BRIEFING

⟨661.2⟩ Plastic Packaging Systems for Pharmaceutical Use, *USP 42* page 6838. The General Chapters—Packaging and Distribution Expert Committee is proposing the following revisions to clarify the intent of the chapter and to increase the ease in utilization. These proposed revisions do not change any of the testing requirements in the chapter. Listed below are the key changes being proposed:

1. The chapter has been reformatted so that all test methods and acceptance criteria for a specific requirement are contained within a section.
2. The implementation date is being changed from May 1, 2020 to December 1, 2025.
3. The Introduction and Scope have been revised to simplify and clarify the text.
4. Text has been added to the chapter to remind that end-users can meet the requirement of *Plastic Materials of Construction* ⟨661.1⟩ by meeting the requirements of this chapter.
5. Table 1 is added to list the application of tests.
6. Guidance has been given on how to address the testing of small fill volume containers (e.g., vials, blisters, etc.) to produce sufficient extract volume to accomplish the required testing.
7. The Chemical Safety Assessment section has been omitted and the entire Specifications section has been deleted as the acceptance criteria has been inserted under Physicochemical and Biological Reactivity Test Methods.

Additionally, minor editorial changes have been made to update this chapter to current *USP* style.

(GCPD: D. Hunt.)

Correspondence Number—C207490

⟨661.2⟩ PLASTIC PACKAGING SYSTEMS FOR PHARMACEUTICAL USE

Change to read:

(This chapter will become official on ~~May 1, 2020~~▲December 1, 2025.▲ (USP 1-Aug-2020) **Early adoption of the requirements in this chapter and its companion chapter *Plastic Materials of Construction* ⟨661.1⟩ are permitted by USP. ~~When early adoption is not used, *Plastic Packaging Systems and Their Materials of Construction* ⟨661⟩ will apply and must be met wherever ⟨661.1⟩ or this chapter is referenced in the *USP–NF*.)~~▲If ⟨661.1⟩ or ⟨661.2⟩ are referenced elsewhere in *USP-NF* prior to December 1, 2025, the standards in *Plastic Packaging Systems and Their Materials of Construction* ⟨661⟩ will apply if early adoption of ⟨661.1⟩ or ⟨661.2⟩ has not occurred.▲** (USP 1-Aug-2020)

Change to read:

INTRODUCTION

A packaging system, as defined in *Packaging and Storage Requirements* ⟨659⟩, contains or is intended to contain a medical article, such as a ~~pharmaceutical~~▲▲ (USP 1-Aug-2020) drug product. ~~As such, a packaging system provides the means for manufacturing, distributing, and storing these articles and products, and potentially for administering a drug product. A plastic packaging system is composed wholly or of a substantial portion of plastic materials. The term "plastic packaging system" refers to the sum of packaging components that together contain the pharmaceutical product,~~

~~including closures. This sum of packaging components includes: 1) primary packaging components, which are those that directly contact the pharmaceutical product at some time during the product's manufacturing, distribution, storage, or use; and 2) secondary packaging components, which are those that may interact with the pharmaceutical product during the product's manufacturing, distribution, storage, and use, although the component does not directly contact the pharmaceutical product.~~ ▲The packaging system provides the means for packaging, distributing, and storing drug products, and potentially for administering. A plastic packaging system is composed wholly or of a substantial portion of plastic materials and refers to the sum of packaging components that together contain the drug product, including closures.▲ (USP 1-Aug-2020)

Change to read:

SCOPE

This chapter applies specifically to plastic packaging ▲components and▲ (USP 1-Aug-2020) systems ▲used for packaging final drug products. Associated components, as defined in ⟨659⟩, are not within the scope of this chapter.▲ (USP 1-Aug-2020) The testing of materials of construction used in packaging systems is addressed in *Plastic Materials of Construction* ⟨661.1⟩. ▲The requirements of ⟨661.1⟩ are met by performing the tests in ⟨661.1⟩ or if the material is used in a packaging component or system that meets the requirements of ⟨661.2⟩.▲ (USP 1-Aug-2020) A product's packaging ▲component or system▲ (USP 1-Aug-2020) is deemed chemically suited for its intended use, ~~with respect to safety~~▲▲ (USP 1-Aug-2020) if it meets the requirements in ⟨661.2⟩.

