

Insert Company Logo here	SOP NAME	Specification & Formulation Control Procedure			
	SOP Category	SOP Number	Revision Number	Date of Previous Revision	Revision Effective Date
Page 1 of 3	Q	004	00	N/A	XX/XX/XX
Supersedes: Original	Prepared by G. Host			Date	XX/XX/XX
CONFIDENTIAL	Approved by G. Host			Date	XX/XX/XX

1. PURPOSE

To describe the procedure established for Specification and Formulation Control.

To ensure that all packaging and labeling components are properly handled and controlled from purchase and receipt and use through the entire production process to meet the requirements of part **111 of the Dietary Supplement** Regulations.

2. SCOPE (Optional)

2.1 The scope of this SOP applies to Specification and Formulation Control.

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 XXX

5. REFERENCES

5.1 21 CFR **111.70(b) & (d)**

5.2 21 CFR **111.75(a) & (f)**

5.3 21 CFR **111.95(b)(3)**

5.4 21 CFR **111.127(d)**

5.5 NSF Guidelines

5.6 ANSI 455-2

5.7 (Q001 *Document and Data Control Procedure*)

6. SAFETY

Personnel working at **enter 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 Internal or customer specifications must be available that define acceptable product attributes. Each specification must be maintained and tracked under a defined quality assurance program.

7.2 Procedures must be in place to ensure compliance with specifications and control of product formulations.

7.3 Records must be available to demonstrate compliance with all manufacturing and finished product specifications including customer specifications.

7.4 Products with multiple ingredients must have appropriate formulation controls available to operators as well as procedures to ensure regular verification of accuracy.