level wherever applicable.

5.2.2 Cleaning:

- 5.2.2.1 Ensure balance is in 'OFF' condition before cleaning.

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5.2.2.2 Open the shutter of the balance and remove pan which is inside the balance.

(Applicable to those balances who have pan or shutter).

5.2.2.3 Remove dust and powder with the help of brush. If required use IPA -70% solution to clean and remove oily substances or any spot inside the balance.

5.2.2.4 Finally clean it with tissue paper, care to be taken for proper drying after use of IPA- 70%.

5.2.2.5 Clean outside of balance & shutter with tissue paper wetted with 70% IPA then clean with dry tissue paper.

5.2.2.6 After cleaning close the shutter, switch on the main and press power button.

5.2.2.7 Frequency: Daily/Whenever necessary.

5.2.3 Operation (Weighing Balance):

5.2.3.1 Ensure that the instrument is clean and dust free.

5.2.3.2 Ensure that the balance is calibrated.

5.2.3.3 Switch ON the mains. Then press the power button  present on balance.

5.2.3.4 The balance will display zero reading.

5.2.3.5 Ensure spirit level (bubble position) is at the center and make adjustment if required. OR Rotate the level screw of the balance so that bubble position come to the center and rectify if necessary. (Use portable spirit level whenever required)

5.2.3.6 Place the material on weighing pan and record the reading.

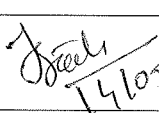
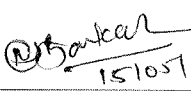
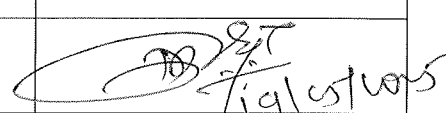
5.2.3.7 Ensure that the balance is in standby mode; when not in use.

5.2.4 Operation (Analytical Balance):

5.2.4.1 Ensure that the instrument is clean and dust free.

5.2.4.2 Ensure that the balance is calibrated.

5.2.4.3 Ensure that the analytical balance is leveled by checking the spirit level and make adjustments if required using the leveling screws.

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5.2.4.4 Switch ON the mains and then press power button  present on balance and allow it to stabilize for 30 minutes.

5.2.4.5 Press Tare key, and Balance will display zero reading.

5.2.4.6 Open the shutter and Place the material to be weighed on the pan.

5.2.4.7 Close the shutter and print out the weight displayed on balance screen.

5.2.4.8 On the weight print, immediately put details of product, test name, sign with date.

5.2.4.9 Open the shutter and remove the material from the pan after weighing.

5.2.4.10 Check that the display shows zero reading on the screen. If not press Tare key.

5.2.4.11 Ensure that when balance is not in use; then press power button  present on balance and switch off the mains.

5.2.5 Calibration:

5.2.5.1 Daily calibration of Analytical Balance:

5.2.5.1.1 After equilibration of the instrument, turn on the balance by pressing power button.

5.2.5.1.2 Place the standard calibrated 100 g weight on the pan and press F key. (for Auto calibration)

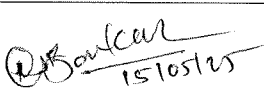
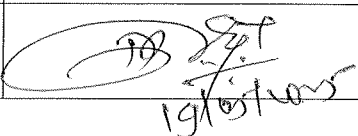
5.2.5.1.3 After completion of auto calibration, open the shutter place 50 mg standard weight on the center of the pan, display the reading and take printout.

5.2.5.1.4 Remove the weight from the pan and close the shutter.

5.2.5.1.5 Repeat the steps from 5.2.5.1.3 to 5.2.5.1.4 for standard weights of 0.5000 g, 1.0 g, 10 g, 50 g and 100 g and note down the weights.

5.2.5.1.6 Acceptance criteria: ± 0.1 % of actual standard weight.

5.2.5.1.7 If calibration results are found to be **outside the acceptance criteria** then follow the procedure outlined in flowchart for

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cleaning, operation and calibration of Analytical and Weighing balance. Refer Annexure No. A/SOP/QA/062/03.

5.2.5.1.8 Maintain the record in the format for Daily calibration of analytical balance. Format No. F/SOP/QA/062/01.

5.2.5.1.9 Frequency of calibration: Daily or prior to use

5.2.5.2 Daily verification of Weighing Balance:

5.2.5.2.1 Operate the weighing balance as per point No.5.2.3

5.2.5.2.2 Place the standard calibrated weights on the center of the balance platform gently as specified in the format for daily verification of balance. Format No. F/SOP/QA/062/03, F/SOP/QA/062/05, F/SOP/QA/062/07, F/SOP/QA/062/08, F/SOP/QA/062/11, F/SOP/QA/062/13 & F/SOP/QA/062/15. The weights specified in the format should be kept in the ascending order.

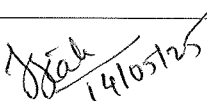
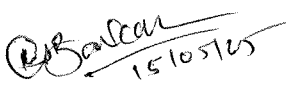
5.2.5.2.3 For daily verification of 600 gm Weighing Balance in Production and Warehouse refer the Format No. F/SOP/QA/062/07 and for Quality control and F&D refer Format No. F/SOP/QA/062/08.

5.2.5.2.4 Record the displayed reading on balance and check the variation; it should be within the specified tolerance limit: ± 0.1 % of actual standard weight.

5.2.5.2.5 If the variation is within the specified tolerance limit then continue to use the balance.

5.2.5.2.6 Remove the standard weight and keep it in the weight box. Display shows Zero Reading.

5.2.5.2.7 If the variation is not within tolerance limit then label the balance as "Out of Calibration" as per Label No. (L/SOP/QA/062/02-00). Inform the User Department Head and Quality Assurance Head.

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5.2.5.2.8 Inform Maintenance department or contract agency responsible for servicing and rectification.

5.2.5.2.9 Do not uses balance until the error is rectified. After rectification, recalibrate the balance before use.

5.2.5.2.10 Maintain the record in the format for Daily verification of weighing balance. Format No. F/SOP/QA/062/03, F/SOP/QA/062/05, F/SOP/QA/062/07, F/SOP/QA/062/09, F/SOP/QA/062/11, F/SOP/QA/062/13, F/SOP/QA/062/15

5.2.5.2.11 Frequency of daily verification: Daily or prior to use.

5.2.6 Monthly Calibration of Balance:

5.2.6.1 Accuracy:

5.2.6.1.1 Operate the weighing balance as per point No.5.2.3 & 5.2.4

5.2.6.1.2 Place the standard calibrated weights on the center of the balance platform gently specified in the format for monthly calibration of balance.

5.2.6.1.3 Record the value the balance shows.

5.2.6.1.4 Compare the displayed value to the **true value** of the standard weight.

5.2.6.1.5 The balance shall be accurate, meaning that the difference between the measured value and the known value of the weight used shall not exceed 0.10%.

5.2.6.1.6 Use following formula to calculate Accuracy Deviation

$$\text{Accuracy Deviation (\%)} = \left(\frac{\text{Displayed Value} - \text{True Weight}}{\text{True Weight}} \right) \times 100$$

5.2.6.1.7 The deviation should be within the specified tolerance limit $\leq 0.10\%$ actual standard weight.

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5.2.6.1.8 Remove the standard weight and keep it in the box. Display shows Zero reading.

5.2.6.2 Full Range Calibration Test:

5.2.6.2.1 Place the standard calibrated weights on the center of the balance platform gently specified in the format for monthly calibration of balance. The weights specified in the format should be kept in the ascending order.

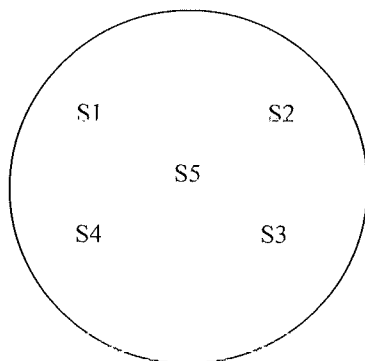
5.2.6.2.2 Record the displayed reading on balance and check the variation; it should be within the specified tolerance limit: ± 0.1 % of actual standard weight.

5.2.6.2.3 Remove the standard weight and keep it in the box. Display shows Zero reading.

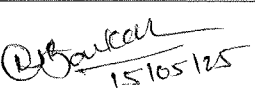
5.2.6.3 Corner Load Test (Eccentricity):

5.2.6.3.1 Place the standard calibrated weights as per balance capacity (Refer format for monthly calibration) at different location of pan. (Refer below diagram)

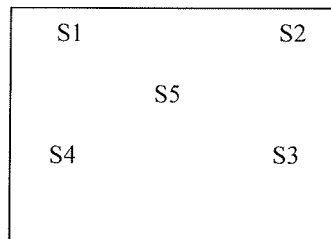
Eg: Round Pan for 230 gm, 300 gm, 320 gm & 600 gm:



For 6.000 Kg, 50.000 Kg & 100.000 Kg:

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5.2.6.3.2 Record the displayed reading on balance and calculate the average weight; it should be within the specified tolerance limit: $\pm 0.1\%$ of actual standard weight.