~~The applicant who secures and owns the regulatory approval of a packaging system or packaged drug product is responsible for establishing that the product's packaging system meets these expectations, and thus is suited for its intended use, by ensuring that the packaging system itself and/or the packaged pharmaceutical product has been appropriately tested and that the test results have been appropriately evaluated. A packaging system is chemically suited for its intended use with respect to safety if:~~

- ~~The packaging system is constructed from well-characterized materials that have been intentionally chosen for use as established by testing according to ⟨661.1⟩.~~

▲The packaging component or system should be constructed from well-characterized materials as defined in ⟨661.1⟩ and is chemically suited for its intended use if:▲ (USP 1-Aug-2020)

- The packaging ▲component's or▲ (USP 1-Aug-2020) system's general physicochemical properties have been established.
- The packaging ▲component's or▲ (USP 1-Aug-2020) system's biocompatibility (biological reactivity) has been appropriately established.
- The packaging ▲component or▲ (USP 1-Aug-2020) system has been established to be ~~safe~~▲suitable▲ (USP 1-Aug-2020) by means of the appropriate chemical ~~testing, such as extractables or leachables profiling, and toxicological assessment of the test data. This combination of chemical testing and toxicological assessment is termed "chemical safety assessment".~~▲suitability for use assessment.

Table 1 provides the appropriate application of the physicochemical and biological reactivity tests.

Table 1. Application of Tests

Test Parameter	Oral and Topical Dosage Forms[a]	All Other Dosage Forms
Physicochemical		
UV absorbance	X	X
Acidity/alkalinity	X[b]	X[b]
TOC	X	X
Appearance of solution	X	X
Total terephthaloyl moieties	PET and PETG only[c]	PET and PET G only[c]
Biological Reactivity		
Biological Reactivity Tests, In Vitro ⟨87⟩	—	X
Biological Reactivity Tests, In Vivo ⟨88⟩	—	As required
Chemical Suitability for Use Assessment	Risk-based testing	Risk-based testing
Spectral Transmission	If light protection is necessary	If light protection is necessary

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[a] For aqueous-based oral drug products that contain cosolvents (or if, for any reason, it may be expected to extract greater amounts of substances from plastic packaging components than water), additional extractables information may be needed to determine suitability.

[b] Conduct the test for *Acidity* or *alkalinity* only when packaging systems are intended to hold a liquid product or a product that is dissolved in its container before use.

[c] Polyethylene terephthalate (PET) and polyethylene terephthalate G (PETG).

▲ (USP 1-Aug-2020)

Change to read:

▲PHYSICOCHEMICAL AND BIOLOGICAL REACTIVITY▲ (USP 1-AUG-2020) TEST METHODS

Biological Reactivity

In vitro biological tests are performed on the packaging systems ▲and components▲ (USP 1-Aug-2020) according to the test procedures described in *Biological Reactivity Tests, In Vitro* ⟨87⟩. In vitro testing described in ⟨87⟩ and the in vivo testing described in *Biological Reactivity Tests, In Vivo* ⟨88⟩ are not required for packaging systems used for solid and aqueous-based oral and topical dosage forms. Packaging systems that meet the requirements of ~~the in vitro tests~~ ▲⟨87⟩▲ (USP 1-Aug-2020) are not required to undergo ~~any further in vivo testing~~▲⟨88⟩ testing.▲ (USP 1-Aug-2020) Packaging systems that do not meet the requirements of the biological reactivity tests (⟨87⟩ and ⟨88⟩, if appropriate) are not suitable as packaging systems for pharmaceutical use. If a plastic class designation (classes I–VI) is needed, analysts should perform the appropriate in vivo tests specified by ⟨88⟩. Information about the appropriate plastic class that should be selected is provided in *The Biocompatibility of Materials Used in Drug Containers, Medical Devices, and Implants* ⟨1031⟩.

