



## ***Commentary***

### **Interim Revision Announcements published in January 2024**

#### **January 26, 2024**

In accordance with USP's *Rules and Procedures of the Council of Experts ("Rules")*, and except as provided in Section 9.02 *Accelerated Revision Processes*, USP publishes proposed revisions to the *United States Pharmacopeia and the National Formulary (USP–NF)* for public review and comment in the *Pharmacopeial Forum (PF)*, USP's free bimonthly journal for public notice and comment. After comments are considered and incorporated as the Expert Committee (EC) deems appropriate, the proposal may advance to official status or be re-published in *PF* for further notice and comment, in accordance with the Rules. In cases when proposals advance to official status, a summary of comments received and the appropriate Expert Committee's responses, as well as Expert Committee-initiated changes, are published in the Proposal Status/Commentary section of USP.NF.com once the official revision is published.

The *Commentary* is not part of the official text and is not intended to be enforceable by regulatory authorities. Rather, it explains the basis of Expert Committees' responses to public comments on proposed revisions. If there is a difference or conflict between the contents of the *Commentary* and the official text, the official text prevails.

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**Comments were received for the following when they were proposed in Pharmacopeial Forum (PF):**

**General Chapters**

<64> Probiotic Tests

**Monographs**

Fosfomycin Tromethamine

**No comments were received for the following proposals:**

**Monographs**

Ligilactobacillus salivarius

Lactobacillus acidophilus

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<b>Chapter/Section(s):</b>	General Chapter <64> Probiotic tests
<b>Expert Committee:</b>	Non-Botanical Dietary Supplements
<b>No. of Commenters:</b>	3

*Enumeration*

**Comment Summary #1:** The commenter recommended adding clarity to probiotics with multiple species/strains. Example: Total CFU of all species/strains or Total CFU of each species/strain. There are *Lactobacillus* and *Bifidobacteria* which require supplements to grow.

**Response:** Comment not incorporated. This comment is out of the scope of the proposed revision. This recommendation will be further discussed with the newly formed Subcommittee on Microbiological Issues in Foods and Dietary Supplements for a potential revision of this general chapter.

**Comment Summary #2:** The commenter recommended adding a statement/section related to growth supplements.

**Response:** Comment not incorporated. This comment is out of the scope of the proposed revision. This recommendation will be further discussed with the newly formed Subcommittee on Microbiological Issues in Foods and Dietary Supplements for a potential revision of this general chapter.

**Comment Summary #3:** The commenter recommended adding the melting conditions for stored agar/media.

**Response:** Comment not incorporated. This comment is out of the scope of the proposed revision. This recommendation will be further discussed with the newly formed Subcommittee on Microbiological Issues in Foods and Dietary Supplements for a potential revision of this general chapter.

*Analysis*

**Comment Summary #1:** The commenter recommended adding the specific anaerobic conditions for incubation, GasPack system or anaerobic incubator (with gas mixture N<sub>2</sub>/CO<sub>2</sub>/H<sub>2</sub> = 80%/10%/10% or N<sub>2</sub> = 100%).

**Response:** Comment not incorporated. Additional supporting information is needed to support the requested change. Comments and recommendations received by commenters will be

further discussed with the newly formed Subcommittee on Microbiological Issues in Foods and Dietary Supplements for a potential revision of this general chapter.

**Comment Summary #2:** The commenter recommended a growth time of 2-5 days due to the slow growth of *Lactobacillus* and *Bifidobacteria*.

**Response:** Comment not incorporated. Additional supporting information is needed to support the requested change. Comments and recommendations received by commenters will be further discussed with the newly formed Subcommittee on Microbiological Issues in Foods and Dietary Supplements for a potential revision of this general chapter.

#### *Contaminants*

**Comment Summary #1:** In Table 4, the commenter recommended adding clarity to acceptable/recommended test methods for *L. monocytogenes*, *C. perfringens* and *C. sakazakii*. For example, USP <2022> is only for the absence of *Clostridium* species while this chapter is testing for the absence of *C. perfringens* specifically.

**Response:** Comment not incorporated. This comment is out of the scope of the proposed revision. This recommendation will be further discussed with the newly formed Subcommittee on Microbiological Issues in Foods and Dietary Supplements for a potential revision of this general chapter.

**Comment Summary #2:** The commenter stated that the testing should include the identification of objectionable microorganisms and the performing of the BET test, as the commenting organization has FDA approval for specifications outside of the range of this proposal.

**Response:** Comment not incorporated. This comment is out of the scope of the proposed revision. This recommendation will be further discussed with the newly formed Subcommittee on Microbiological Issues in Foods and Dietary Supplements for a potential revision of this general chapter.

**Comment Summary #3:** The commenter suggested adding a statement/section pertaining to Tyndallized probiotics.

**Response:** Comment not incorporated. This comment is out of the scope of the proposed revision. This recommendation will be further discussed with the newly formed Subcommittee on Microbiological Issues in Foods and Dietary Supplements for a potential revision of this general chapter.

**Monograph/Section(s):** Fosfomycin Tromethamine /Organic Impurities  
**Expert Committee:** Small Molecules 1  
**No. of Commenters:** 2

**Comment Summary #1:** The commenter indicated concerns with peak response variability during evaluation of system suitability due to the RI detector and low standard concentration. The commenter recommended revising the proposed %RSD acceptance criterion for the Standard solution in the System Suitability from NMT 5.0% to NMT 10.0%.

**Response:** Comment incorporated.

**Comment Summary #2:** The commenter recommended removing the reporting threshold in the test for *Organic Impurities* as it will vary based on product-specific factors.

**Response:** Comment not incorporated. General Chapter (477) *User-Determined Reporting Thresholds* was published in *USP-NF 2024 Issue 1*; this chapter supports a flexible reporting *Commentary for Interim Revision Announcements published on January 26, 2024*

threshold to accommodate product-specific factors. The Expert Committee may consider incorporating this new approach in future revisions.