5.2.6.3.3 Note: Standard calibrated weights should be used as per balance capacity usually should be 30% of the capacity of the balance or higher.

5.2.6.4 Measurement Repeatability Test:

5.2.6.4.1 Place the standard weights on balance for repeatability test as per balance capacity. (Refer Format for monthly calibration)

5.2.6.4.2 Take 9 more observations.

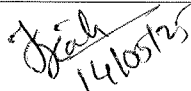
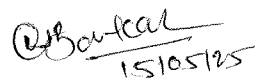
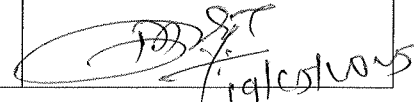
5.2.6.4.3 Calculate the standard deviation for 10 weights.

5.2.6.4.4 Acceptance criteria: Standard Deviation should not be more than 0.10%

5.2.6.4.5 Based on the observed reading, standard deviation to be calculated as per given formula,

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

Where, Standard Deviation is

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$$s = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n - 1}}$$

Where,

s = standard deviation

x_i = each weight reading (corner positions)

$\bar{x}$ = mean (average) of the readings

n = number of positions or readings

$\sum$ = sum of squared differences from the mean

5.2.6.4.6 Frequency of calibration: Monthly

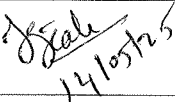
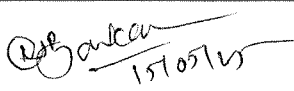
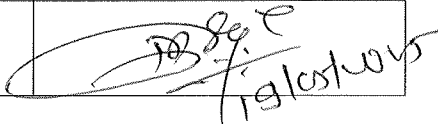
Tolerance: on or before 3 working days of due date.

5.2.6.5 Record the observation of Accuracy, Full range calibration, Corner load test and measurement repeatability test in respective balance monthly calibration Format No. F/SOP/QA/062/02, F/SOP/QA/062/04, F/SOP/QA/062/06, F/SOP/QA/062/09, F/SOP/QA/062/10, F/SOP/QA/062/12, F/SOP/QA/062/14 & F/SOP/QA/062/16.

5.2.6.6 For Monthly calibration of 600 gm Weighing Balance in Production and Warehouse refer the Format No. F/SOP/QA/062/09 and for Quality control and F&D refer Format No. F/SOP/QA/062/10.

5.2.6.7 Weighing Range of Balances:

Weighing shall be performed using a balance that is calibrated over the operating range. A minimum accuracy of 0.10% for important measurements is now dictated. To weigh 10 mg sample, you have to use $10 \times 0.1\% = 0.01$ mg least count balance. It shows that if you have a balance with least count 0.01 mg, you can weigh minimum 10 mg sample on it. Other weights can be calculated accordingly.

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5.2.7 Standard weights used for the verification and calibration of analytical and weighing balances shall be maintained in the Annexure for list of standard weight boxes as per Annexure No. (A/SOP/QA/062/02).

5.2.8 Note:

5.2.8.1 During Daily and Monthly calibration if variation observed out of tolerance limit, immediately inform to User Department Head, QA Head & Maintenance department & labeled as “Out of Calibration” as per Label No. (L/SOP/QA/062/02).

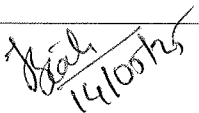
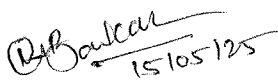
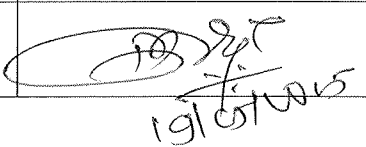
5.2.8.2 Recalibration should be done after rectification, unwanted shutdown or after maintenance work.

5.2.8.3 If calibration is not performed within tolerance limit due to holidays it can be performed on immediate working day before use.

5.2.8.4 Frequency of balance calibration from external agency: Yearly.
Tolerance criteria is “on or before 20 days of due date”.

6. LIST OF ATTACHMENTS:

Sr. No.	Title	Attachment No.
1	List of Analytical and Weighing Balances	A/SOP/QA/062/01-00
2	List of Standard Weight Boxes	A/SOP/QA/062/02-00
3	Flow chart for Cleaning ,Operation and Calibration of Analytical and Weighing Balance	A/SOP/QA/062/03-00
4	Daily calibration of Analytical Balance (230g)	F/SOP/QA/062/01-00
5	Monthly Calibration of Analytical Balance (230g)	F/SOP/QA/062/02-00
6	Daily Verification of Weighing Balance (300g)	F/SOP/QA/062/03-00
7	Monthly Calibration of Weighing Balance (300g)	F/SOP/QA/062/04-00
8	Daily Verification of Balance (320g)	F/SOP/QA/062/05-00
9	Monthly Calibration of Balance (320g)	F/SOP/QA/062/06-00

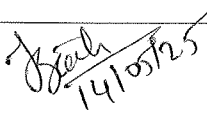
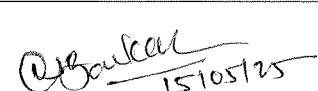
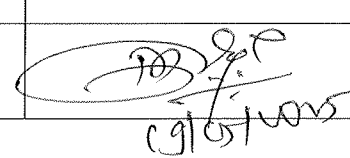
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Sr. No.	Title	Attachment No.
10	Daily Verification of Weighing Balance (600 g)	F/SOP/QA/062/07-00
11	Daily Verification of Weighing Balance (600 g)	F/SOP/QA/062/08-00
12	Monthly Calibration of Weighing Balance (600 g)	F/SOP/QA/062/09-00
13	Monthly Calibration of Weighing Balance (600 g)	F/SOP/QA/062/10-00
14	Daily Verification of Weighing Balance (6.000 Kg)	F/SOP/QA/062/11-00
15	Monthly Calibration of Weighing Balance (6.000 Kg)	F/SOP/QA/062/12-00
16	Daily Verification of Weighing Balance (50.000 Kg)	F/SOP/QA/062/13-00
17	Monthly Calibration of Weighing Balance (50.00Kg)	F/SOP/QA/062/14-00
18	Daily Verification of Weighing Balance (100.000 Kg)	F/SOP/QA/062/15-00
19	Monthly Calibration of Weighing Balance (100.000 Kg)	F/SOP/QA/062/16-00
20	Calibration Status Label	L/SOP/QA/062/01-00
21	Label For Out of Calibration	L/SOP/QA/062/02-00

7. DISTRIBUTION LIST:

Copy No.	Copy Distributed to Department
Master Copy	Quality Assurance Department
Controlled Copy No.1	Quality Assurance Department
Controlled Copy No.2	Production Department
Controlled Copy No.3	Quality Control Department
Controlled Copy No.4	Quality Control-Microbiology Department
Controlled Copy No.5	Formulation & Development Department
Controlled Copy No.6	Warehouse Department
Controlled Copy No.7	Maintenance Department
Controlled Copy No.8 to 24	Display Copy (Production Department)
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Sign/Date	 14/05/25	 15/05/25	 15/05/25

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	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT		
SOP Title :	SOP for Cleaning, Operation and Calibration of Analytical and Weighing Balances.		
SOP No.:	SOP/QA/062	Page No.:	13 of 13
Revision No.:	00		

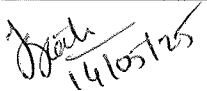
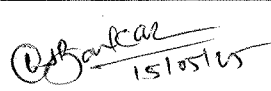
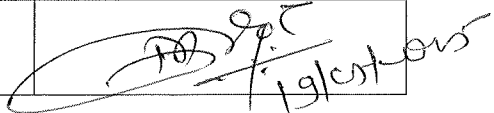
Copy No.	Copy Distributed to Department
Controlled Copy No.28 to 33	Display Copy (Formulation & Development Department)
Controlled Copy No.34 to 39	Display Copy (Warehouse Department)

8. REVISION HISTORY:

Sr. No.	Version No.	Effective Date	Revision Description	Change Control No.
01	00	01/06/2025	New SOP prepared.	CC/QA/25/001

9. REFERENCES:

- 9.1 User Manual.
- 9.2 USP Chapter <41> and <1251>
- 9.3 SOP on SOP: SOP/QA/001

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Sign/Date	 14/05/25	 15/05/25	 19/05/25

	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT		
Annexure Title :	List of Analytical and Weighing Balances		
Annexure No.:	A/SOP/QA/062/01-00	Page No.:	1 of 5
Ref SOP No.	SOP/QA/062		

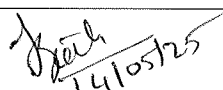
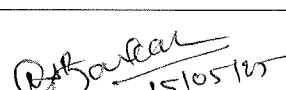
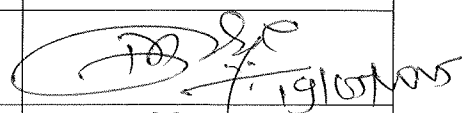
Revision No.	00	Effective Date:	
Supersedes No.	NA		

Analytical Balances:

Sr. No.	Balance ID No.	Capacity	Make	Department	Location	Model No.:	Sr. No. of Balance	Least Count
01	QC-002 (230 g)	230g	Contech	Quality Control	Instrument Room	CAS-234	1803093	0.0001 g
02	FD-001 (230 g)	230g	Contech	Formulation Development	Novomix F&D II	CAS-234	1803094	0.0001 g