▲ACCEPTANCE CRITERIA

Test results are consistent with the relevant chapters (⟨87⟩ or ⟨88⟩) when applicable.▲ (USP 1-Aug-2020)

~~WATER EXTRACTION~~ ▲(USP 1-Aug-2020)

Solution C1:

Fill the packaging system to its nominal capacity with *Purified Water* and close it, if possible, using the normal means of closure. Otherwise, close with an inert closure. Heat in an autoclave until 121 ± 2° is reached (typically in 20–30 min), and maintain at this temperature for 30 min. If heating at 121° leads to the deterioration of the container, heat at 100 ± 2° for 2 h or at 70 ± 2° for 24 ± 2 h. Cool the filled packaging system and empty its contents. The emptied contents are *Solution C1*.

▲In certain situations, packaging systems may have sufficiently small fill volumes that an alternative testing method is necessary. One possible alternative would be to combine the contents of many individual systems in order to produce sufficient extract volume to accomplish the required analytical testing. It is also possible to construct a model packaging system of sufficient fill volume. When such an approach is being used care must be taken to preserve the required contact conditions (e.g., solution contact surfaces, extracted surface area per unit volume of extraction solution, etc.).▲ (USP 1-Aug-2020)

If the test is being performed on a component, then the component is placed in an inert extraction vessel and put into contact with an amount of *Purified Water* that is equal to the packaging system's nominal capacity. The extraction vessel is closed and then heated as described above for a packaging system. Cool the extraction vessel and empty its contents. The emptied contents are *Solution C1*.

▲Blank:▲ (USP 1-Aug-2020)

Prepare a blank by heating *Purified Water* in a borosilicate glass flask closed with an inert closure; heat the flask at the same temperature and for the same length of time as used for the preparation of *Solution C1*. Use *Solution C1* and the blank within 4 h of preparation.

Appearance of solution, color

Standard solution CS1:

Mix 3 mL of cobaltous chloride CS, 3 mL of ferric chloride CS, 2.4 mL of cupric sulfate CS, and 1.6 mL of 10 g/L of hydrochloric acid to produce the standard solution.

Reference solution RS1:

Add 1.0 mL of *Standard solution CS1* to a 100-mL volumetric flask and dilute with 10 g/L of hydrochloric acid to volume.

Procedure:

Transfer equal portions of *Reference solution RS1*, *Purified Water*, and *Solution C1* to individual identical, colorless, transparent, neutral, flat-based glass vessels (internal diameter of 15–25 mm). Compare the colors in diffuse daylight, viewing vertically against a white background.

Solution C1 is colorless if it has the appearance of *Purified Water* and is not more intensely colored than *Reference solution RS1*.

▲*Acceptance criteria:*

Solution C1 is colorless.▲ (USP 1-Aug-2020)

Appearance of solution, clarity (visual method)

Hydrazine sulfate solution:

Dissolve 1.0 g of hydrazine in *Purified Water* and dilute with *Purified Water* to 100 mL. Allow to stand for 4–6 h.

Hexamethylenetetramine solution:

Using a 100-mL stoppered flask, dissolve 2.5 g of hexamethylenetetramine in 25.0 mL of *Purified Water*.

Primary opalescent suspension:

Add 25 mL of the *Hydrazine sulfate solution* to the volumetric flask containing the *Hexamethylenetetramine solution*. Mix and allow to stand for 24 h. This suspension is stable for 2 months, provided that it does not adhere to the glass and it is well mixed prior to use.

Standard of opalescence:

Dilute 15 mL of the *Primary opalescent suspension* with *Purified Water* to 1000 mL. This solution can be stored for 24 h.

Reference suspension:

Add 5 mL of the *Standard of opalescence* and 95 mL of *Purified Water* and mix well.

Procedure:

Transfer equal portions of *Reference suspension*, *Purified Water*, and *Solution C1* to individual identical, colorless, transparent, neutral, flat-based

glass vessels (internal diameter of 15–25 mm). Compare the solutions in diffuse daylight 5 min after preparation, viewing vertically against a black background.

Solution C1 is clear if its clarity is the same as *Purified Water* and its opalescence is not more pronounced than that of the *Reference suspension*.

