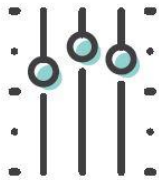


1. PROCESS FROM PRODUCT FORMULATION TO SHIPMENT

Parameters that must typically be considered when manufacturing a probiotic, from the formulation to the blending and the packaging are detailed in the guidelines, though details regarding manufacturing of the active ingredients, i.e. the probiotics, are not addressed. The IPA Probiotic Manufacturing Process Map is included.

2. BEST PRACTICES TO ACHIEVE COMPLIANCE

Within the guidelines, processes and practices are described as Acceptable to Optimal. Acceptable practices should achieve probiotic finished products that are within specification assuming other GMP's are adhered to during processing. Moving towards Optimal practices and processes should be the aim of probiotic powder finished supplement manufacturers as described in the guidelines.



3. RECOMMENDED PROCESS PARAMETERS

Various limits or ranges for some specific parameters are addressed for each step of the production and shipment of a Probiotic Dietary Supplement. These parameters include Temperatures & Relative Humidity in the area, as of the product, and more. Guidance and recommendations are outlined for each step. Recommendation for Retain samples procedures are also addressed.

4. QC TESTING?

Recommendations for Microorganism's ID and enumeration and evaluation of contaminants are also suggested in these guidelines.



5. A RECOMMENDATION FOR CONTINUOUS PROCESS IMPROVEMENT

These guidelines are not to be considered all-encompassing with regards to regulatory and GMP requirements as set forth by the various regulatory authorities and recognized certifications. As such, they address only certain "typical" areas of possible concerns and therefore provide recommendations. It remains the manufacturers' responsibility to build and demonstrate scientific rationales, and therefore information provided herewith serves only as examples, while providing opportunities for continuous process improvement. To access the IPA Probiotic Manufacturing Guidelines contact: info@internationalprobiotics.org.



The Global Voice of Probiotics®

Probiotics are unique food and dietary supplement ingredients. The World Health Organization defines these beneficial bacteria as “live microorganisms which, when administered in adequate amounts, confer a health benefit to the host.” As live microorganisms, probiotics require special handling and other considerations to ensure the safety, quality, and efficacy of finished products.

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