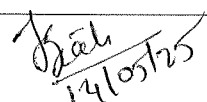
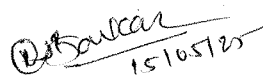
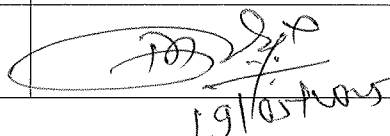
Weighing Balances:

Sr. No.	Balance ID No.	Capacity	Make	Department	Location	Model No.:	Sr. No. of Balance	Least Count
01	QC-010 (600 g)	600g	Contech	Quality Control	Wet Chemistry Lab	CB-600	1100726	0.01g
02	QC-034 (320 g)	320 gm	Contech	Quality Control	Wet Chemistry Lab	CAH-323	3204138	0.001g
03	WR-001 (600 g)	Max. Wt. 500.0 g, Min Wt. 0.5 g	Contech	Warehouse	Sampling Booth For Powder	CBB-600	1803110	0.01g

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhav	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

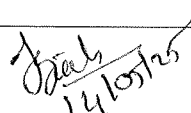
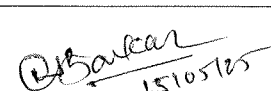
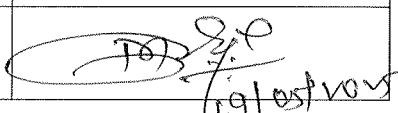
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Annexure Title :	List of Analytical and Weighing Balances		
Annexure No.:	A/SOP/QA/062/01-00	Page No.:	2 of 5

Sr. No.	Balance ID No.	Capacity	Make	Department	Location	Model No.:	Sr. No. of Balance	Least Count
04	WR-002 (600gm)	Max.Wt.50 0.00 g, Min Wt.0.5 g	Contech	Warehouse	Dispensing Booth for Powder	CBB- 600	1803116	0.01g
05	WR-003 (600gm)	Max.Wt.50 0.00 g, Min Wt.0.5 g	Contech	Warehouse	Sampling and Dispensing Booth for Liquid	CBB- 600	1803117	0.01g
06	WR-004 (50 kg)	Max. Wt. 30.000 Kg, Min Wt. 0.250 Kg.	Contech	Warehouse	Sampling and Dispensing Booth for Liquid.	CP-50 K5	1804511	5 g
07	WR-005 (100 kg)	Max. Wt. 60.0 Kg, Min Wt. 0.500 Kg	Contech	Warehouse	Dispensing Booth for Powder	CP- 100K10	1803169	10 g
08	WR-006 (100 kg)	Max. Wt. 60.0 Kg, Min Wt. 0.500 Kg	Contech	Warehouse	RM/PM Receiving Area	CP- 100K10	1300165	10 g
09	QM-012 (600gm)	Max.Wt.60 0g, Min Wt.0.2g	Contech	Quality Control Microbiology	Media Preparation Room	CBB- 600	1804321	0.01g
10	QM-014 (300gm)	Max.Wt.30 0g, Min Wt.0.2g	Contech	Quality Control Microbiology	Testing Room	CBB- 300	1804322	0.01g
11	FD-002 (600 g)	Max.Wt.60 0 g , Min Wt.0.2 g	Contech	Formulation Development	Novopower F&D I	CB-600	1300053	0.01g

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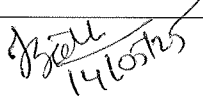
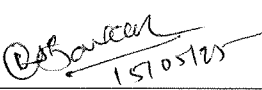
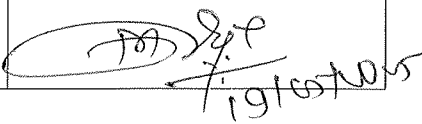
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Annexure Title :	List of Analytical and Weighing Balances		
Annexure No.:	A/SOP/QA/062/01-00	Page No.:	3 of 5

Sr. No.	Balance ID No.	Capacity	Make	Department	Location	Model No.:	Sr. No. of Balance	Least Count
12	FD-003 (600 g)	Max.Wt.60 0 g , Min Wt.0.2 g	Contech	Formulation Development	Novomix F&D II	CB-600	1300054	0.01g
13	FD-004 (600 g)	Max.Wt.60 0 gm , Min Wt.0.2 gm	Contech	Formulation Development	NPD F&D III	CB-600	1300052	0.01g
14	FD-005 (6 kg)	Max.Wt.6 kgs , Min Wt. 2 g	Contech	Formulation Development	Novopower F&D I	CB-6001	1300024	0.100g
15	FD-006 (6 kg)	Max.Wt.6 kgs , Min Wt.2 g	Contech	Formulation Development	Novomix F&D II	CB-6001	1300027	0.100g
16	PR-001 (600 g)	Max. Wt. 500 gm , Min Wt.0.100 g	Contech	Production	MFG-01	CBB- 600	1803111	0.010 g
17	PR-002 (600 g)	Max. Wt. 500 gm , Min Wt.0.100 g	Contech	Production	MFG-02	CBB- 600	1803112	0.010 g
18	PR-003 (600 g)	Max. Wt. 500 gm , Min Wt.0.100 g	Contech	Production	MFG-03	CBB- 600	1803113	0.010 g
19	PR-004 (600 g)	Max. Wt. 500 gm , Min Wt.0.100 g	Contech	Production	MFG-04	CBB- 600	1803114	0.010 g
20	PR-005 (600 g)	Max. Wt. 500 gm , Min Wt.0.100 g	Contech	Production	IPQC room	CBB- 600	1803115	0.010 g

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	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT		
Annexure Title :	List of Analytical and Weighing Balances		
Annexure No.:	A/SOP/QA/062/01-00	Page No.:	4 of 5

Sr. No.	Balance ID No.	Capacity	Make	Department	Location	Model No.:	Sr. No. of Balance	Least Count
21	PR-006 (6 kg)	Max. Wt. 5000.0 gm ,Min Wt. 10.0 g	Contech	Production	MFG-01	CTM-6001	1300025	0.100 g
22	PR-007 (6 kg)	Max. Wt. 5000.0 gm ,Min Wt. 10.0 g	Contech	Production	MFG-02	CTM-6001	1300026	0.100 g
23	PR-008 (6 kg)	Max. Wt. 5000.0 gm ,Min Wt. 10.0 g	Contech	Production	MFG-03	CTM-6001	1802998	0.100 g
24	PR-009 (6 kg)	Max. Wt. 5000.0 gm ,Min Wt. 10.0 g	Contech	Production	MFG-04	CTM-6001	1802999	0.100 g
25	PR-010 (6 kg)	Max. Wt. 5000.0 gm ,Min Wt. 10.0 g	Contech	Production	MFG-05	CTM-6001	1803000	0.100 g
26	PR-011 (50 kg)	Max. Wt. 30.000 kg ,Min Wt. 0.250 kg	Contech	Production	MFG-01	CP-50K5	1804514	5.00 g
27	PR-012 (50 kg)	Max. Wt. 30.000 kg ,Min Wt. 0.250 kg	Contech	Production	MFG-02	CP-50K5	1804515	5.00 g
28	PR-013 (50 kg)	Max. Wt. 30.000 kg ,Min Wt. 0.250 kg	Contech	Production	MFG-03	CP-50K5	1804509	5.00 g

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QUALITY ASSURANCE DEPARTMENT**

Annexure Title : List of Analytical and Weighing Balances

Annexure No.: A/SOP/QA/062/01-00

Page No.:

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Sr. No.	Balance ID No.	Capacity	Make	Department	Location	Model No.:	Sr. No. of Balance	Least Count
29	PR-014 (50 kg)	Max. Wt. 30.000 kg ,Min Wt. 0.250 kg	Contech	Production	MFG-04	CP-50K5	1804512	5.00 g
30	PR-015 (50 kg)	Max. Wt. 30.000 kg ,Min Wt. 0.250 kg	Contech	Production	MFG-05	CP-50K5	1804513	5.00 g
31	PR-016 (50 kg)	Max. Wt. 30.000 kg ,Min Wt. 0.250 kg	Contech	Production	Intermediate mfg.	CP-50K5	1804510	5.00 g
32	PR-017 (100 kg)	Max. Wt. 60.000 kg ,Min Wt. 0.500 kg	Contech	Production	Secondary Packing	CP-100K 10	1300020	10.00 g

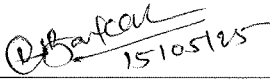
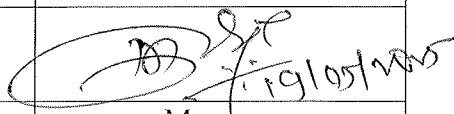
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Sign/Date	<i>Jhal</i> 14/05/25	<i>Q. Sankar</i> 15/05/25	<i>[Signature]</i> 19/05/25