▲*Acceptance criteria:*

Solution C1 is clear.▲ (USP 1-Aug-2020)

Absorbance:

Determine the spectrum of *Solution C1* between 230 and 360 nm, using the *Solution C1* blank as the compensation liquid.

▲*Acceptance criteria:*

NMT 0.20. If the acceptance criteria for absorbance is exceeded, then the packaging system can still be considered acceptable if the chemicals responsible for the test results can be established (identity and concentration) and the chemicals are assessed to establish that the probable risk posed by all the chemicals, considered individually, is within acceptable parameters.▲ (USP 1-Aug-2020)

Acidity or alkalinity:

Conduct the test for *Acidity or alkalinity* only when packaging systems are intended to hold a liquid product or a product that is dissolved in its container before use.

To 20 mL of *Solution C1* obtained either as a portion of the fill solution or by combining the fill solution from several containers, add 0.1 mL of

phenolphthalein TS; note the solution's color. Add 0.4 mL of 0.01 N *sodium hydroxide*; note the solution's color. Add 0.8 mL of 0.01 N *hydrochloric acid* and 0.1 mL of methyl red TS 2; note the solution's color.

Methyl red TS 2:

Test for sensitivity: Add 0.1 mL of ~~methyl red~~▲methyl red TS 2▲ (USP 1-Aug-2020) solution to 100 mL of carbon dioxide-free *Purified Water* and 0.05 mL of 0.02 N hydrochloric acid. NMT 0.1 mL of 0.02 N sodium hydroxide is required to change the color from red to yellow.

▲*Acceptance criteria:*

The solution is colorless after the addition of phenolphthalein solution, pink after the addition of 0.01 N sodium hydroxide, and orange-red or red after the addition of 0.01 N hydrochloric acid and 0.1 mL of methyl red TS 2 solution.▲ (USP 1-Aug-2020)

TOTAL ORGANIC CARBON

Refer to *Total Organic Carbon* ⟨643⟩.

The total organic carbon (TOC) content of *Solution C1* is measured according to ⟨643⟩. However, ⟨643⟩ is designed for testing high-purity water that has low TOC values. Because of extracted organic substances, material extracts may have TOC values that are much higher than those of *Purified Water*. Thus, the TOC analyses performed have a limit of detection of 0.2 mg/L (ppm) and have a demonstrated linear dynamic range of 0.2–20 mg/L (which encompasses the TOC limit). A linear range with a higher upper concentration can be used if linearity is established. If sample

extracts exceed this upper linear range, then they should be diluted appropriately for analysis.

▲Acceptance criteria:

The difference in TOC concentrations between *Solution C1* and a suitable blank is NMT 8 mg/L. If the acceptance criteria for TOC is exceeded, then the packaging system can still be considered acceptable if the chemicals responsible for the test results can be established (identity and concentration) and the chemicals are assessed to establish that the probable risk posed by all the chemicals, considered individually, is within acceptable parameters.▲ (USP 1-Aug-2020)

TOTAL TEREPHTHALOYL MOIETIES IN POLYETHYLENE TEREPHTHALATE AND POLYETHYLENE TEREPHTHALATE G PACKAGING SYSTEMS

Polyethylene terephthalate extracting media:

50% alcohol (dilute 125 mL of *alcohol* with *Purified Water* to 238 mL, and mix), *n-heptane*, and *Purified Water*. For each extracting medium, fill a sufficient number of test packaging systems to 90% of their nominal capacity to obtain NLT 30 mL. Fill a corresponding number of glass bottles with each extracting medium for use as blanks. Fit the bottles with impervious seals such as aluminum foil and apply closures. Incubate the test packaging systems and the glass bottles at 49° for 10 days. Remove the test systems and glass bottles, and store at room temperature. Do not transfer the extracting medium samples to alternative storage vessels.

Polyethylene terephthalate G extracting media:

25% alcohol (dilute 125 mL of 50% alcohol with *Purified Water* to 250 mL, and mix), *n-heptane*, and *Purified Water*. Proceed as directed in *Polyethylene terephthalate extracting media*.

