
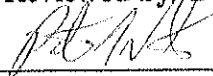



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	Standard Operating Procedure		SOP Number D-794	Revision 1
	Use and Calibration of an Analog Brix Meter		Effective Date 05/16/23	Page Page 1 of 5
Written by/ Date K. Munnich 04/15/23		Reviewed by/ Date  05/10/23	Approved by/ Date  05/10/23	
Title: Quality Assurance Director		Title: Technical Product Manager – Gummies	Title: Quality Control Director	

1.0 Purpose

This procedure provides instructions on the use and calibration of Analogue 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

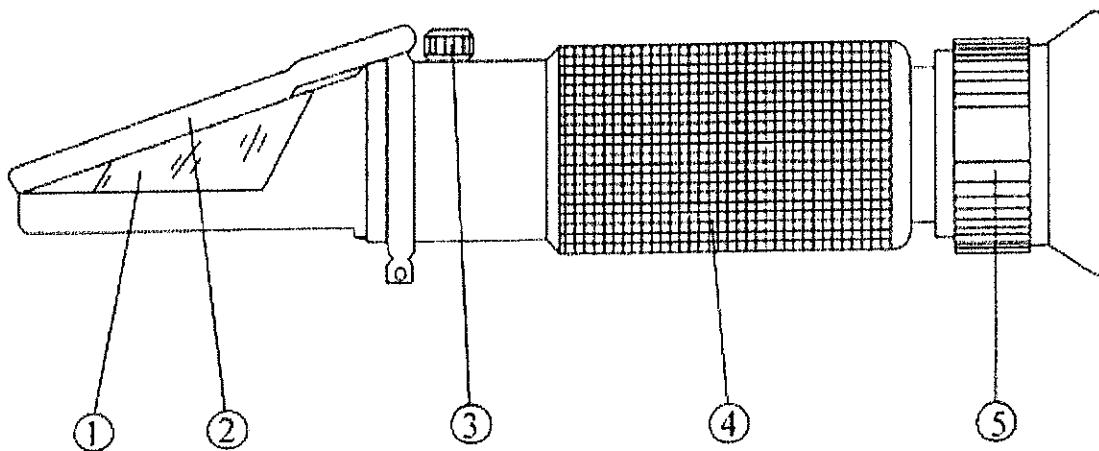
- 4.1 **Brix Refractometer** – an instrument for measuring the % Brix of materials using the refractive index or other methods
- 4.2 **Degrees Brix (°Bx)** – (of a material/substance) is a common method for measuring dissolved solids in a solution. It is routinely used to measure the % weight of sugar 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-794-F1, Form, Brix% Test Ticket
- 5.4 D-794-F2, Form, Refractometer Daily Calibration Log
- 5.5 A-106, SOP, Documentation Guidelines for cGMP Records
- 5.6 C-502, SOP, Record Storage, Retention, and Destruction

6.0 Procedure



Description

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

6.1 General

- 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.

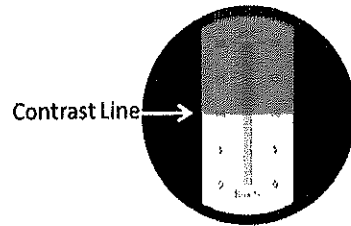
6.3.2 Record the calibration activities on Form D-794-F2 Refractometer Daily Calibration Log.

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-794-F1 Brix% Test Ticket.

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.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	02/10/20	New.	N/A	J. Maignan
1	04/15/23	Updated logo and format. Revised responsibilities.	CC-23-0186	K. Burris

**Brix % Test Ticket**

Form: D-794-F1

CCR No. CC-23-0186

Revision: 1

Sample Prep

Sample Name:

Sample Batch / R Number:

Sample SKU / RMID:

Test Date:

Equipment

Refractometer Ion ID #:

Calibration Results:

 Pass 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: _____

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