Comments were received for the following proposals when they were published in *Pharmacopeial Forum* 49(2)

- <660> Container- Glass
- <661.2> Plastic Packaging Systems for Pharmaceutical Use

General Chapter/Sections: ⟨660⟩ Container-Glass
Expert Committee(s): General Chapters—Packaging and Distribution
No. of Commenters: 8

General

Comment Summary #1: The commenter recommended: 1) Propose to replace Table 1 and Table 2 with Table 1 from Ph. Eur. 2) Remove Glass Grains as it is not a performance test, but an identity test between borosilicate and soda lime, 3) Focus on the inner surface of glass container or contact surface for pharmaceuticals, 4) Replacement of the Glass Grains with WD-XRF for identity glass, 5) Update to Arsenic Extraction method via ICP analysis and correction of limits to align with Ph. Eur, and; 6) Spectral Transmission / Absorbance based on wall weight not filling volume
Response: Comment not incorporated. USP will consider these recommendations in a future revision of the chapter.
Comment Summary #2: The commenter recommended to enlarge section on impurities beyond arsenic which may be inherent to new glasses compositions.
Response: Comment not incorporated. USP will consider these recommendations in a future revision of the chapter.
Comment Summary #3: The commenter suggested adopting heating up (1°/min) and cooling down (0.5°/min) procedure in Ph. Eur. 3.2.1 as it does not require a rate for heating up and cooling down.
Response: Comment not incorporated. USP will consider these recommendations in a future revision of the chapter.
Comment Summary #4: The chapter references materials specific to borosilicate (SRM 623) and soda lime-silica (SRM 622) glasses. The commenter suggested including reference standards that are applicable to all glass types exhibiting similar performance characteristics.
Response: Comment not incorporated. USP will consider these recommendations in a future revision of the chapter.
Comment Summary #5: The commenter recommended that USP reevaluate the change from composition to performance and develop a common approach with other pharmacopeias or national/international standards to widen the container classification to new material types based on the relevant performance.
Response: Comment not incorporated. As USP moves forward with a more thorough revision next year, open dialogue with other pharmacopeias and national/international standards will be a priority to see where there are opportunities for collaboration.

General Chapter/Sections: ⟨661.2⟩ Plastic Packaging Systems for Pharmaceutical Use
Expert Committee(s): General Chapters—Packaging and Distribution
No. of Commenters: 4

Scope
Comment Summary #1: The commenter recommended expanding the text to clarify that a risk-based approach and additional testing (depending on the dosage form and other drug product attributes) may be required to assess the suitability of plastic packaging systems for pharmaceutical use.
Response: Comment not incorporated. USP feels the text as currently written is sufficient.

Table 1
Comment Summary #2: The commenter recommended revising the Table's title to be more descriptive.
Response: Comment incorporated.
Comment Summary #3: The commenter recommended revising the text to clarify that medical devices and combination products regulated as medical devices should refer to specific regulatory guidance to assess suitability for use.
Response: Comment incorporated.
Comment Summary #4: The commenter suggested that solid oral dosage forms should be exempt from USP testing based on FDA guidance.
Response: Comment not incorporated. Based on dialogue with the FDA, compendial testing is necessary for plastic packaging components and systems used for the packaging of solid oral dosage form.

Physicochemical Tests-Solution C1
Comment Summary #5: The commenter suggested adding text that packaging system can be filled with water or a representative cosolvent inclusive of all intended drug formulation.
Response: Comment not incorporated. The extraction conditions outlined in the chapter is meant to be standardized and by opening the door to the use of other solvents, standardization would be lost.
Comment Summary #6: The commenter suggested that the heating duration was inadvertently deleted and should be added back to chapter.
Response: Comment incorporated.
Comment Summary #7: The commenter suggested that if the melting point of the plastic is known in advance to be below the higher incubation temperatures, the tester should be allowed to begin incubation at a temperature below that melting point.
Response: Comment not incorporated. The standard does not exclude one's ability to use relevant component or system data/information. However, the most stringent extraction condition outline in the chapter should be used.

Comment Summary #8: The commenter suggested packaging systems of solid oral dosage forms should not be required to do the physiochemical testing outlined in the chapter. Instead, they should be required to just meet the identity test (IR, DSC) and applicable Indirect Food Additive tests/certifications.
Response: Comment not incorporated. Based on dialogue with the FDA, all compendial testing is necessary for plastic packaging components and systems used to package solid oral dosage form.
Comment Summary #9: The commenter recommended adding the option of a food simulant test similar to what has been adopted in the European Union (EU) Commission Regulation No. 10/ 2011.
Response: Comment not incorporated. USP could not identify a simulant test that had an appropriate extraction time and temperature.

Total Organic Carbon
Comment Summary #10: The commenter suggested that total organic carbon testing should only be required for packaging systems that hold drug forms other than solid oral dosage forms.
Response: Comment not incorporated. Based on dialogue with the FDA, all compendial testing is necessary for plastic packaging components for solid oral dosage form.
Comment Summary #11: The commenter suggested it is unclear in the chapter whether the container volume on which to base the total organic carbon limits should be that of the full container (as in <643>) or the "nominal volume."
Response: Comment not incorporated. The chapter is specific for "plastic packaging components and systems used for packaging final drug products." Thus, the final product volume should be used for testing and not the maximum volume for the packaging systems.

UV Absorbance
Comment Summary #12: The commenter suggested that the UV absorbance acceptance criteria should be system-volume-specific rather than fixed because it is likely that multiple small systems will have a greater C1 concentration than a large container of the same volume.
Response: Comment not incorporated. This comment may be considered in a future revision with the receipt of additional data.

Chemical Suitability Assessment
Comment Summary #13: The commenter suggested including a reference to <232> *Elemental Impurities – Limits* and <233> *Elemental Impurities – Procedures*. Elemental impurities related to container closure interaction can affect drug product quality and should be assessed as part of chemical testing.
Response: Comment not incorporated. <232> is specific for final drug products.

Functionality Test Method

Summary #14: The commenter suggested clarifying whether “Nominal Size” and “Nominal Volume” are synonymous and recommends using “Nominal Volume” throughout chapter.
Response: Comment incorporated.