Procedure:

Determine the absorbance of the 50% alcohol or 25% alcohol extracts in a 1-cm cell at the wavelength of maximum absorbance at about 244 nm (see *Ultraviolet-Visible Spectroscopy* ⟨857⟩). For the blank, use the corresponding extracting medium blank.

Determine the absorbance of the *n-heptane* extract in a 1-cm cell at the wavelength of maximum absorbance at about 240 nm (see ⟨857⟩). For the blank, use the *n-heptane* extracting medium.

▲Acceptance criteria:

The absorbance of the 50% alcohol, 25% alcohol, and *n-heptane* extracts does not exceed 0.150, corresponding to NMT 1 ppm of total terephthaloyl moieties.▲ (USP 1-Aug-2020)

ETHYLENE GLYCOL IN POLYETHYLENE TEREPHTHALATE AND POLYETHYLENE TEREPHTHALATE G PACKAGING SYSTEMS

Periodic acid solution:

Dissolve 125 mg of *periodic acid* in 10 mL of *Purified Water*.

Dilute sulfuric acid:

To 50 mL of *Purified Water* slowly add, with constant stirring, 50 mL of *sulfuric acid*, and allow to cool to room temperature.

Sodium bisulfite solution:

Dissolve 0.1 g of sodium bisulfite in 10 mL of *Purified Water*. Use this solution within 7 days.

Disodium chromotropate solution:

Dissolve 100 mg of *disodium chromotropate* in 100 mL of *sulfuric acid*. Protect this solution from light and use within 7 days.

Standard solution:

Dissolve an accurately weighed quantity of *ethylene glycol* in *Purified Water*, and dilute quantitatively and stepwise if necessary to obtain a solution having a known concentration of about 1 µg/mL.

Sample solution:

Use the *Purified Water* extract from *Total Terephthaloyl Moieties in Polyethylene Terephthalate and Polyethylene Terephthalate G Packaging Systems*.

Procedure:

Transfer 1.0 mL of the *Standard solution* to a 10-mL volumetric flask. Transfer 1.0 mL of the *Sample solution* to a second 10-mL volumetric flask. Transfer 1.0 mL of the *Purified Water* extracting medium to a third 10-mL volumetric flask to serve as the method blank. To each of the three flasks, add 100 µL of *Periodic acid solution*, swirl to mix, and allow to stand for 60 min. Add 1.0 mL of *Sodium bisulfite solution* to each flask, and mix. Add 100 µL of *Disodium chromotropate solution* to each flask, and mix. [NOTE—All solutions should be analyzed within 1 h after addition of the *Disodium chromotropate solution*.] Cautiously add 6 mL of *sulfuric acid* to each flask, mix, and allow the solutions to cool to room temperature.[**CAUTION—**Dilution of sulfuric acid produces substantial heat and can cause the solution to boil. Perform this addition carefully. Sulfur dioxide gas will be evolved. Use of a fume hood is recommended.]

Dilute each solution with *Dilute sulfuric acid* to volume, and mix.

Concomitantly determine the absorbances of the solutions from the *Standard solution* and the *Sample solution* in 1-cm cells at the wavelength

of maximum absorbance at about 575 nm (see ⟨857⟩), using the solution from the *Purified Water* extracting medium as the method blank.

▲Acceptance criteria:

The absorbance of the solution from the *Sample solution* does not exceed that of the solution from the *Standard solution*, corresponding to NMT 1 ppm of ethylene glycol.▲ (USP 1-Aug-2020)

