

Updates on USP Standards for Probiotics

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- 2016 - 2017
 - Established the Probiotics Expert Panel
 - Proposed a general chapter, <64> PROBIOTIC TESTS
 - Proposed monographs (*B. coagulans* and its capsules) in PF 43(1)
 - Published 5 official monographs (4 *Lactobacillus* + 3 *Bifidobacterium* strains) in USP40-NF35
- 2015
 - Probiotic Roundtable
- Before 2015
 - 8 monographs in FCC
 - 2012 USP-IFT Workshop: A co-sponsored workshop on identity and characterization of a probiotic microorganism used in food ingredients: Importance to Safety and Efficacy

- *Lactobacillus acidophilus* LA-14 → Approved
- *Lactobacillus acidophilus* NCFM → Approved
- *Lactobacillus paracasei* Lpc-37 → Approved
- *Lactobacillus rhamnosus* HN001 → Approved
- *Bifidobacterium animalis* ssp. *lactis* → Approved

- *Bacillus coagulans** → Proposed
- *Bacillus coagulans** Capsules → Proposed
- General Chapter <64> Probiotics Tests → Proposed

* The title is at the species level to include multiple strains in one monograph. Strain-level titled monographs will be revised to the species level in near future.

- Industry needs science-based quality testing
 - Most manufacturers use ID test with limited specificity.
 - Very few ingredient manufacturers promote DNA-based ID test.
- Best Practices Guidelines for Probiotics (CRN+IPA)
 - Address strength, stability, and label claims
 - Does not address ID tests and contaminants
 - Does not address public standards of probiotics (USP monographs)
- Limited awareness of USP probiotic standards
 - Not familiar with USP standards
 - Most DS manufacturers (ingredients/dosage forms) are not familiar with DNA-based ID tests as a QC release test.
 - Need to address limits for micro-contaminants for probiotics
 - Need to promote public standards for probiotics

- ▶ Probiotic EP
 - Formed in April 2017
 - Review monographs and provide recommendation to NBDS-EC
- ▶ Dr. Mary Ellen Sanders - Chair
- ▶ Dr. Chris Elkins – FDA Government Liaison
- ▶ Expert Panel Members (14)
 - Subject-matter experts from major manufacturers (ingredients, dosage forms and testing laboratories)
 - Experts in FDA, NIH, and NIST



Probiotics Expert Panel – Members

	Name	Member	Affiliation
1	Sanders, Mary Ellen	Chair	ISAPP
2	Elkins, Chris	GL	FDA
3	Davis, Cindy Dyann	GL	NIH
4	Jackson, Scott	Member	NIST
5	Keller, David	Member	Ganeden
6	Pane, Marco	Member	Probiotal Healthcare
7	Schoeni, Jean L.	Member	Covance
8	Stahl, Buffy	Member	DuPont
9	Tartera, Carmen	Member	FDA
10	Christina Skovgaard Vegge	Member	Chr Hansen
11	Burguiere, Pierre	Member	Lallemand
12	Brooks, James	Member	USP NBDS-EC
13	Bradley, Mike	Member	USP-NBDS-EC
14	Roe, Amy	Member	USP-NBDS-EC

- ▶ Monograph review and recommendation to NBDS-EC
 - *Bacillus coagulans*
 - *Bacillus coagulans* Capsules
 - General chapter: <64> Probiotic Tests
- ▶ Informational General Chapter of Probiotics – *proposed*
 - Planned in 2018-2019
 - Testing methods, principles, requirements etc. focusing on ID, purity, strength, and limits for contaminants etc.
- ▶ Some EP members will speak at the IPA-Probiotic Workshop co-sponsored by USP (Rockville, MD on 10/26/2017)
 - Tentative topics: regulatory compliance, standards, industry practices, advanced sciences etc.
- ▶ USP Probiotic Expert Panel meeting scheduled on 10/25/2017(Rockville, MD)

<64> PROBIOTIC TESTS - Proposed

- ▶ Posted in PF 43(2) on March 1 – May 31, 2017.
- ▶ Avoid duplicated procedures in monographs for Lactobacillus or Bifidobacterium (e. g. PCR, MRS enumeration, contaminants)
- ▶ Subject to EP review and recommendation
- ▶ Addresses probiotics used as dietary ingredients as well as dietary supplements such as dosage forms (tablets, capsules, etc.).
- ▶ The scope of the chapter includes definition, identification, enumeration, specific tests, contaminants and other requirements for dietary supplement probiotics.
- ▶ This chapter also provides tests for probiotic microorganisms as well as contaminant microorganisms which may be present in dietary supplement probiotics from raw materials to the finished forms.

Under development

- *Lactobacillus fermentum* strains
- *Bacillus coagulans* with additional strains



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Stakeholder Perspectives on USP Probiotic Standards

USP Stakeholder Forum
Buffy Stahl – DuPont Nutrition and Health
7 June 2016



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Discussions