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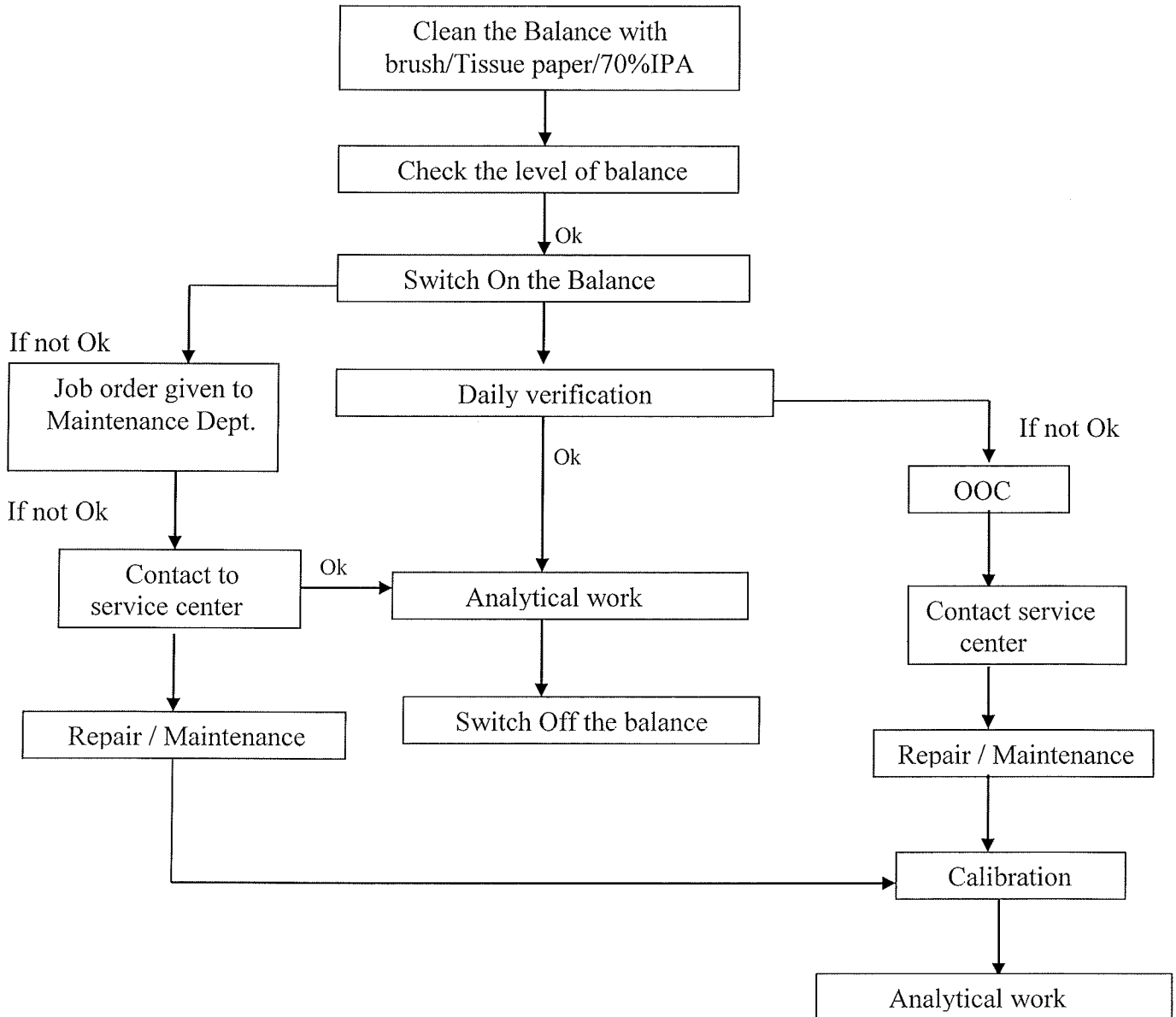
	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT		
	Annexure Title : List of standard Weight boxes		
	Annexure No.: A/SOP/QA/062/02-00	Page No.:	1 of 1
	Ref SOP No. SOP/QA/062		

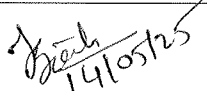
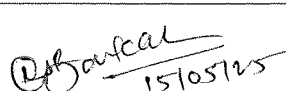
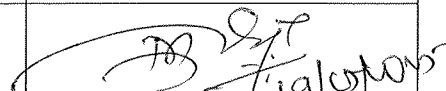
Revision No.	00	Effective Date:	
Supersedes No.	NA		

Sr. No.	Weight Box ID No.	Department	Weight Box	Serial No.	Quantity in Numbers

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT		
Annexure Title :	Flow chart for Cleaning ,Operation and Calibration of Analytical and Weighing Balance		
Annexure No.:	A/SOP/QA/062/03-00	Page No.:	1 of 1
Ref. SOP No.:	SOP/QA/062		



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Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 15/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance



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Least Count :0.0001g	
Weight Box ID No.:	

[illegible]

APPROVED BY

Mr. Manish Mahajan



Manager

Quality Assurance

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QUALITY ASSURANCE DEPARTMENT

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Format Title:

Daily calibration of Analytical Balance (230g)

Format No.:

F/SOP/QA/062/01-00

Page No.:

Page 2 of 3

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Format No.:	F/SOP/QA/062/02-00	Page No.:	1 of 4	
Ref. SOP No.:	SOP/QA/062			

ID No.:	Capacity:Max.Wt.230 gm
Make: CONTECH	Model No.:
Sr. No.:	Least Count :0.0001g
Location:	Weight Box ID No.:
Date of calibration :	Next calibration due date :

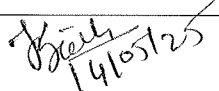
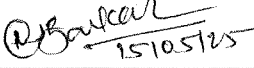
1) Accuracy:

$$\text{Accuracy Deviation (\%)} = \frac{\text{Displayed Value} - \text{True Weight}}{\text{True Weight}} \times 100$$

Acceptance Criteria: Not more than 0.10%

2) Full Range Calibration:

Standard weights	Observed Weight	Acceptance Criteria
200 g		199.8 – 200.2 g
100 g		99.9 – 100.1 g
50 g		49.95 – 50.05 g
20 g		19.98 – 20.02 g
10 g		9.99 – 10.01 g

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

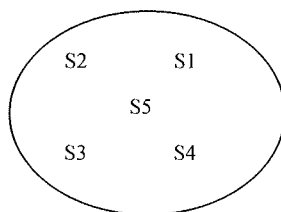
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	Format Title : Monthly Calibration of Analytical Balance (230g)			
	Format No.: F/SOP/QA/062/02-00	Page No.:	2 of 4	

Standard weights	Observed Weight	Acceptance Criteria
1 g		0.999 – 1.001 g
500 mg		499.5 – 500.5 mg
100mg		99.9 – 100.1 mg
50 mg		49.95 – 50.05 mg
20 mg		19.98 – 20.02 mg
10 mg		9.99 - 10.01mg

Done By/On :	Checked By/On :
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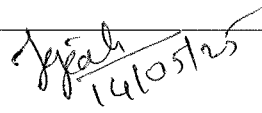
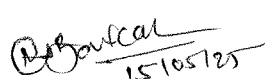
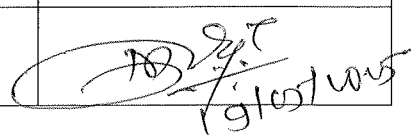
3) Corner Load Test:

Eg: Round Pan



Location	Standard Wt.	Average Weight	Acceptance Criteria
S1			± 0.1%
S2			
S3			
S4			
S5			

Done By/On :	Checked By/On :
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Sign/Date	 14/05/25	 15/05/25	 15/05/25

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Format Title :	Monthly Calibration of Analytical Balance (230g)			
Format No.:	F/SOP/QA/062/02-00	Page No.:	3 of 4	

4) Repeatability Test:

Sr. No	Standard Weight	Displayed Weight
01	100 g	
02		
03		
04		
05		
06		
07		
08		
09		
10		
Standard deviation		

Standard Deviation(S):

$$s = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n - 1}}$$

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	<i>J. Shah</i> 14/05/25	<i>R. Bantel</i> 15/05/25	<i>[Signature]</i> 19/05/2025

	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT		Issued By/ On:	
Format Title :	Monthly Calibration of Analytical Balance (230g)			
Format No.:	F/SOP/QA/062/02-00	Page No.:	4 of 4	

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

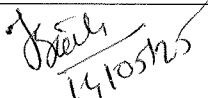
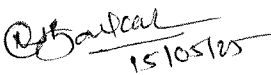
$$\text{Repeatability} = \frac{\text{X 2}}{\text{X 100}}$$

Repeatability =

Acceptance Criteria: Repeatability: Not more than 0.10%

Remark: The calibration of Analytical Balance Complies / Does not comply with the acceptance criteria.

Done By/On :	Checked By/On :
---------------------	------------------------

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Format No.:	F/SOP/QA/062/03-00	Page No.:	1 of 2	
Ref. SOP No.:	SOP/QA/062			

ID No.:	Capacity:Max.Wt.300g, Min Wt.0.2g
Make/Model No.: CONTECH/	Least Count :
Sr. No.:	Location:
Weight Box ID No.:	Calibration of weight box valid up to:

[illegible]

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

**Issued By/
On:**

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Sign/Date	 14/05/25	 15/05/25	 T. B. S. S.

