ION LABS	Standard Operating Procedure Handling and Storage of Probiotics	SOP Number E-804	Revision 0
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Written by/ Date	Reviewed by/ Date	Approved by/ Date
10/06/22	10/06/22	10-10-22
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1.0 Purpose

The purpose of this procedure is to set guidelines for the handling and storage of probiotics throughout Ion Labs.

2.0 Scope

This procedure applies to all Warehouse, Production, and QC Laboratory areas, to avoid cross-contamination of probiotics.

3.0 Responsibility

3.1 It is the responsibility of Warehouse personnel, Production personnel and QC Laboratory personnel to adhere to this procedure to ensure proper handling and storage to avoid cross-contamination of probiotics.

3.2 It is the responsibility of Quality Control Management to implement this procedure and to ensure that the procedure is followed.

3.3 It is the responsibility of Quality Control Management to keep this procedure aligned with current practices.

4.0 Definitions

4.1 **Probiotic** – live microorganism which when administered in adequate amounts confer a health benefit to the host

4.2 **Cross-Contamination** – the process by which bacteria or other microorganisms are unintentionally transferred from one substance or object to another, with harmful effect

4.3 **QC** – Quality Control

4.4 **NMT** – Not More Than

4.5 **COA** – Certificate of Analysis

5.0 References

5.1 E-204, SOP, Receiving Process for Raw Materials and Packaging Components

5.2 International Probiotics Association, Probiotic Manufacturing Guidelines

5.3 USP-NF 56, Chapter <64>, Probiotic Testing

5.4 USP-NF 56, Chapter <1079>, Good Storage and Shipping Practices

6.0 Procedure

6.1 Probiotics should be stored in a temperature and humidity controlled area, as indicated on material Certificate of Analysis.

6.1.1 Various strains of probiotics require different storage conditions. The Certificate of Analysis for each material should be consulted for specific storage conditions.

6.2 Probiotics should be stored and sampled in locations that provide sufficient separation.

6.2.1 Certain strains of probiotics are known to be more sensitive to environmental conditions, and exposure to other probiotic strains.

6.2.1.1 For example, Bifidobacterium is known to be more sensitive to environmental conditions than Lactobacillus, If cross-contamination would occur between these two species, Lactobacillus may inhibit the ability for Bifidobacterium to form colonies when cultured.

6.3 Receipt of Probiotics

6.3.1 Follow SOP E-204 Receiving Process for Raw Materials and Packaging

Components. Quickly receive any probiotic raw material and place probiotic raw material into the appropriate storage locations.

6.4 Sampling (sampling for QC Laboratory testing / dispensing for manufacturing process)

6.4.1 The Sampling/ Weighing rooms should be at a temperature and humidity that will allow for little to no impact on the material being managed.

6.4.2 The ideal humidity for probiotic sampling is NMT 40%.

6.4.3 Only sample one probiotic at a time. Sampling should occur as quickly as possible to limit any exposure of the material.

6.4.4 Clean sampling area between sampling different probiotics.

6.5 Transferring probiotic materials between sites

6.5.1 Probiotics should be transferred in temperature controlled vehicles at 2-8°C. Note: Ambient conditions are allowed for short term storage/ material transfer (Not more than 1 business day). Once probiotic is at production facility it must be transferred to appropriate storage conditions as indicated on the material COA.

6.5.2 Ship as quickly as possible to the manufacturing department to avoid excessive humidity and temperature fluctuations.

6.6 Handling and Storage in Production area (Blending, Compression, Liquid and Encapsulation areas)

6.6.1 Prior to blending, probiotics should be stored as indicated on material COA.

6.6.2 Hold times between dosage manufacturing and finished packaging in general should be minimized.

6.7 Finished product storage after packaging

6.7.1 All finished products should be stored onsite as indicated on product label.

6.8 QC Laboratory Receipt and Testing

6.8.1 Upon receipt into the QC Laboratory, probiotics should be stored as indicated on material COA until all testing is completed.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	10/06/22	New procedure.	N/A	G. Shaw