Insert Company Logo here	**SOP NAME**	**Equipment Calibration, and Control of Inspection, Measuring and Test Equipment Procedure**			
	SOP Category	SOP Number	Revision Number	Date of Previous Revision	Revision Effective Date
Page 1 of 5	E	001	00	N/A	XX/XX/XX
Supersedes: Original Document	Prepared by G. Host			Date	XX/XX/XX
CONFIDENTIAL	Approved by G. Host			Date	XX/XX/XX

1. **OBJECTIVE**

   To describe the procedure established for Equipment Calibration, and Control of Inspection, Measuring and Test Equipment.

2. **SCOPE (Optional)**

   2.1 The scope of this SOP applies to Equipment Calibration, and Control of Inspection, Measuring and Test Equipment.

3. **PERSONNEL RESPONSIBILITIES**

   3.1 It is the responsibility of the Quality Manager or a member chosen and trained by the Quality Department to ensure these procedures are being enforced and followed.

4. **DEFINITIONS**

   4.1 N/A

5. **REFERENCES**

   5.1 21 CFR 111.27(b)

   5.2 NSF Guidelines

   5.3 GMP requirements are listed in NSF/ANSI 455-2 which is the only American National Standard in the dietary supplement industry developed in accordance with the FDA's 21 CFR part 111.

6. **SAFETY**

   Personnel working at insert your company's name shall follow necessary procedures to protect themselves and others from physical harm per the guidelines provided by the Company and/or OSHA.

7. PROCEDURE

7.1 General Requirements

7.1.1 Test equipment that is used to verify the conformance of a product to specifications is controlled, calibrated, and maintained to assure their accuracy. The Quality Assurance Manager facilitates this process.

7.1.2 Each piece of inspection, measuring and test equipment is labeled with a suitable indicator (label, sticker or tag) that shows calibration status.

7.1.3 Critical product and process characteristics are identified with the quality system documentation. Management personnel assign an appropriate measuring device of suitable accuracy and precision, to verify these characteristics. The equipment that is selected must have an uncertainty (accuracy) that is less than 25% of the product or process tolerance.

7.1.4 The Quality Assurance Manager is responsible for maintenance, calibration, and control of all inspection, measuring, and test equipment, including equipment belonging to employees or on loan.

7.1.5 Calibration of measuring and test equipment is carried out using calibration instruments or standards certified to have a known relationship to a nationally recognized standard, such as National Institute of Standards Testing (NIST). This relationship is identified on the calibration record. Equipment that is sent out for calibration is required to be returned with certification that is likewise traceable to a national standard. Calibration records and certificates are maintained by the Quality Assurance Manager.

7.1.6 Calibrated equipment is labeled with a sticker indicating the due date for next calibration. Such equipment is traceable to its calibration record through its serial number or other unique marking. Do not use equipment with a past-due calibration date or without a calibration sticker. Immediately return to the Quality Assurance Manager.

7.1.7 QA maintains a master list of all active measuring and test equipment, whether or not the equipment is owned by the company. The master list identifies every piece of equipment by its name, type, identification number, location, calibration frequency, last calibration date, and next calibration due date. The list is updated as needed.

7.1.8 Manufacturer's recommendations on calibration are used to determine the maximum amount of time (intervals) between calibrations.

7.1.9 Refer to the following table for guidelines on how often calibrations should be performed.

1. Equipment Type	2. Calibration Interval
3. RH/Temperature Gauges	4. 1 year
5. Scales (Balances)	6. 1 year
7. Test Weights	8. 1 year
9. Gauss Meters	10. 1 year
11. Magnehelic Differential pressure gages	12. 1 year

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7.2 **Equipment Exempted from Calibration**

7.2.1 Inspection and test equipment used in situations where the accuracy of measurements is not important, or where the measurement does not have any relation to verification of products, are exempted from the calibration requirement. Uncalibrated equipment is labeled as *For Reference Only*. Production and Inspection personnel are made aware of the limitations in using un-calibrated equipment.

7.3 **Environmental Considerations**

7.3.1 Management ensures that the environmental conditions and the handling, preservation, and storage of inspection, measuring and test equipment are suitable for the evaluations being performed. Equipment that is out of calibration or is otherwise not fit for use is withdrawn from the inspection and production areas, and is segregated or otherwise clearly identified.

7.4 **Electronic Database**

7.4.1 As equipment is calibrated, the equipment user/owner contacts the Quality Assurance Manager to ensure entry of the applicable information into the calibration database (QAF-008). This database serves as the master list of inspection, measuring and test equipment. It includes a unique equipment identification number, a description of the equipment, and information on calibration intervals, due dates, last known location, history and additional related information, as necessary.