Chemical ~~Safety~~▲Suitability for Use▲ (USP 1-Aug-2020) Assessment

The ~~safety~~▲suitability▲ (USP 1-Aug-2020) of the packaging system must be established on the basis of relevant and appropriate chemical testing of 1) the packaging system, 2) its materials of construction, 3) its components of construction, as appropriate, or 4) the packaged drug product. Appropriate chemical testing of materials of construction is specified in ⟨661.1⟩. ~~and may include the demonstration of conformance with the appropriate sections of 21 Code of Federal Regulations (CFR) *Indirect Food Additives* regulations.~~▲▲ (USP 1-Aug-2020) With regard to the testing of the packaging system (and/or its components ~~of construction~~▲▲ (USP 1-Aug-2020) as appropriate) and the packaged drug product, an appropriate and rigorous chemical ~~safety~~▲suitability for use▲ (USP 1-Aug-2020) assessment ~~would~~▲ may▲ (USP 1-Aug-2020) include extractables testing of the packaging ▲component or▲ (USP 1-Aug-2020) system and leachables testing of the packaged drug product. It is expected that the design of the extractables and leachables study would be based on sound and justifiable scientific principles, and that the studies themselves would be consistent with 1) the nature of both the packaging system and packaged drug product, 2) the clinical use of the packaged drug product, and 3) the perceived safety risk associated with the

packaging system and dosage form. Although no dosage form is excluded from ~~this testing requirement~~ a chemical suitability for use assessment, (USP 1-Aug-2020) it is anticipated that the nature and degree of testing would be dosage form-dependent and consistent with a risk-based approach. For example, the testing of packaging components or (USP 1-Aug-2020) systems for low-risk dosage forms, such as solid and aqueous-based oral and topicals, should be consistent with the low risk associated with these dosage forms. In view of the considerable diversity of packaging systems, dosage forms, and packaged drug products, it is not possible to provide specific test conditions for performing extractables and leachables studies. Nevertheless, general essential principles and demonstrated best-practices recommendations for extractable and leachable studies can be found in *Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems* ⟨1663⟩ and *Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems* ⟨1664⟩, respectively. These chapters may serve as helpful resources for designing and justifying rigorous and appropriate studies.

Alternative testing strategies for chemical safety assessment may be appropriate in justified circumstances, subject to agreement by an appropriate regulatory authority.

Delete the following:

^SPECIFICATIONS

Biological Reactivity

Test results are consistent with the relevant chapters (⟨87⟩ or ⟨88⟩) when applicable.

Physicochemical Tests

Appearance of solution: *Solution C1* is clear and colorless.

Absorbance: NMT 0.20

Acidity or alkalinity: The solution is colorless after the addition of *phenolphthalein* solution, pink after the addition of 0.01 N *sodium hydroxide*, and orange-red or red after the addition of 0.01 N *hydrochloric acid* and 0.1 mL of methyl red solution.

Total organic content: The difference in TOC concentrations between *Solution C1* and a suitable blank is NMT 8 mg/L.

Ethylene glycol in polyethylene terephthalate and polyethylene terephthalate G packaging systems: The absorbance of the solution from the *Sample solution* does not exceed that of the solution from the *Standard solution*, corresponding to NMT 1 ppm of *ethylene glycol*.

Total terephthaloyl moieties in polyethylene terephthalate and polyethylene terephthalate G packaging systems: The absorbance of the 50% alcohol, 25% alcohol, and *n*-heptane extracts does not exceed 0.150, corresponding to NMT 1 ppm of total terephthaloyl moieties.

If the specification for absorbance or TOC is exceeded, then the packaging system can still be deemed to be acceptable if the chemicals responsible for the test results can be established (identity and concentration) and the chemicals are safety assessed to establish that the probable safety risk posed by all the chemicals, considered individually, is within acceptable parameters.

Chemical Safety Assessment

The data and information obtained in the *Chemical Safety Assessment* must be interpreted in the context of establishing the patient safety risk associated with the use of the packaging system and the administration of the packaged drug product. Most typically, such an interpretation of the chemical data involves the toxicological safety assessment of extractables and leachables data, supported, as appropriate, by other relevant testing. In this circumstance, the toxicological safety assessment should be performed for each individual relevant member of the packaging system's extractables profile (or each relevant member of the contained product's leachables profile, as appropriate). The assessment should demonstrate that the user safety risk associated with each individual relevant leachable (or extractable as a worst-case leachable) is acceptable and that the probable safety risk posed by all leachables (or extractables as worst-case leachables), considered individually, is within acceptable parameters. The term “relevant extractable or leachable” refers to those extractables that are present in a packaging system and those leachables that are present in a packaged drug product at levels sufficiently high that they have been deemed to have a potential safety impact, based, for example, on a comparison of the levels of extractables or leachables with a recognized