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Format No.:	F/SOP/QA/062/04-00	Page No.:	1 of 4	
Ref. SOP No.:	SOP/QA/062			

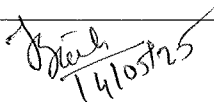
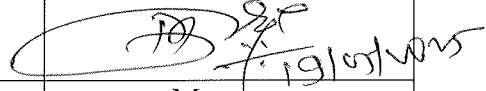
/Balance ID No.:		Capacity:	Max.Wt.300g, Min Wt.0.2g
Make:	CONTECH	Model No.	
Sr. No.:		Least Count :	

Weight Box ID No.:		Calibration of Weight Box valid up to:	
Date of Calibration		Next Due Date :	
Location			

1. Accuracy:

$$\text{Accuracy Deviation (\%)} = \frac{\text{Displayed Value} - \text{True Weight}}{\text{True Weight}} \times 100$$

Acceptance Criteria: Not more than 0.10%

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

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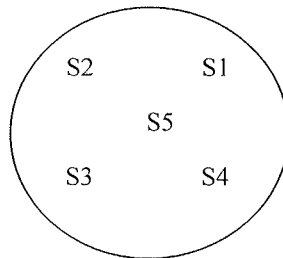
2. FULL RANGE CALIBRATION OF WEIGHING BALANCE:

Standard weights	Observed Weight	Remark C/NC	Acceptance Criteria	Done By/On
			$\pm 0.1\%$ of Standard weight	
1g			0.99 – 1.01 g	
5g			4.99 – 5.01 g	
10g			9.99 – 10.01 g	
50g			49.95 – 50.05 g	
100g			99.90 – 100.10 g	
200g			199.80 – 200.20 g	

Note: C- Complies, NC- Not Complies

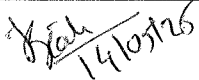
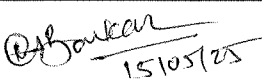
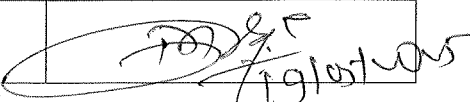
3. ECCENTRICITY CHECKS OF WEIGHING BALANCE:

Eg: Round Pan



Location	Min Wt. (1g)	Average Weight	Remark C/NC	Max Wt. (200g)	Average Weight	Remark C/NC	Acceptance Criteria
S1							± 0.1%
S2							
S3							
S4							
S5							
Done By/On:							

Note: C- Complies, NC- Not Complies

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 14/05/25	 15/05/25	 19/05/25

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4. MEASUREMENT OF REPEATABILITY:

Sr. No.	Standard Weight	Displayed Weight
1	100 g	
2		
3		
4		
5		
6		
7		
8		
9		
10		
Standard deviation		

Standard Deviation(S):

$$s = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n - 1}}$$

Standard deviation X 2
 Repeatability = ----- X 100
 Actual Weight

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	<i>J. Khan</i> 14/05/25	<i>R. B. Bhalerao</i> 25/05/25	<i>[Signature]</i> 19/05/25

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Format No.:	F/SOP/QA/062/04-00	Page No.:	4 of 4

$$\text{Repeatability} = \frac{\text{X 2}}{\text{-----}} \times 100$$

$$\text{Repeatability} = \underline{\hspace{2cm}}$$

Acceptance Criteria: Repeatability: Not more than 0.10%

Remark: The calibration of Analytical Balance Complies / Does not comply with the acceptance criteria.

	Done By/On	Checked By/On
Sign/Date		

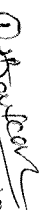
	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	<i>J. Shah</i> 14/05/25	<i>R. Bhatkal</i> 15/05/25	<i>[Signature]</i> 19/05/25



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No. of Copies:	

ID No.:	Capacity: Max. Wt. 320 gm	Str. No.:	Least Count :
Make: CONTECH	Model No.	Location:	Weight Box ID No.:

[illegible]

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

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QUALITY ASSURANCE DEPARTMENT**

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Format Title:	Daily Verification of Balance (320g)
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Format No.:	F/SOP/QA/062/05-00
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Page No.:

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[illegible]

PREPARED BY

REVIEWED BY

APPROVED BY

Sign/Date

26/11/2024

Chandler
15107W

Signature

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Ref. SOP No.:	SOP/QA/062			

ID No.		Capacity	Max. Wt. 320 g
Make	CONTECH	Least Count	
Model No.		Location	
Sr. No.		Weight Box ID No.	
Date of calibration		Next calibration due date	

1. Accuracy:

Displayed Value - True Weight

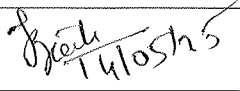
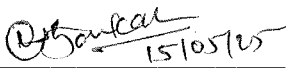
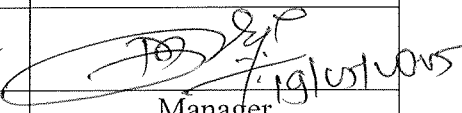
Accuracy Deviation (%): $\frac{\text{Displayed Value} - \text{True Weight}}{\text{True Weight}} \times 100$

Acceptance Criteria: Not more than 0.10%

Done By/On:	Checked By/On:
-------------	----------------

2. Full Range Calibration:

Standard weights	Observed Weight	Acceptance Criteria
200 g		199.8 – 200.2 g
100 g		99.9 – 100.1 g

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date			
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

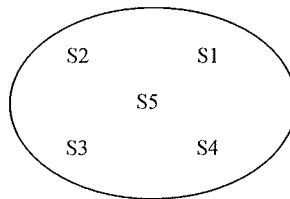
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	Format Title: Monthly Calibration of Balance (320g)			
Format No.:	F/SOP/QA/062/06-00	Page No.:	2 of 4	

Standard weights	Observed Weight	Acceptance Criteria
50 g		49.95 – 50.05 g
20 g		19.98 – 20.02 g
10 g		9.99 – 10.01 g
1 g		0.999 – 1.001 g

Done By/On:	Checked By/On:
-------------	----------------

3. Corner Load Test:

Eg: Round Pan



Location	Standard Wt.	Average Weight	Acceptance Criteria
S1			± 0.1%
S2			
S3			
S4			
S5			

Done By/On:	Checked By/On:
-------------	----------------

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	<i>[Signature]</i> 14/05/25	<i>[Signature]</i> 15/05/25	<i>[Signature]</i> 19/05/25

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4. Repeatability Test:

Sr. No	Standard Weight	Displayed Weight
01	100 g	
02		
03		
04		
05		
06		
07		
08		
09		
10		
Standard deviation		

Standard Deviation(S):

$$s = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n - 1}}$$

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	<i>J. Bhat</i> 14/05/25	<i>A. Bhatkar</i> 15/05/25	<i>[Signature]</i> 19/05/2025

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

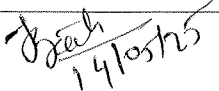
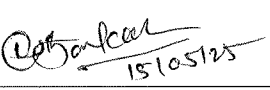
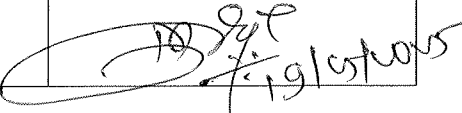
$$\text{Repeatability} = \frac{\text{X 2}}{\text{X 100}}$$

$$\text{Repeatability} = \underline{\hspace{2cm}}$$

Acceptance Criteria: Not more than 0.10%

Remark: The calibration of weighing balances Complies / Does not comply with the acceptance criteria.

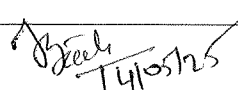
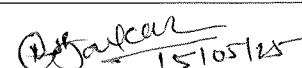
Done By/On:	Checked By/On:
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	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 14/05/25	 15/05/25	 19/05/25

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Ref. SOP No.:	SOP/QA/062			

Month/Year		Weight Box ID No.:	Location:
ID No.:	Capacity(a): 600 g	Min. Wt.: 0.100 g	Max. Wt. : 500.000 g
Make: CONTECH	Model No. :	Sr. No.:	Least Count(e):

Date	Cleaning status	Spirit Level ↓	Standard weight			Remark C/NC	Done by/On	Checked By/On	Verified By QA
		± 0.10 % of Actual Standard weight							
		Actual Weight →	0.100g	300.000g	500.000g				
		Acceptance Criteria →	0.099 to 0.101g	299.700 to 300.300g	499.500 to 500.500g				

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

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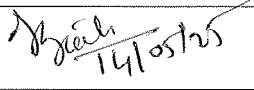
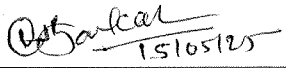
[illegible]

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	<i>Bach</i> 14/05/25	<i>A. Boukai</i> 15/05/25	<i>[Signature]</i> 19/05/25

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Ref. SOP No.:	SOP/QA/062			

Month/Year		Weight Box ID No.:	Location:
ID No.:	Capacity(a): 600 g	Min. Wt.: 0.100 g	Max. Wt. : 500.000 g
Make: CONTECH	Model No. :	Sr. No.:	Least Count(e):

