ION Nutritional Labs	Standard Operating Procedure **Calibration, Use, and Cleaning of Inline pH Meters**	**SOP Number** D-826	**Revision** 1
		Effective Date 03/07/25	**Page** Page 1 of 4

Written by/ Date	Reviewed by/ Date	Approved by/ Date
09/4/24	09/17/24	01/27/25
Title: Technical Product Manager – Gummies	**Title: Gummy Manager**	**Title: Quality Control Director**

1.0 Purpose

This procedure provides instructions on the use, calibration, and cleaning of inline pH meters in use on the continuous gummy manufacturing lines.

2.0 Scope

This procedure applies to all inline pH meters used on the continuous gummy manufacturing lines at Ion Nutritional Labs.

3.0 Responsibility

3.1 It is the responsibility of Production (Continuous Gummy Manufacturing) personnel to follow this procedure.

3.2 It is the responsibility of Production Management to implement this procedure and to ensure that the procedure is being followed.

3.3 It is the responsibility of QC Laboratory Management or Metrology to keep this procedure aligned with current practices.

4.0 Definitions

4.1 **pH** – Potential of Hydrogen

4.2 **Standard Buffer** – a buffered salt solution with a known pH value

4.3 **QC** – Quality Control

5.0 References

5.1 USP <791> pH

5.2 D-706, SOP, Use and Calibration of pH Meters

5.3 B-911, SOP, Continuous Gummy Manufacturing Process

5.4 B-911-F1, Form, Gummy Line Equipment Calibration Verification Log

6.0 Equipment

6.1 Inline pH Meter

6.2 Standard buffer solution

6.3 pH Storage Solution

7.0 Assembly

7.1 Carefully connect the electrical plug to the pH meter.

7.2 Install the meter in the pipes Using a 1 1.2in gasket and clamp.

8.0 Calibration

Standard buffer solutions used for calibration are available from the QC lab. Do not use expired buffers. Rinse the pH electrode with DI water between each measurement. The pH meter may be calibrated to 1 -3 pre-set buffers. Because the pH range of the gummy mass is close to or below the lowest pre-set buffer, it is sufficient to use single point calibration. Because the calibration is done using room temperature buffer standards, while the gummy mass is done at ~ 90 °C, manual temperature compensation must be performed.

8.1 Press the Menu button, the password is 0000, then scroll and select Signal Settings, followed by Temp Compensation, and Artificial Compensation.

8.2 Adjust the temperature correction to 25 °C, then press enter to save the results.

8.3 Return to the main menu and select Online Calibration, then pH Calibration.

8.4 Select the correct standard set based on what standards are available. The two pre-set standards differ by 0.01 pH units. E.g. 4.01 vs 4.00.

8.5 The lowest pH standard will be first. Clean the pH probe, then submerge it in the standard solution. Wait until the reading becomes static, this may take several minutes. Press Enter to confirm the reading.

8.6 The middle pH standard will be second. If only doing single point calibration, press escape until return to the main menu. If doing multi-point calibration, use the appropriate standard(s) and calibrate in the same manner as with the lower standard solution.

8.7 Return to the Temp Compensation setting and adjust the temperature to 90 °C, confirm by pressing Enter.

8.8 Document that this process was performed on Form B-911-F1 Gummy Inline Equipment Verification Log under the pH Meter column.

9.0 Cleaning & Storage

The probe must be cleaned and stored in proper storage solution overnight after each use.

9.1 Carefully remove the probe from the pipe.

9.2 Clean the probe with hot water and if necessary, a clean rag.

9.3 Store the pH probe in Oakton® pH electrode storage solution or equivalent.

9.4 Clean the housing of the pH probe thoroughly, as it is an area where set gummy accumulates.

10.0 Maintenance

Proper storage of the probe will extend its life. Typical lifespan of a pH probe is 12-18 months.

10.1 When the pH probe can no longer be calibrated, check the following:

10.1.1 Are the calibration solutions fresh?

10.1.2 Is the probe clean?

10.1.3 Is the probe damaged?

10.1.4 Is the cord damaged?

10.2 If the probe is clean, and there is no damage to the probe or cord. Then a replacement is necessary.

11.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	10/20/23	New.	N/A	B. Eschevarria
1	09/18/24	Simplified instructions specific to the meters on the gummy line. Added instructions for temperature compensation. Added maintenance section. Added instructions to store in solution after every use.	CC-24-0458	Patrick Wilson