ION Nutritional Labs	Standard Operating Procedure **Use of Balances in the QC Laboratory**	**SOP Number** **D-828**	**Revision** **8**
		Effective Date 11/29/23	**Page** **Page 1 of 8**

Written by/ Date	**Reviewed by/ Date**	**Approved by/ Date**
11/04/23	SAS 11/06/23	11/07/23
Title: Quality Assurance Director	**Title: Analytical Development Scientist**	**Title: Quality Control Director**

1.0 Purpose

This procedure provides internal guidelines for the calibration and use of balances in the QC Laboratory.

2.0 Scope

This procedure generally applies to all analytical and micro balances installed at Ion Labs with a scale interval between 0.001 mg and 1 mg. This procedure utilizes guidance from USP <1251> Weighing on an Analytical Balance and USP <41> Weights and Balances.

3.0 Responsibility

3.1 It is the responsibility of QC Laboratory Analysts to comply with this procedure.

3.2 It is the responsibility of QC Laboratory Management to implement this procedure and to ensure compliance.

3.3 It is the responsibility of QC Laboratory Management and/or Analytical Development personnel to keep this procedure aligned with current practices.

4.0 Definitions

4.1 **QC** – Quality Control

4.2 **Hysteresis** – In a balance, is caused by excessive stretching of the springs and is primarily due to overloading or dropping an object on the pan (excessive stretching of springs is cause for major repair)

5.0 References

5.1 D-828-F1, Form, QC Laboratory Balance Log

5.2 USP <1251> Weighing on an Analytical Balance

5.3 USP <41> Weights and Balances

5.4 ANSI/ASTM E617, American National Standard, Laboratory Weights and Precision Mass Standards

5.5 G-201, SOP, Calibration Program

5.6 C-501, SOP, Document Control Procedure

5.7 C-502, SOP, Record Storage, Retention, and Destruction

6.0 Location and Setup

6.1 Laboratory balances will be located on a solid, level, nonmagnetic surface.

6.2 Laboratory balances will be isolated from vibrations and air currents. A granite weigh bench is ideal to minimize vibrations.

6.3 Laboratory balances will be isolated from excessive temperature or humidity variations.

6.4 Laboratory balances will be isolated from sources of electromagnetic radiation and magnetic fields.

6.5 After powering up, the balance should be allowed to equilibrate according to the manufacturer's instructions (typically 1-24 hours) before use. Some balances use a standby mode and are ready for operation immediately after being changed out of standby.

7.0 General Use

7.1 Ensure that the weekly precision check has been performed within the last week. If not, perform the weekly precision check as outlined in section 10.0.

7.2 Ensure that the daily accuracy check has been performed on the day of use. If not, perform the daily accuracy check as outlined in section 11.0.

7.3 Note the current minimum net sample weight. Ensure that the desired sample weight is not less than the specified minimum weight.

7.4 Record the Ion number of the balance, the next calibration due date, and the specified minimum weight in the laboratory notebook.

7.5 Wear powder free gloves or use forceps to handle any material being weighed.

7.6 Inspect balance pan for loose debris and remove as necessary before weighing. A camel hair brush or equivalent can be used to clean the balance pan of loose debris before each use.

7.7 The level of the balance should be verified each day prior to the balance check and before each use. Leveling can be accomplished by rotating clockwise or counterclockwise the adjustable feet on the balance until the bubble is inside of the circle.

7.8 Use a weigh boat or weigh paper of the appropriate size to hold all of the material being measured and never measure directly on the balance pan.

7.9 Take extra precautions when weighing liquids as not to spill on the balance pan or inside the weigh chamber, as serious damage could result.

7.10 Take extra precautions when weighing materials that are potentially corrosive to the analytical balance as not to spill on to balance surfaces. Immediate cleanup is required if material falls outside the weigh boat.

7.11 Weigh the material either by quantitative transfer or by difference as outlined in section 13.0.

7.12 Print the weigh result and affix the weigh tape in the laboratory notebook.

7.13 Clean the balance pan and immediate area after use.

8.0 Calibration Weights

8.1 Traceable calibration weights spanning the range of the balance and conforming to ASTM E617 standards should be used for the Weekly Precision Check and Daily Accuracy Check.