Date	Cleaning Status	Spirit Level	Standard weight			Remark C/NC	Done by/On	Checked By/On
		↓	± 0.10 % of Actual Standard weight					
		Actual Weight →	0.100g	300.000g	500.000g			
		Acceptance Criteria →	0.099 to 0.101g	299.700 to 300.300g	499.500 to 500.500g			

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 15/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

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QUALITY ASSURANCE DEPARTMENT

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Sign/Date	 14/05/25	 15/05/25	 15/05/25

19/05/2005

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Month/Year		Capacity(a)	600 g
ID No.		Min. Wt.:	Max. Wt. :
Make	CONTECH	Least Count(e)	0.010 g
Model No.	CBB-600	Location	
Sr. No.		Weight Box ID No.	
Date of calibration		Next calibration due date	

1) Accuracy:

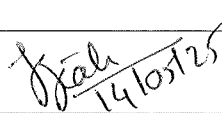
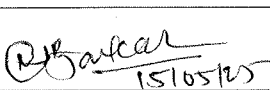
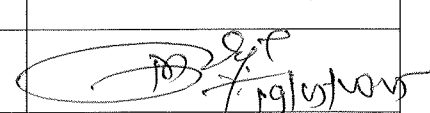
Displayed Value - True Weight

Accuracy Deviation (%): ----- X 100

True Weight

Acceptance Criteria: Not more than 0.10%

Done By/On :	Checked By/On :	Verified By(QA):
--------------	-----------------	------------------

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

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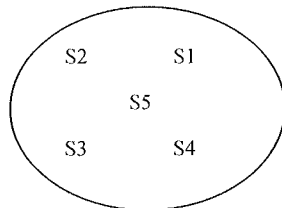
2) Full Range Calibration Test:

Standard weights		Observed Weight	Acceptance Criteria ($\pm 0.10\%$)
Minimum Weight (In house)	0.100 g		0.099 – 0.101 g
Middle 1 Weight (5% of a)	30.000 g		29.970 – 30.030 g
Middle 2 Weight (20% of a)	120.000 g		119.880 – 120.120 g
Middle 3 Weight (40% of a)	240.000 g		239.760 – 240.240 g
Middle 4 Weight (60% of a)	360.000 g		359.640 – 360.360 g
Maximum Weight (In house)	500.000 g		499.500 – 500.500 g

Done By/On :	Checked By/On :	Verified By(QA):
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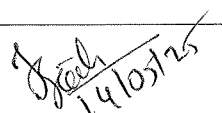
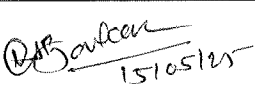
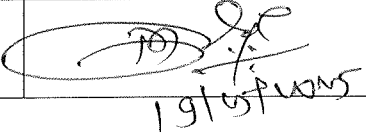
3) Corner Load Test :

Eg: Round Pan



Location	Standard Wt.	Average Weight	Acceptance Criteria
S1			$\pm 0.1\%$
S2			
S3			
S4			
S5			

Done By/On :	Checked By/On :	Verified By(QA):
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	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 14/05/25	 15/05/25	 19/05/25

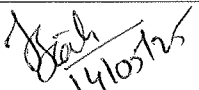
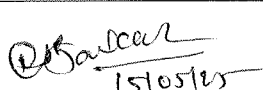
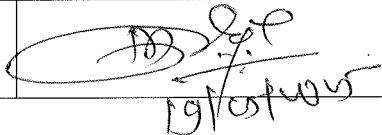
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4) Measurement of Repeatability Test:

Sr. No	Standard Weight	Displayed Weight
01	100 g	
02		
03		
04		
05		
06		
07		
08		
09		
10		
Standard deviation		

Standard Deviation(S):

$$s = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n - 1}}$$

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 14/05/25	 15/05/25	 19/05/25

	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT	Issued By/ On:	
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Format No.:	F/SOP/QA/062/09-00	Page No.:	4 of 4

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

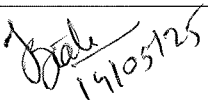
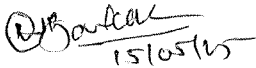
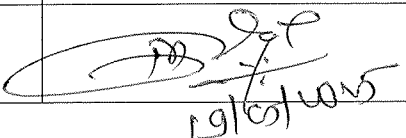
$$\text{Repeatability} = \frac{\text{X 2}}{\text{X 100}}$$

$$\text{Repeatability} = \underline{\hspace{2cm}}$$

Acceptance Criteria: Not more than 0.10%

Remark: The calibration of weighing balances Complies / Does not comply with the acceptance criteria.

Done By/On :	Checked By/On :	Verified By(QA):
---------------------	------------------------	-------------------------

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 19/05/25	 15/05/25	 19/05/2025

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Format No.:	F/SOP/QA/062/10-00	Page No.:	1 of 4	
Ref. SOP No.:	SOP/QA/062			

Month/Year		Capacity(a)	600 g
ID No.		Min. Wt.:	Max. Wt. :
Make	CONTECH	Least Count(e)	0.010 g
Model No.	CBB-600	Location	
Sr. No.		Weight Box ID No.	
Date of calibration		Next calibration due date	

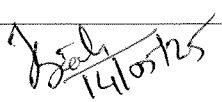
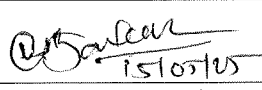
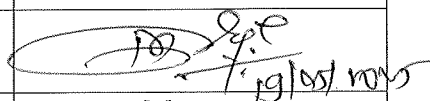
1. Accuracy:

Displayed Value - True Weight

Accuracy Deviation (%): $\frac{\text{Displayed Value} - \text{True Weight}}{\text{True Weight}} \times 100$

Acceptance Criteria: Not more than 0.10%

Done By/On:	Checked By/On:
--------------------	-----------------------

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT	Issued By/ On:	
Format Title :	Monthly Calibration of Weighing Balance (600 g)		
Format No.:	F/SOP/QA/062/10-00	Page No.:	2 of 4

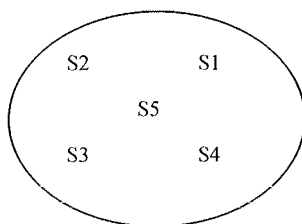
2. Full Range Calibration Test:

Standard weights		Observed Weight	Acceptance Criteria ($\pm 0.10\%$)
Minimum Weight (In house)	0.100 g		0.099 – 0.101 g
Middle 1 Weight (5% of a)	30.000 g		29.970 – 30.030 g
Middle 2 Weight (20% of a)	120.000 g		119.880 – 120.120 g
Middle 3 Weight (40% of a)	240.000 g		239.760 – 240.240 g
Middle 4 Weight (60% of a)	360.000 g		359.640 – 360.360 g
Maximum Weight (In house)	500.000 g		499.500 – 500.500 g

Done By/On :	Checked By/On :
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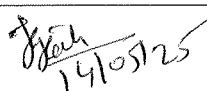
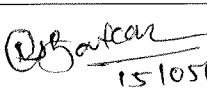
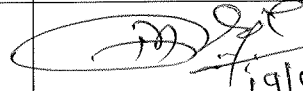
3. Corner Load Test :

Eg: Round Pan



Location	Standard Wt.	Average Weight	Acceptance Criteria
S1			$\pm 0.1\%$
S2			
S3			
S4			
S5			

Done By/On :	Checked By/On :
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	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 15/05/25	 15/05/25	 15/05/25

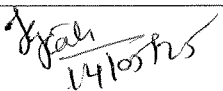
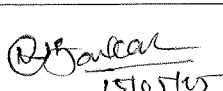
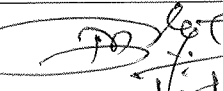
	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT	Issued By/ On:	
Format Title :	Monthly Calibration of Weighing Balance (600 g)		
Format No.:	F/SOP/QA/062/10-00	Page No.:	3 of 4

4. Measurement Repeatability Test:

Sr. No	Standard Weight	Displayed Weight
01	100 g	
02		
03		
04		
05		
06		
07		
08		
09		
10		
Standard deviation		

Standard Deviation(S):

$$s = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n - 1}}$$

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 14/05/15	 15/05/15	 19/05/15

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Format No.:	F/SOP/QA/062/10-00	Page No.:	4 of 4	

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

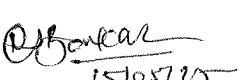
$$\text{Repeatability} = \frac{\text{X 2}}{\text{X 100}}$$

$$\text{Repeatability} = \underline{\hspace{2cm}}$$

Acceptance Criteria: Not more than 0.10%

Remark: The calibration of weighing balances Complies / Does not comply with the acceptance criteria.

