1.0 Purpose

This procedure defines the requirements for testing under non-GMP guidelines during raw material and finished product evaluation.

2.0 Scope

This procedure applies to all raw materials and finished products used or produced at Ion Labs Inc.

3.0 Responsibility

3.1 It is the responsibility of QC and Analytical Chemists to follow this procedure.

3.2 It is the responsibility of QC Laboratory Management to implement this procedure and to select appropriate methods when non-GMP testing is elected.

3.3 It is the responsibility of QC Laboratory Management and/or Analytical Development Personnel to keep this procedure aligned with current practices.

3.4 It is the responsibility of R&D to determine customer testing needs for raw materials and finished products and to work with QC Laboratory Personnel to categorize the required tests.

4.0 Definitions

4.1 **GMP** – Good Manufacturing Practices

4.2 **GLP** – Good Laboratory Practices

4.3 **QC** – Quality Control

4.4 **FDA** – Food and Drug Administration

4.5 **USP** – United States Pharmacopeia

4.6 **CFR** – Code of Federal Regulations

4.7 **AOAC** – Association of Analytical Communities

4.8 **CofA** – Certificate of Analysis

5.0 References

5.1 21 CFR 111 - Code Of Federal Regulations, Current Good Manufacturing Practice In Manufacturing, Packaging, Labeling, Or Holding Operations For Dietary Supplements

6.0 Procedure

6.1 When a test is requested by the customer or is a part of an Ion Labs internal quality metric and the test is not mandatory under FDA 21 CFR 111 guidelines, the method used can be performed under Non-GMP guidelines using any validated method without requiring further validation or formal verification by the Ion Labs QC Laboratory.

6.1.1 The preferred methods for non-GMP testing of finished products and raw materials are AOAC Methods. Other published methods may be used.

6.1.2 Sufficient system suitability requirements need to be met which verify that the test results meet predetermined accuracy and precision requirements.

6.1.3 The preferred standards are traceable analytical standards. Highly purified chemicals with purity on the CofA are acceptable alternatives.

6.1.4 Minor deviations from the published methods or monographs are permitted with documentation of the deviation(s) and rationale in the Laboratory Notebook.

6.1.5 The non-GMP test designator for GMP documentation is "D-203".

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	01/05/16	New	16-0016	N. Zhang
1	02/04/19	Scheduled Review: Changed GLP to Non-GMP throughout document.	19-0119	J. Maignan
2	04/15/23	Update format and logo. Added definitions. Changed responsibilities section.	CC-23-0187	K. Burris