Application Note

Pharma

Spectral Transmission Measurements of Pharmaceutical Packaging

Using the Agilent Cary 60 UV-Vis Diffuse Reflectance Accessory following EP <3.2.1>, USP <660>, and USP <661.2>

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Abstract

Packaging used for pharmaceutical products must adhere to strict global regulatory requirements to ensure product safety and quality throughout its life cycle. As many pharmaceuticals are light-sensitive, pharmaceutical packaging systems that are intended to provide protection from light must demonstrate light resistance. The European Pharmacopeia (EP) and United States Pharmacopeia (USP) specify requirements for a pharmaceutical packaging to demonstrate light resistance as per EP <3.2.1>, USP <660>, and USP <661.2>, respectively.

In this application note, an Agilent Cary 60 UV-Vis spectrophotometer, fitted with an Agilent Cary 60 UV-Vis diffuse reflectance accessory (DRA), was used to reliably measure the amount of light transmitted by one glass and two plastic pharmaceutical containers using the respective functionality test methods specified in the EP <3.2.1>, USP <660>, and USP <661.2> compendial chapters.

Introduction

Pharmaceutical containers play a significant role in maintaining final drug stability, integrity, and safety, from manufacturing to distribution to the end user. The ability of the packaging system to protect the drug from external agents is critical for quality assurance. Therefore, all pharmaceutical packaging systems must conform to stringent standards.

Plastic and glass are commonly used materials for packaging, and they are typically transparent or opaque. Transparency to ultraviolet (UV) light can pose a risk to light-sensitive pharmaceuticals, as exposure can initiate adverse—and sometimes harmful—photochemical reactions that can significantly affect drug quality and reduce shelf-life.[1]

The EP and USP define well-established standards, designed to measure physiochemical and functional properties of packaging components intended to contain a drug product (pharmaceutical containers), to meet regulatory requirements. The EP Chapter <3.2.1> Glass Containers for Pharmaceutical Use includes a functionality test method to demonstrate adequate light resistance of colored glass containers through spectral transmission measurement. An included acceptance criterion specifies the allowed maximum amount of light transmitted by the tested material, defined by the drug product dosage administration form. For example, for glass containers that package oral drug products, the acceptance criterion defines that the observed spectral transmission should not exceed 10% at any wavelength in the range of 290 to 450 nm (< 10%T).[2] The identical test and criterion are found in USP Chapter <660> Containers – Glass.[3] In addition, the USP Chapter <661.2> Plastic Packaging Systems for Pharmaceutical Use also includes the analogous functionality test method and acceptance criterion for plastic pharmaceutical packaging.[4]

The Cary 60 UV-Vis spectrophotometer, equipped with the Cary 60 UV-Vis DRA, was chosen for measurement due to its extended ability to reliably measure precise transmission of scattering materials (Figure 1). The Cary 60 UV-Vis is a versatile spectrophotometer; however, measuring materials like plastics and glass, which are textured, translucent, or opaque in a manner that scatters light can result in challenges in satisfactorily measuring light transmittance with standard techniques. In a standard spectrophotometer, scattering materials tend to diffuse transmitted light, deviating an unquantifiable amount of light from the direct optical path of the detector. The detector may not collect all the scattered (lost) light, resulting in inaccurate measurements and results. For this reason, the Cary 60 UV-Vis was equipped with an internal DRA, which uses a 50 mm integrating PTFE-coated sphere that easily sits inside the spectrophotometer's sample compartment. For these applications, using a DRA can optimize light collection. The sphere's design captures all scattered light uniformly, overcoming scattering losses for accurate measurement of transmitted light. In applications where total transmission is crucial for quality assurance, the DRA is an essential tool for accurate measurements.