Done By/On :	Checked By/On :
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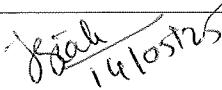
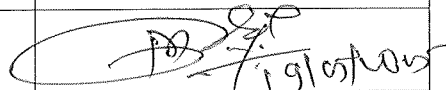
	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 14/05/25	 15/05/25	 15/05/25

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Format No.:	F/SOP/QA/062/11-00	Page No.:	1 of 2	
Ref. SOP No.:	SOP/QA/062			

Month/Year		Weight Box ID No.:	Location:
ID No.:	Capacity(a): 6.000 Kg	Min. Wt.:	Max. Wt. :
Make: CONTECH	Model No.:	Sr. No.:	Least Count(e): 0.1g

Date	Cleaning Status	Spirit Level ↓	Standard weight			Remark C/NC	Done by/ On	Checked By/On	Verified By QA
			± 0.10 % of Actual Standard weight						
		Actual Weight →	10.0 g	3000.0 g	5000.0 g				
		Acceptance Criteria →	9.9 to 10.1 g	2997.0 to 3003.0 g	4995.0 to 5005.0 g				

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

**Issued By/
On:**

Format No.:	F/SOP/QA/062/11-00
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Page No.:

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Sign/Date	J. Jale 14/07/25	D. Bantel 15/07/25	T. D. 15/07/25

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Format No.:	F/SOP/QA/062/12-00	Page No.:	1 of 4	
Ref. SOP No.:	SOP/QA/062			

Month/Year		Capacity(a)	6.000 Kg
ID No.		Min. Wt.:	Max. Wt. :
Make	CONTECH	Least Count (e)	
Model No.		Location	
Sr. No.		Weight Box ID No.	
Date of calibration		Next calibration due date	

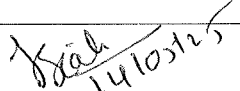
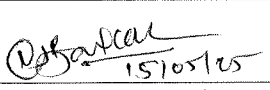
1. Accuracy:

Displayed Value - True Weight

Accuracy Deviation (%): $\frac{\text{Displayed Value} - \text{True Weight}}{\text{True Weight}} \times 100$

Acceptance Criteria: Not more than 0.10%

Done By/On :	Checked By/On :	Verified By(QA):
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	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/2025
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

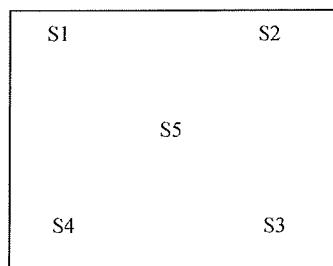
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Format Title :	Monthly Calibration of Weighing Balance (6.000 Kg)		
Format No.:	F/SOP/QA/062/12-00	Page No.:	2 of 4

2. Full Range Calibration Test:

Standard weights		Observed Weight	Acceptance Criteria ($\pm 0.10\%$)
Minimum Weight (In house)	10.0 g		9.9 – 10.1 g
Middle 1 Weight (10% of a)	600.0 g		599.4 – 600.6 g
Middle 2 Weight (20% of a)	1200.0 g		1198.8 – 1201.2 g
Middle 3 Weight (40% of a)	2400.0 g		2397.6 – 2402.4 g
Middle 4 Weight (60% of a)	3600.0 g		3596.4 – 3603.6 g
Maximum Weight (In house)	5000.0 g		4995.0 – 5005.0 g

Done By/On :	Checked By/On :	Verified By(QA):
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3. Corner Load Test:



Location	Standard Wt.	Average Weight	Acceptance Criteria
S1			$\pm 0.1\%$
S2			
S3			
S4			
S5			

Done By/On :	Checked By/On :	Verified By(QA)
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	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	<i>[Signature]</i> 14/05/25	<i>[Signature]</i> 15/05/25	<i>[Signature]</i> 19/05/25

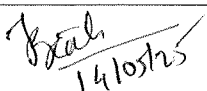
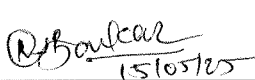
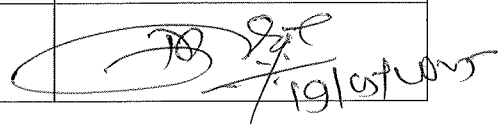
	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT	Issued By/ On:	
Format Title :	Monthly Calibration of Weighing Balance (6.000 Kg)		
Format No.:	F/SOP/QA/062/12-00	Page No.:	3 of 4

4. Measurement of Repeatability Test:

Sr. No	Standard Weight	Displayed Weight
01	3000.0 g	
02		
03		
04		
05		
06		
07		
08		
09		
10		
Standard deviation		

Standard Deviation(S):

$$s = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n - 1}}$$

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 14/05/25	 15/05/25	 19/05/25

	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT		Issued By/ On:	
Format Title :	Monthly Calibration of Weighing Balance (6.000 Kg)			
Format No.:	F/SOP/QA/062/12-00	Page No.:	4 of 4	

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

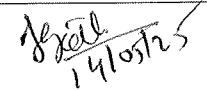
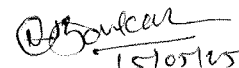
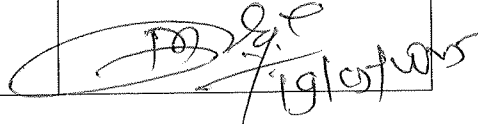
$$\text{Repeatability} = \frac{\text{X 2}}{\text{X 100}}$$

$$\text{Repeatability} = \underline{\hspace{2cm}}$$

Acceptance Criteria: Not more than 0.10%

Remark: The calibration of weighing balances Complies / Does not comply with the acceptance criteria.

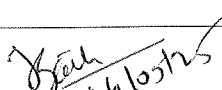
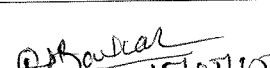
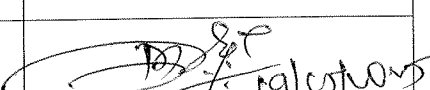
Done By/On :	Checked By/On :	Verified By(QA):
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	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 14/05/25	 15/05/25	 19/05/25

	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT		Issued By/ On:	
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Format No.:	F/SOP/QA/062/13-00	Page No.:	1 of 2	
Ref. SOP No.:	SOP/QA/062			

Month/Year		Weight Box ID No.:	Location:
ID No.:	Capacity(a): 50.000 Kg	Min. Wt.:	Max. Wt. :
Make: CONTECH	Model No. :	Sr. No.:	Least Count(e):

Date	Cleaning Status	Spirit Level	Standard weight			Remark C/NC	Done by/On	Checked By/On	Verified By QA
		↓	± 0.10 % of Actual Standard weight						
		Actual Weight →	0.250 Kg	10.000 Kg	30.000 Kg				
		Acceptance Criteria →	0.249 to 0.251 Kg	9.990 to 10.010 Kg	29.970 to 30.030 Kg				

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

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Page 2 of 2

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	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 14/05/25	 15/05/25	 15/05/25

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Ref. SOP No.:	SOP/QA/062			

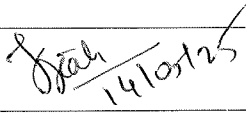
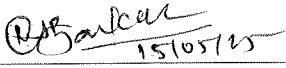
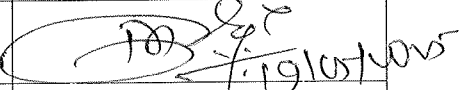
Month/Year		Capacity (a)	50.000 Kg
ID No.		Min. Wt.:	Max. Wt. :
Make	CONTECH	Least Count (e)	
Model No.		Location	
Sr. No.		Weight Box ID No.	
Date of calibration		Next calibration due date	

1. Accuracy:

$$\text{Accuracy Deviation (\%)} = \frac{\text{Displayed Value} - \text{True Weight}}{\text{True Weight}} \times 100$$

Acceptance Criteria: Not more than 0.10%

Done By/On :	Checked By/On :	Verified By(QA):
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	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/15	 15/05/15	 19/05/15
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT	Issued By/ On:	
Format Title :	Monthly Calibration of Weighing Balance (50.00Kg)		
Format No.:	F/SOP/QA/062/14-00	Page No.:	2 of 4

2. Full Range Calibration Test:

Standard weights		Observed Weight	Acceptance Criteria ($\pm 0.10\%$)
Minimum Weight (In house)	0.250 Kg.		0.249 – 0.251 Kg.
Middle 1 Weight (10% of a)	5.000 Kg.		4.995 – 5.005 Kg.
Middle 2 Weight (20% of a)	10.000 Kg.		9.990 – 10.010 Kg.
Middle 3 Weight (40% of a)	20.000 Kg.		19.980 – 20.020 Kg.
Middle 4 Weight (60% of a)	30.000 Kg.		29.970 – 30.030 Kg.
Maximum Weight (In house)	40.000 Kg.		39.960 – 40.040 Kg.