8.2 Calibration weights should be calibrated at the frequency specified in SOP G-201 Calibration Program.

9.0 Annual Calibration

9.1 Laboratory balances should be calibrated by an external entity at the frequency specified in SOP G-201 Calibration Program.

10.0 Weekly Precision Check

10.1 An evaluation of precision should be conducted on a weekly basis or after the balance has been moved. The result of the precision check is used to determine the minimum weight that can be accurately measured.

10.2 Because the standard deviation of measurement is virtually independent of sample mass within the balance's capacity, the use of a small test weight, which may be difficult to handle, is not required.

10.3 The analyst performing the precision check should record his or her initials and date on the Weekly Precision check form.

10.4 Document the Ion number, nominal mass, and next calibration due date of the calibration weight used for the Weekly Precision Check.

10.5 Ensure that the balance is level as outlined in section 7.7.

10.6 Perform ten replicate measurements of the calibration weight

10.6.1 On the balance keypad, print the header for documentation of the date and time of precision check.

10.6.2 Remove all objects from the balance pan, allow the reading to stabilize, and tare the balance.

10.6.3 Transfer the calibration weight to the balance pan using forceps or static free gloves.

10.6.4 Allow the balance reading to stabilize.

10.6.5 On the balance keypad, press print to record the weight.

10.6.6 Repeat steps 10.6.2 - 10.6.5 for a total of ten replicate measurements.

10.6.7 Affix the weigh tape to the Weekly Precision Check form.

10.7 Calculate the minimum net sample weight.

10.7.1 Calculate the standard deviation of the ten replicate measurements.

10.7.2 If the standard deviation is less than 0.41 times the scale interval, replace the standard deviation by 0.41 times the scale interval in step 10.7.3.

10.7.3 The minimum net sample weight is equal to 2000 times the standard deviation.

Example 1: The balance capacity is 220 g and the scale interval is 0.00001 g (0.01 mg). Ten replicate measurements of a 2 g weight are performed, and the standard deviation of the measurements is 0.0000096 g. The standard deviation is greater than 0.41 times the scale interval (0.41 X 0.00001 g = 0.0000041 g). The minimum weight is 2000 X 0.0000096 g = 0.0192 g, or 19.20 mg.

Example 2: The balance capacity is 220 g and the scale interval is 0.00001 g (0.01 mg). Ten replicate measurements of a 2 g weight are performed, and the standard deviation of the measurements is 0.0000029 g. The standard deviation is less than 0.41 times the scale interval (0.41 X 0.00001 g = 0.0000041 g). The minimum weight is 2000 X 0.0000041 g = 0.0082 g, or 8.20 mg.

10.8 Enter the minimum net sample weight on the Weekly Precision check form.

10.9 Have a second person review the data and calculations.

10.10 Clearly post the minimum net sample weight on the balance. In practice, a minimum sample weight that is greater than the weight calculated in section 10.7 may be used as a convenience so that the minimum weight does not change frequently.

11.0 Daily Accuracy Check

11.1 An evaluation of balance accuracy will be conducted on a daily basis.

11.2 Two calibration weights spanning the range of the balance capacity should be used for the accuracy check.

11.3 The analyst performing the accuracy check will record his or her initials and date on the Daily Accuracy Check form.

11.4 Document the Ion number and weight specifications (± 0.1%) of the calibration weights used for the Daily Accuracy Check. As an example of weight specification for a calibration weight with a mass of 2.00001 g, the weight specification would be 1.99801 g – 2.00201 g.

11.5 Ensure that the balance is level as outlined in section 7.7.

11.6 Perform the balance internal calibration. Consult the manual for the specific balance for internal calibration procedure. Be very careful not to subject the balance to air currents or vibration while the internal calibration is being performed.

11.7 On the balance keypad, print the header for documentation of the date and time of the accuracy check.

11.8 Remove all objects from the balance pan, allow the reading to stabilize, and tare the balance.

11.9 Transfer the calibration weight to the balance pan using forceps or static free gloves.

11.10 Allow the balance reading to stabilize.

11.11 On the balance keypad, press print to record the weight.

11.12 Repeat steps 11.8 - 11.11 for the second weight used for the accuracy check.

11.13 Affix the weigh tape to Form D-828-F1 QC Laboratory Balance Log.

11.14 The measurements should be within 0.1% of the weights listed on the Certificate of Analysis. On Form D-828-F1 QC Laboratory Balance Log, indicate pass or fail for the accuracy check.