7.4.2 The Calibration System Database (QAF-008) is located on a drive that is backed up weekly. The weekly backups are stored off-campus.

7.5 **Off-Site Calibration (Service Provider)**

7.5.1 Test equipment may also be shipped to the calibration provider's facility for calibration or repair. Some companies also provide a pick-up and delivery service.

7.5.2 Regardless, a PO should be initiated to track the equipment.

7.5.3 The President and/or Quality Assurance Manager coordinates this activity.

7.5.4 The service provider calibrates or repairs the equipment and returns it to insert your company's name.

a) **Note:** All calibration certificates are forwarded to the Quality Assurance Manager when they are received.

7.6 **Off-site Calibration (OEM Manufacturer's Calibration)**

7.6.1 In certain instances, the original equipment manufacturer may perform the calibration. When this happens, a Certificate of Calibration must be provided by the manufacture to ensure traceability of calibration.

a) **Note:** All calibration certificates are forwarded to the Quality Assurance Manager when they are received.

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7.7 **Removal of Equipment**

7.7.1 If a piece of test equipment is damaged beyond repair or is no longer being used, it is removed from service.

7.8 **Out of Tolerance Conditions**

7.8.1 When a piece of inspection, measuring and test equipment is found to be out of specification or needs of repair, it must be removed from service immediately.

7.8.2 If the equipment is in good working order and is or is not delinquent, then it is calibrated.

7.8.3 If the equipment is not in good working order and is or is not delinquent, then it is calibrated, if appropriate. In some cases, the equipment may be replaced; however, the condition of the equipment that did not meet the calibration specifications may be communicated to the proper entities, up to and including customers.

7.8.4 Management takes appropriate action to assess the impact on product in-process and/or in shipping to the customer.

7.8.5 The equipment user/owner is responsible for providing the appropriate Calibration information to the Quality Assurance Manager indicating that the equipment has been removed from service.

a) N**ote:** This is necessary to ensure complete and accurate corrective action

7.9 **Documentation of Corrective Actions:**

7.9.1 There must be documentation of corrective actions when a non-calibrated or inaccurate measuring device has been used (thermometer, scale, flow meter, counting device, metal detector, coder, etc.). All products produced since the last acceptable check must be assessed to determine if it must be held for further evaluation.

7.10 **Receiving and Distribution Scales:**

7.10.1 The accuracy of Receiving and Distribution scales must be verified daily using test weights in the range of the measurements being determined. Documentation of these checks must be available and are part of the routine daily records for the activity being measured.

7.11 **Accuracy of Scales:**

7.11.1 The accuracy of scales used for weighing ingredients, finished product preparation, and packaging must be determined daily using calibrated test weights in the range of the measurements being determined. Daily calibration checks are documented on the Scale Calibration/Verification Log form (QAF-007SC/VL).

7.12 **Test Weights Calibration Frequency:**

7.12.1 Test weights must be calibrated by a certified contractor at least annually, or whenever they are dropped or damaged. Records must be available.

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7.13 **Test weight Preservation:**

7.13.1 Calibrated Test weights must be stored properly off the floor. They should be stored in cabinets or shelves where they are protected against water or potential damage.

7.14 **Production Equipment Validation:**

7.14.1 The maintenance department shall qualify the basis functions of each piece of production equipment through periodic documented inspections (PM's).

7.14.2 Validation shall include speed, temperature, stroke, levels, etc. where applicable.

7.14.3 Suitable calibrated measuring devices shall be used in collecting this data.

8. FORMS

8.1 Calibration System Database (QAF-008)

8.2 Scale Calibration/Verification Log form (QAF-007SC/VL).

9. RECORD RETENTION

9.1 Any record and/or document pertaining to this procedure shall be kept and maintained by the Quality Department.

9.2 In general, any documentation in regards to this procedure, shall be kept, at minimum, per 21 CFR Part 111.605:

9.2.1 "(a) You must keep written records required by this part for 1 year past the shelf-life date, if shelf-life dating is used, or 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records.

9.2.2 (b) Records must be kept as original records, as true copies (such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records.

10. NOTES

10.1 xxx

11. FLOW CHART

N/A

12. APPENDIX

n/a

REVISION	CHANGE CONTENT	No.	EFFECTIVE
E.001.00	New procedure	CO xx-xxx	XX/XX/XXXX
E.001.01			

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