	Standard Operating Procedure	SOP Number D-827	Revision 2
	Calibration and Use of Brix Refractometers	Effective Date 10/28/23	Page Page 1 of 6
Written by/ Date BC 10/23/23	Reviewed by/ Date [Signature] 10/25/23	Approved by/ Date [Signature] 10/23/23	
Title: Metrologist	Title: Technical Product Manager – Gummies	Title: Quality Control Director	

## 1.0 Purpose

This procedure provides instructions on the use and calibration of both analog and digital Brix meters in the QC Laboratory and production.

## 2.0 Scope

This procedure applies to all dietary supplement, pet product, cosmetic, and pharmaceutical raw materials and finished products used or manufactured at Ion Labs that require Brix testing.

## 3.0 Responsibility

- 3.1 It is the responsibility of Production and QC Laboratory personnel to follow this procedure.
- 3.2 It is the responsibility of QC Laboratory and 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 to keep this procedure aligned with current practices.

## 4.0 Definitions

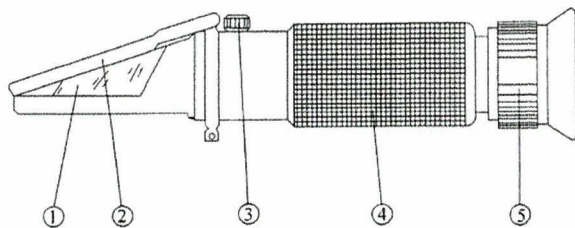
- 4.1 **Brix Refractometer** – an instrument for measuring the % Brix of materials using the refractive index or other methods
- 4.2 **Degrees Brix (°Bx)** – (of a material/substance) is a common method for measuring dissolved solids in a solution. It is routinely used to measure the % weight of sugar in aqueous solutions. Each °Bx is equivalent to 1g sugar per 100g of solution

- 4.3 **IPA** – Isopropyl alcohol
- 4.4 **QC** – Quality Control
- 4.5 **PQV** – Process Quality Verification

## 5.0 References

- 5.1 Instruction manual, Cole-Parmer “Handheld Analog Refractometers”
- 5.2 G-201, SOP, Calibration Program
- 5.3 D-827-F1, Form, Brix% Test Ticket
- 5.4 D-827-F2, Form, Refractometer Daily Calibration Log
- 5.5 B-911, SOP, Continuous Gummy Manufacturing Process
- 5.6 B-911-F1, Form, Gummy Inline Equipment Verification Log
- 5.7 IPRM-G880 In-Line Brix Sensor Instructions
- 5.8 A-106, SOP, Documentation Guidelines for cGMP Records
- 5.9 C-502, SOP, Record Storage, Retention, and Destruction
- 5.10 C-501, SOP, Document Control Procedure

## 6.0 Procedure for Analog Brix Meters



### Description

- 1) Prism
- 2) Cover plate
- 3) Calibration screw
- 4) Mirror tube
- 5) Eyepiece (adjusting ring of diopter)

## 6.1 General Use for Analog Brix Meters

6.1.1 The refractometer should only be read while in a horizontal position.

6.1.2 The front end should be held in the direction of a bright light. Preferably incandescent or natural light.

6.1.3 The eyepiece can be adjusted until the reticle can be seen clearly.

6.1.4 The rubber cover on the calibration screw (3) should be kept covered when not being serviced to keep liquid from entering the refractometer.

## 6.2 Cleaning

6.2.1 The prism (1) and cover plate (2) should be cleaned before and after each use with a clean, soft cloth or paper. IPA can be used to help facilitate the removal of oils or poorly soluble solids on the prism or cover plate.

6.2.2 The refractometer should be dried thoroughly before storage and use.

## 6.3 Calibration

6.3.1 The refractometer should be calibrated daily with extra-virgin olive oil. Olive oil should have a °Bx or Brix% value of 71-72.

6.3.1.1 Using a pipet put about 2-3 drops of olive oil on a clean, dry prism surface.

6.3.1.2 The cover plate should be placed on top of the prism. If bubbles are observed, press lightly on the cover plate to remove them.

6.3.1.3 Holding the refractometer horizontally, look through the eyepiece. There should be a distinct separation between white and blue sections. The line where these sections meet is called the contrast line.

6.3.1.4 If reading is not between 71 and 72, remove calibration screw cover and using an appropriate flat screwdriver, turn the screw (3), clockwise or counterclockwise until the contrast line is approximately 71.5 Brix%.

6.3.1.5 Return the calibration screw cover and notate that the refractometer was calibrated.

6.3.1.6 Clean and dry the prism and cover plate.

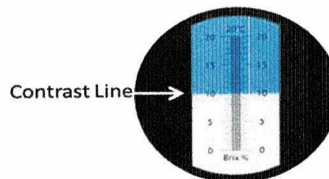
6.3.2 Record the calibration activities on Form D-827-F2 Refractometer Daily Calibration Log.

#### 6.4 Usage

6.4.1 Brix measurements are generally performed at 20°C and is dependent on temperature, however, values for analogue brix measurements are currently for empirical purposes only and were developed at the temperature listed in the specific profile.

6.4.2 To a clean dry prism, add a few drops of sample and cover with the cover plate.

6.4.3 Hold horizontally and read the value where the contrast line lies (example shown below).



6.4.4 Record value on Form D-827-F1 Brix% Test Ticket.

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## 6.5 Documentation Requirements

6.5.1 A PQV check must be performed for each completed logbook page as outlined in SOP A-106 Documentation Guidelines for cGMP Records.

6.5.2 Documents will be maintained following SOP C-502 Record Storage, Retention, and Destruction and C-501 Document Control Procedure.

## 7.0 Calibration Verification of Inline Brix Meters used in Gummy Production

7.1 This procedure applies only to inline Brix meters used in gummy production. It does not apply to handheld or manual models. This procedure must be performed on each brix meter at least once monthly.

### 7.2 Materials Needed

7.2.1 Deionized water

7.2.2 Inline Brix Meter

7.2.3 Brix Meter verification housing

### 7.3 Procedure

7.3.1 While the equipment is not in operation, disassemble the Brix meter from its housing by removing the clamp union. Keep in mind: there may be residual fluid that escapes while removing the meter- this is normal. Next remove the Brix meter, then remove the gasket.

7.3.2 Inspect the prism on the Brix meter. If there is any debris or crystallization on the prism, gently clean with deionized water and a soft cloth.



**Brix % Test Ticket**

Form:

D-827-F1

CCR No.

CC-23-0515

Revision: 2

Logbook Number: \_\_\_\_\_

Logbook Page: \_\_\_\_\_

Sample Prep	
Sample Name:	
Sample Batch / R Number:	
Sample SKU / RMID	
Test Date:	

Equipment	
Refractometer Ion ID #:	
Calibration Results:	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
Temperature (°C):	
Thermometer Ion ID #:	
Last Calibration Date:	

Data / Parameters	
Brix %:	
Specification	

Determination (circle one):                      **Pass**                      **Fail**

Comments:

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Performed By/Date: \_\_\_\_\_

Reviewed By/Date: \_\_\_\_\_