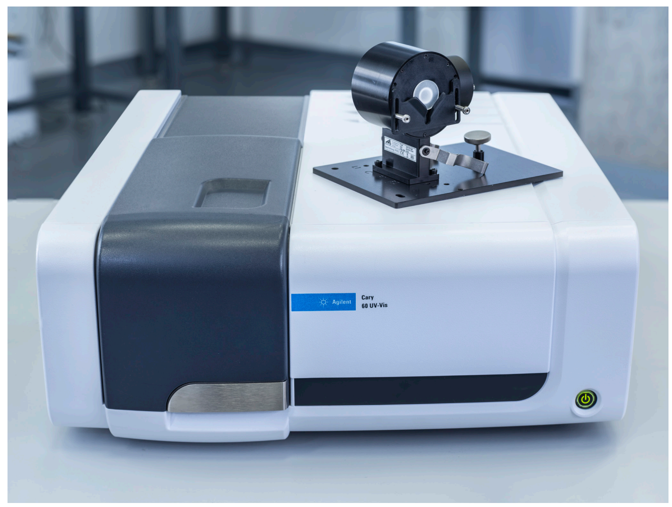

Figure 1. The Agilent Cary 60 UV-Vis spectrophotometer and Cary 60 UV-Vis DRA. The Cary 60 DRA has a 0° port reducer (6 mm aperture) fitted in, with a plastic sample fitted against the port.

In this application note, an Agilent Cary 60 UV-Vis spectrophotometer, Agilent Cary 60 UV-Vis DRA, and Agilent Cary WinUV software were used to assess the spectral transmission of one glass and two plastic pharmaceutical packaging systems of products intended for oral use, following criteria set in the functionality test in the EP <3.2.1>, USP <660>, and USP <661.2> compendial chapters. A note on the revised USP chapter is outlined in the Appendix.

Experimental

Sample preparation

Two different types of pharmaceutical packaging systems either containing liquid or tablet formulations intended for oral administration were selected to be investigated. Three opaque and translucent pharmaceutical packaging systems were procured locally, and the container labels were removed. The sample containers are shown in Figure 2, and the sample identifiers are outlined in Table 1.

Figure 2. Image of pharmaceutical containers selected for testing.

Table 1. Sample identifiers.

Sample Number	Type of Formulation	Sample Container Description
1	Oral liquid	Glass, amber, translucent
2	Oral tablet	Plastic, yellow, opaque
3	Oral tablet	Plastic, amber, translucent

A circular section representing the average wall thickness was cut from each container, with care taken to avoid scratching the surfaces. Each section was washed with soap and water, dried, then wiped with lens tissue to remove any residue marks, smudges, and fingerprints.

For each respective container, the sample section was carefully positioned on the sample holder, at the entrance of the transmission port of the Cary 60 UV-Vis DRA. The transmission port was adjusted with a 0° port reducer (6 mm aperture). The reflection port of the DRA was closed with a PTFE reflection port cover to capture all total transmitted light. Given the shape of the containers, the cut sections are curved. Therefore, to adequately cover the entrance of the DRA (and ensure that no light would escape the detector and cause misreadings), it is important to select a suitable sample holder. The sample was tightly held in place using the Cary 60 UV-Vis DRA clips, ensuring no space or gaps for light to escape from (Figure 3A).

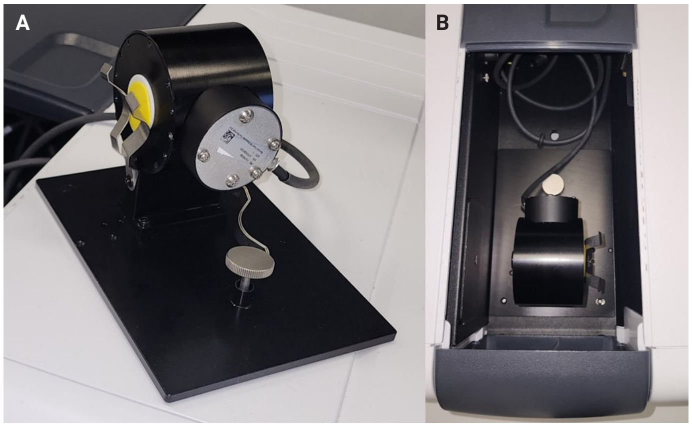

Figure 3. (A) A circular sample section of each container was cut, cleaned, and positioned at the entrance of the transmission port of the DRA, held tightly with clips. Pictured here is a sample section from the yellow opaque container. (B) Birds-eye view of the Agilent Cary 60 UV-Vis DRA mounted inside the sample compartment of the Agilent Cary 60 UV-Vis spectrophotometer.