11.15 Have a second person review the accuracy check.

12.0 Troubleshooting: Causes of Drift

12.1 A balance door is open.

12.2 Temperature of the balance and material to be weighed are not the same.

12.3 The sample is actively loosing or gaining weight.

12.4 The balance has been moved and is not equilibrated to the new environment.

12.5 Air currents are present in the laboratory.

12.6 The balance is not properly leveled.

12.7 The balance is subjected to vibration, electromagnetic radiation, or magnetic field.

12.8 Hysteresis of the mechanical parts occurs during weighing.

13.0 Weighing Methods

13.1 Quantitative Transfer

13.1.1 Center the weigh container on the balance pan, and tare the balance.

13.1.2 Load the material to the desired weight specification.

13.1.3 After the balance has equilibrated print out the result and log in notebook.

13.1.4 Transfer the weighed material to the sample container. Liquid may be used to wash any residue from the weigh container into the sample container to ensure quantitative transfer.

13.2 Weight by Difference

Note: Weighing by difference does not remove the need to meet the minimum weight calculated for the balance in use. The amount weighed is required to be at or above the balance minimum.

13.2.1 Tare the balance with the weigh container centered on the balance pan.

13.2.2 Load the material to the desired weight specification.

13.2.3 After the balance has equilibrated print out the result.

13.2.4 Transfer the weighed material to the test vessel.

13.2.5 Reweigh the weigh boat.

13.2.6 Subtract the weigh boat final weight from the initial material weight to get the transferred weight.

13.2.7 Record the results on Form D-828-F1 QC Laboratory Balance Log and attach printouts.

14.0 Documentation Requirements

14.1 Documents will be distributed and maintained as outlined in SOP C-501 Document Control and SOP C-502 Record Storage, Retention, and Destruction.

15.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/06/10	New	-	-
1	01/24/12	Updated Original Format	-	-
2	02/14/13	Added more troubleshooting information, reformatted for easier interpretation, added more good practice information.	13-090	B. Johns
3	02/04/15	Biennial review. Added specific instruction for the daily calibration of the Adam PW-124 and Mettler Toledo X5204 scales.	15-0136	B. Johns
4	04/04/17	Biennial review. Update Title. Updated check weight specifications. Modified procedure to meet current practices.	17-0341	B. Johns
5	02/22/19	Update for compliance with USP general chapter. Added weekly precision check. Remove instructions for specific balances. Added log.	19-0159	S. Sassman
6	08/05/21	Added micro balance to scope of SOP. Other minor changes.	CC-21-0276	J. Sassman
7	03/23/22	Review to ensure SOP matches current practices.	CC-22-0114	S. Sassman
8	11/04/23	Add references to document control procedures. Add document maintenance requirements. Change SOP number.	CC-23-0544	K. Burris

ION Nutritional Labs	QC Laboratory Balance Log		
	Form: D-828-F1	CCR No. CC-23-0544	Revision: 5

Logbook Number: _____ Logbook Page: _____

Weekly Precision		
	Ion # of Balance: _____ Cal Due Date _____ Weight / Ion # _____ 1- Standard Deviation: _____ 2- Scale Interval: _____ 3- 0.41 X Scale Interval: _____ 4- Greater of #1 and #3: _____ 5- 2000 X #4: _____ **Minimum net weight**: _____ Entered by_____ Review by_____	insert weigh tape here

Daily Accuracy

Date	Weight Ion Number	Weight Specification		Pass / Fail	Entered by	Reviewed by
		_____ _____ _____ _____	insert weigh tape here			
		_____ _____ _____ _____	insert weigh tape here			
		_____ _____ _____ _____	insert weigh tape here			
		_____ _____ _____ _____	insert weigh tape here			
		_____ _____ _____ _____	insert weigh tape here			
		_____ _____ _____ _____	insert weigh tape here			
		_____ _____ _____ _____	insert weigh tape here			