~~and well-established safety alert threshold. Establishing and justifying the acceptable parameters used to assess the safety impact is the responsibility of the applicant who secures and owns the regulatory approval of a packaging system or packaged drug product; such acceptable parameters must be based on and derived from the sound application of established principles of toxicological safety assessment.~~

~~For leachables that are also elemental impurities, note that limits for elemental impurities in marketed pharmaceutical drug products (but not specifically packaging systems) can be found in *Elemental Impurities—Limits* ⟨232⟩.~~

~~Alternative chemical safety assessment specifications may be appropriate in justified circumstances, subject to agreement by an appropriate regulatory authority.~~▲ (USP 1-Aug-2020)

Change to read:

FUNCTIONALITY

Spectral Transmission Requirements for Light-Resistant Containers

APPARATUS‡▲ ▲ (USP 1-Aug-2020)

Use a UV-visible spectrophotometer of suitable sensitivity and accuracy ▲(see ⟨857⟩),▲ (USP 1-Aug-2020) adapted for measuring the amount of light transmitted by plastic materials used for pharmaceutical containers. ~~In addition, the spectrophotometer is capable of measuring and recording light transmitted in diffused as well as parallel rays.~~▲ ▲ (USP 1-Aug-2020)

~~METHOD~~ PROCEDURE (USP 1-Aug-2020)

Select ~~sections~~ a section (USP 1-Aug-2020) to represent the average wall thickness. ~~Cut circular sections from two or more areas of the container~~ Cut a circular section from the packaging component or system, (USP 1-Aug-2020) and trim ~~them~~ (USP 1-Aug-2020) as necessary to ~~give segments of a size~~ get a segment (USP 1-Aug-2020) convenient for mounting in the spectrophotometer. After cutting, wash and dry ~~each~~ the (USP 1-Aug-2020) specimen, taking care to avoid scratching the surfaces. If the specimen is too small to cover the opening in the specimen holder, mask the uncovered portion of the opening with opaque paper or masking tape, provided that the length of the specimen is greater than that of the slit in the spectrophotometer. Immediately before mounting in the specimen holder, wipe the specimen with lens tissue. Mount the specimen with the aid of a tacky wax, or by other convenient means, taking care to avoid leaving fingerprints or other marks on the surfaces through which light must pass. Place the section in the spectrophotometer with its cylindrical axis parallel to the plane of the slit and approximately centered with respect to the slit. When properly placed, the light beam is normal to the surface of the section, and reflection losses are at a minimum.

Continuously measure the transmittance of the section with reference to air in the spectral region of interest with a recording instrument or at intervals of about 20 nm with a manual instrument, in the region of 290–450 nm.

~~SPECIFICATIONS~~ ACCEPTANCE CRITERIA (USP 1-Aug-2020)

The observed spectral transmission is NMT the limits given in ~~Table 1~~ Table 2 (USP 1-Aug-2020) for ~~containers~~ plastic packaging components and systems (USP

1-Aug-2020) intended for parenteral use. The observed spectral transmission for plastic containers for products intended for oral or topical administration does not exceed 10% at any wavelength in the range of 290–450 nm.

~~**Table 1. Limits for Plastic Containers**~~**Table 2. Spectral Transmission Limits for Plastic Packaging Components or Systems** (USP 1-Aug-2020)

Nominal Size (mL)	Maximum Percentage of Spectral Transmission at Any Wavelength between 290 and 450 nm (%)
1	25
2	20
5	15
10	13
20	12
50	10
>50 (USP 1-Aug-2020)	10 (USP 1-Aug-2020)

[NOTE—~~Any container of a size intermediate to those listed in Table 1 exhibits a spectral transmission NMT that of the next larger size container listed in Table 1. For containers larger than 50 mL, the limits for 50 mL apply.~~ For components or systems of an intermediate size, the acceptance criterion is the spectral transmission of the next larger size. (USP 1-Aug-2020)]

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[1] For further details regarding the apparatus and procedures, reference may be made to the latest edition of ASTM Standard D1003 *Standard Test Method for Haze and Luminous Transmittance of Transparent Plastics*, from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959. (USP 1-Aug-2020)