

*Microbiological Challenges in
Establishing and Meeting Specifications
for Contaminants Limits Under the New
Dietary Supplement GMP's*

KML Laboratories, Inc.



Purpose of a Microbial Specifications

- Safety of Product
- Control Spoilage of Product
- Ensure Product Meets Established Expiry Date

Recommended Maximum Microbial Limits for Dried Agricultural Commodities (units in cfu/g or ml)

Organization	AHPA	EHIA	EP	NSF/ANSI	USP	WHO
Plant Material	Includes Cut and Powdered Forms Used as Ingredients and Subject to Further Processing	NA	NA	Botanical Ingredient, Non-Extract	Dried or Powdered Botanicals	Untreated Crude Intended for Further Processing
Total Aerobic Microbial Count	10 ⁷	NA	NA	10 ⁷	10 ⁵	NA or 10 ⁵ -10 ⁷ as per specific monographs
Total Combined Yeast & Molds	10 ⁵	NA	NA	10 ⁵	10 ³	10 ⁵ (mold propagules); Occasionally 10 ⁴ for specific monographs
Enterobacteria (Bile-tolerant Gram-negative Bacteria)	10 ⁴ (coliforms)	NA	NA	10 ⁴	10 ³	10 ³
<i>E. coli</i>	absent in 1 g	NA	NA	10 ²	absent in 10 g	10 ⁴
<i>Salmonella</i> spp.	absent in 10 g	NA	NA	absent	absent in 10 g	NA or absent
<i>Staphylococcus aureus</i>	NA	NA	NA	absent	NA	NA or absent

Selection Criteria of a Microbial Specification

- Type of Matrix
- % Water Activity
- Finish Product Type ex. Capsule ,powder
- Storage Conditions
- Packaging

Method of Testing

- Rapid Methods
- Official Methods
- Automated Methods
- Pro/Cons
- Choosing a Method

Qualifying the Matrix to the Method

- USP – Spike Recovery
- AOAC- None
- BAM- None

Knowledge Gained !!!!!

Limit of Detection

Neutralizing Agents if needed

Method is suitable for matrix

Result Issues

- Reporting
- Common Errors
- What Does presence/absence mean to you?!
- Sampling Plans! Are they really needed in today's world?

Points of Interest

- Get to know what your microbiologist is talking about
- Have open communication with your third party contract laboratory
- Be Aware of the current issues at the time
- Learn the Methods or at least Make a Flowchart!