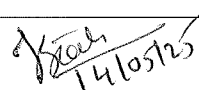
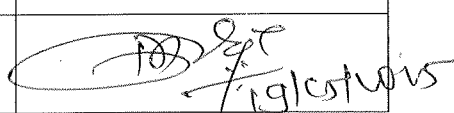
Done By/On :	Checked By/On :	Verified By(QA):
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3. Corner Load Test:



Location	Standard Wt.	Average Weight	Acceptance Criteria
S1			$\pm 0.1\%$
S2			
S3			
S4			
S5			

Done By/On :	Checked By/On :	Verified By(QA):
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Sign/Date	 14/05/25	 15/05/25	 19/05/25

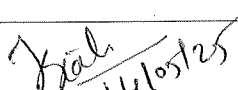
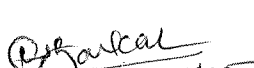
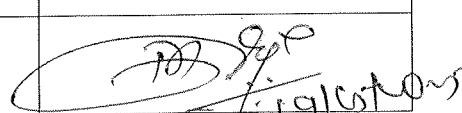
 NOVO EXCIPIENTS PVT. LTD.	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT		Issued By/ On:	
Format Title :	Monthly Calibration of Weighing Balance (50.00Kg)			
Format No.:	F/SOP/QA/062/14-00	Page No.:	3 of 4	

4. Measurement Repeatability Test:

Sr. No	Standard Weight	Displayed Weight
01	25.000 kg	
02		
03		
04		
05		
06		
07		
08		
09		
10		
Standard deviation		

Standard Deviation(S):

$$s = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n - 1}}$$

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 14/05/25	 15/05/25	 15/05/25

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Format No.:	F/SOP/QA/062/14-00	Page No.:	4 of 4

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

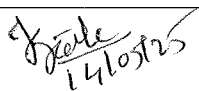
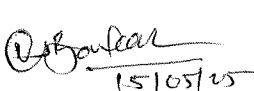
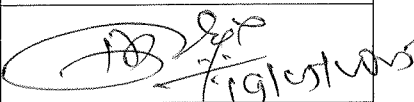
$$\text{Repeatability} = \frac{\text{X 2}}{\text{X 100}}$$

$$\text{Repeatability} = \underline{\hspace{2cm}}$$

Acceptance Criteria: Not more than 0.10%

Remark: The calibration of weighing balances Complies / Does not comply with the acceptance criteria.

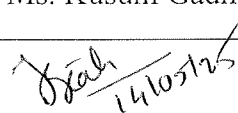
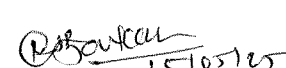
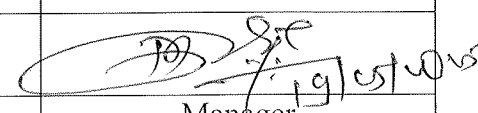
Done By/On :	Checked By/On :	Verified By(QA):
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	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date			

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Format No.:	F/SOP/QA/062/15-00	Page No.:	1 of 2	
Ref. SOP No.:	SOP/QA/062			

Month/Year		Weight Box ID No.:	Location:
ID No.:	Capacity(a): 100.000 Kg	Min. Wt.:	Max. Wt.:
Make: CONTECH	Model No.	Sr. No.:	Least Count(e):

Date	Cleaning Status	Spirit Level	Standard weight			Remark C/NC	Done by/On	Checked By/On	Verified By QA
		↓	± 0.10 % of Actual Standard weight						
		Actual Weight →	0.500 Kg	20.000 Kg	60.000 Kg				
		Acceptance Criteria →	0.499 to 0.501 Kg	19.980 to 20.020 Kg	59.940 to 60.060 Kg				

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Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/25
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

Issued By

Page 2 of 2

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	<i>J. Lee</i> 14/05/26	<i>W. Barker</i> 15/05/25	<i>W. Barker</i> 15/05/25

Sign/Date

Year 14/05/26

Decker
15105/25

19/05/2005

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Format Title :	Monthly Calibration of Weighing Balance (100.000 Kg)			
Format No.:	F/SOP/QA/062/16-00	Page No.:	1 of 4	
Ref. SOP No.:	SOP/QA/062			

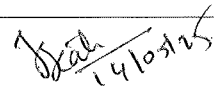
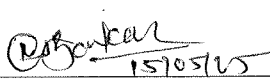
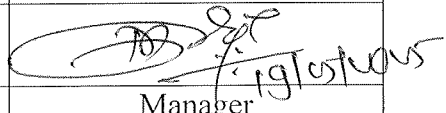
Month/Year		Capacity (a)	100.000 Kg
ID No.		Min. Wt.:	Max. Wt. :
Make	CONTECH	Least Count (e)	
Model No.		Location	
Sr. No.		Weight Box ID No.	
Date of calibration		Next calibration due date	

1. Accuracy:

$$\text{Accuracy Deviation (\%)} = \frac{\text{Displayed Value} - \text{True Weight}}{\text{True Weight}} \times 100$$

Acceptance Criteria: Not more than 0.10%

Done By/On :	Checked By/On :	Verified By(QA):
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Sign/Date	 14/05/25	 15/05/25	 19/05/2025
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Department	Quality Assurance	Quality Assurance	Quality Assurance

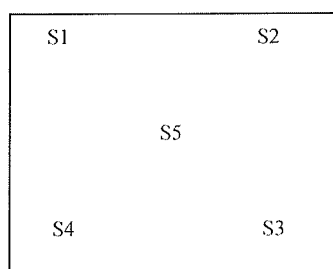
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Format Title :	Monthly Calibration of Weighing Balance (100.000 Kg)			
Format No.:	F/SOP/QA/062/16-00	Page No.:	2 of 4	

2. Full Range Calibration Test:

Standard weights		Observed Weight	Acceptance Criteria ($\pm 0.10\%$)
Minimum Weight (In house)	0.500 Kg.		0.499 – 0.501 Kg.
Middle 1 Weight (10% of a)	10.000 Kg.		9.990 – 10.010 Kg.
Middle 2 Weight (20% of a)	20.000 Kg.		19.980 – 20.020 Kg.
Middle 3 Weight (40% of a)	40.000 Kg.		39.960 – 40.040 Kg.
Middle 4 Weight (60% of a)	60.000 Kg.		59.940 – 60.060 Kg.
Maximum Weight (In house)	80.000 Kg.		79.920 – 80.080 Kg.

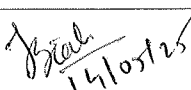
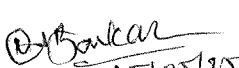
Done By/On :	Checked By/On :	Verified By(QA):
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3. Corner Load Test:



Location	Standard Wt.	Average Weight	Acceptance Criteria
S1			$\pm 0.1\%$
S2			
S3			
S4			
S5			

Done By/On :	Checked By/On :	Verified By(QA):
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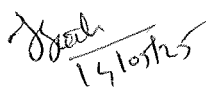
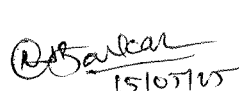
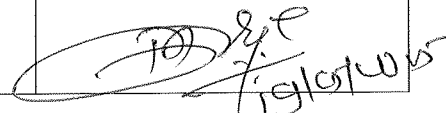
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Format Title :	Monthly Calibration of Weighing Balance (100.000 Kg)			
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4. Measurement of Repeatability Test:

Sr. No	Standard Weight	Displayed Weight
01	50.000 kg	
02		
03		
04		
05		
06		
07		
08		
09		
10		
Standard deviation		

Standard Deviation(S):

$$s = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n - 1}}$$

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

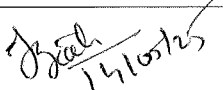
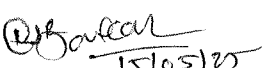
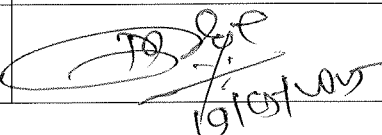
$$\text{Repeatability} = \frac{\text{X 2}}{\text{X 100}}$$

$$\text{Repeatability} = \underline{\hspace{2cm}}$$

Acceptance Criteria: Not more than 0.10%

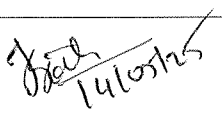
Remark: The calibration of weighing balances Complies / Does not comply with the acceptance criteria.

Done By/On :	Checked By/On :	Verified By(QA):
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	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 14/05/25	 15/05/25	 19/05/25

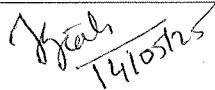
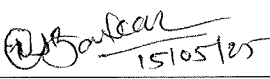
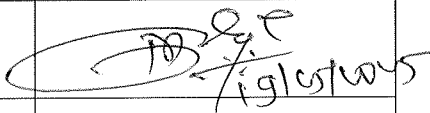
	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT		
Label Title :	CALIBRATION STATUS LABEL		
label No.:	L/SOP/QA/062/01-00	Page No.:	1 of 1
Ref. SOP No.:	SOP/QA/062		

	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT	
CALIBRATION STATUS LABEL		
Name Of Equipment :	Analytical/Weighing Balance	
ID No. :		
Capacity :		
Calibrated On :		
Next Calibration On :		
Operating Range	Minimum Wt.	
	Maximum Wt.	
Calibrated By :		
Frequency :	On or before 3 days from due date	
L/SOP/QA/062/01-00		

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Ms. Kusum Gadhave	Mr. Rahul Bankar	Mr. Manish Mahajan
Sign/Date	 14/05/25	 15/05/25	 19/05/2025
Designation	Officer	Sr. Executive	Manager
Department	Quality Assurance	Quality Assurance	Quality Assurance

	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT		
Label Title :	Label for out of Calibration		
label No.:	L/SOP/QA/062/02-00	Page No.:	1 of 1
Ref. SOP No.:	SOP/QA/062		

	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI QUALITY ASSURANCE DEPARTMENT
OUT OF CALIBRATION	
L/SOP/QA/062/02-00	

	PREPARED BY	REVIEWED BY	APPROVED BY
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