The Cary 60 UV-Vis DRA was quickly set up within the Agilent Cary 60 UV-Vis spectrophotometer's sample compartment, with a single thumbscrew locking the accessory in place (Figure 3B). The convenient plug-and-play mode of the instrument and accessory allowed for easy installation without the need for extra configuration or user intervention.

Method parameters

Once the Cary 60 UV-Vis DRA was mounted inside the spectrophotometer sample compartment, the spectral transmission measurements were collected using the Scan application in Agilent Cary WinUV software, following the experimental parameters reported in Table 2.

Table 2. Spectral transmission analysis parameters for the Agilent Cary 60 UV-Vis spectrophotometer.

Parameter	Setting
Ordinate Mode	% Transmittance (%T)
Wavelength Range	290 to 450 nm
Spectral Bandwidth	1.5 nm
Signal Averaging Time	0.1 s
Data Interval	1 nm
Aperture Size (T Port)	0° port reducer (6 mm aperture)
Baseline	Air

A baseline was collected, then each sample section was measured.

Results and discussion

The observed spectral transmission measurements, obtained for each respective pharmaceutical container, are shown in Figure 4.

As the packaging systems investigated in this application note contained drugs intended for oral administration, as per the analogous acceptance criteria in EP <3.2.1>, USP <660>, and USP <661.2>, the maximum percentage of spectral transmission at any wavelength between 290 and 450 nm should not exceed 10%.

An observation of the graph elucidates that all samples were below the maximum 10%T. To numerically corroborate this, the maximum observed %T across the 290 to 450 nm range (Y-Max) was calculated per sample as shown in Table 3.

Table 3. Maximum value of %T per sample following the EP <3.2.1>, USP <660>, and USP <661.2> acceptance criteria for pharmaceutical packaging systems.

Sample Number	Type of Formulation	Sample Container Description	Y-Max (%)
1	Oral liquid	Glass, amber, translucent	1.121
2	Oral tablet	Plastic, yellow, opaque	0.155
3	Oral tablet	Plastic, amber, translucent	9.570

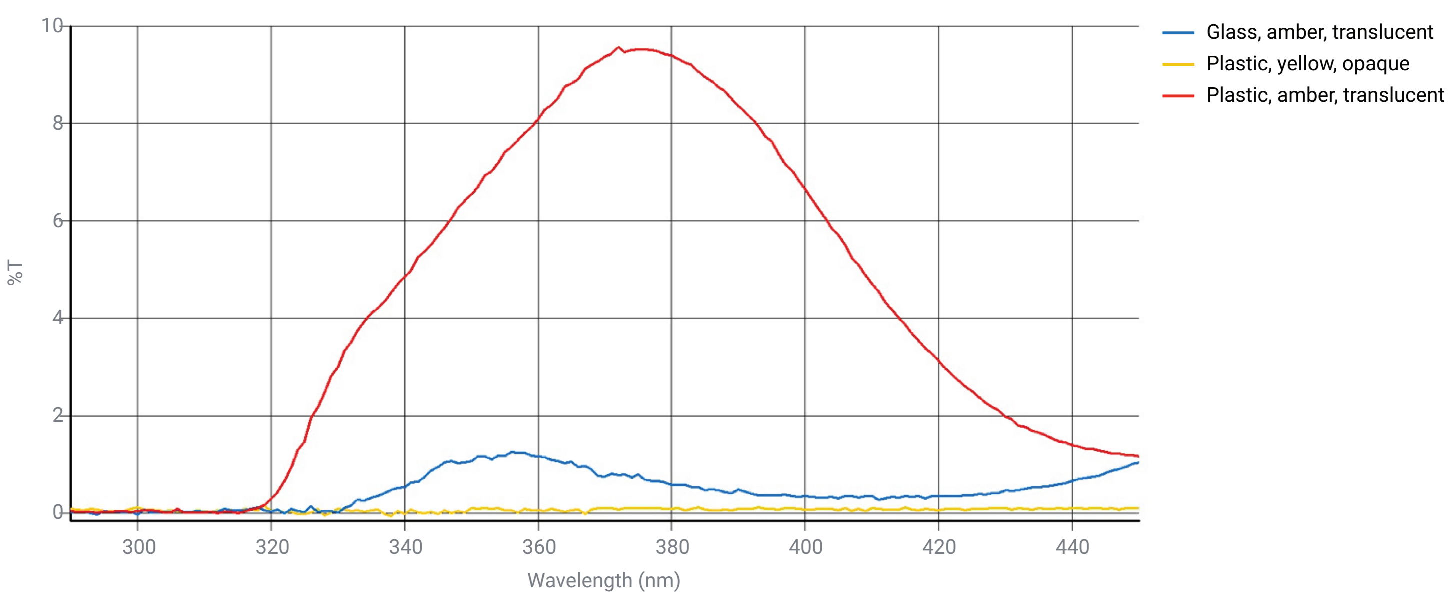

Figure 4. Spectral transmission of the three pharmaceutical packaging systems.

The maximum %T of each pharma container sample confirms that all three samples met the light-resistance requirements of the functionality test, as exhibited by their values of 1.121% (sample 1), 0.155% (sample 2), and 9.570% (sample 3). Therefore, they are suitable for containing light-sensitive pharmaceuticals as per EP <3.2.1>, USP <660>, and USP <661.2>. Notably, sample 3 was just under the specified maximum, demonstrating the importance of accurate measurements.

Conclusion

In this application note, an Agilent Cary 60 UV-Vis spectrophotometer, fitted with an Agilent Cary 60 UV-Vis DRA, was used to reliably and quickly determine the spectral transmission of packaging systems used for pharmaceuticals, following the EP <3.2.1>, USP <660>, and USP <661.2> test methods for functionality of light-resistant packaging systems. The integrating sphere enabled the instrument to accurately measure total transmittance of plastic and glass (scattering) materials.

All containers presented less than the defined maximum %T specification, demonstrating light-resistance functionality for containing light-sensitive drug products for oral administration. This method illustrates the importance of accurate testing for quality assurance of pharmaceutical packaging. The Agilent Cary 60 UV-Vis spectrophotometer, paired with Cary WinUV Pharma software, delivers secure data management and compliance for regulated pharmaceutical labs.

References

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2. Ph. Eur. 3.2.1. Glass containers for pharmaceutical use. Pharmeuropa 37.3. Strasbourg, France: Council of Europe; **2019**.
3. United States Pharmacopeia and National Formulary (USP 40-NF 35), General Chapter <660>, Containers - Glass.
4. United States Pharmacopeia and National Formulary (USP 42-NF 37), General Chapter <661.2>, Plastic Packaging Systems for Pharmaceutical Use.
5. https://www.gmp-compliance.org/gmp-news/usp-clarifies-requirements-for-plastic-packaging-systems. Date accessed: November 2025.
6. United States Pharmacopeia and National Formulary (USP 42-NF 37), General Chapter <671>, Containers – Performance Testing.

Appendix

Note on revised USP chapter

USP <661> Plastic Packaging Systems and Their Materials of Construction, which contains revised Chapter <661.2> Plastic Packaging Systems for Pharmaceutical Use, became official on December 1, 2025.[5]

Furthermore, as the apparatus, procedure, and acceptance criteria of this chapter are equivalent to the ones described in the current USP <671> Containers – Performance Testing, the analytical test presented in this application note, referencing USP <661.2>, can also be implemented following the guidelines of USP <671>.[6]

Further information

- Agilent Cary 60 UV-Vis spectrophotometer
- Cary WinUV Software for UV-Vis Applications
- UV-Vis Spectroscopy Learning Tools
- UV-Vis & UV-Vis-NIR Instrument Selection Guide
- UV-Vis Spectrophotometer Applications Overview
- UV-Vis Spectroscopy FAQs

www.agilent.com/chem/cary-60-uv-vis

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