Application Note

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Spectral Transmission Requirements for Plastic Pharmaceutical Packaging in Accordance with USP <671>

Benefits of the Agilent Cary 3500 Flexible UV-Vis spectrophotometer for performing easy, fast, and reliable transmission measurements

Authors

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Abstract

One of the key factors in maintaining the quality of a pharmaceutical product throughout its shelf life is the integrity of the packaging. Plastic packaging systems that are intended to provide protection from light or are specified as light resistant must meet the spectral transmission requirements outlined in the U.S. Pharmacopeia (USP) chapter <671>. The Agilent Cary 3500 Flexible UV-Vis spectrophotometer, fitted with a solid-sample holder, was used to measure the amount of light transmitted by plastic pharmaceutical containers using the method explained in USP <671>. The solid-sample holder accessory kit consists of a range of accessories that provide greater flexibility to analyze various sample shapes and sizes conveniently and accurately.

Introduction

Packaging materials are an integral part of pharmaceutical finished products to ensure their integrity and shelf life. Packaging these products should follow global regulatory requirements. The packaging must provide an adequate degree of protection while being compatible with drug products. To achieve the established requirements, packaging should not interact physically or chemically with the contents in a way that identity, purity, stability, efficacy, or safety is affected. Most pharmaceutical packaging is made from plastics, while polyethylene, polyolefins, and polyvinyl chlorides are the most frequently used polymers. Commonly used packaging systems include bottles, vials, bags, cartridges, inhalers, syringes, pouches, and closures for capsules and tablets.

The USP outlines various testing methods and standards for pharmaceutical packaging systems. The USP chapter <671>, titled "Containers–Performance Testing," provides standards for the functional properties of plastic packaging systems that are used in pharmaceutical containers and dietary supplements when they are labeled as being USP-compliant. Plastic packaging systems that intend to provide protection from light or are specified as light-resistant must meet the spectral transmission requirements specified in the USP chapter <671>.[1] This application note describes the determination of spectral transmission measurements of plastic pharmaceutical packaging using the Cary 3500 Flexible UV-Vis spectrophotometer in accordance with USP <671>.

The Cary 3500 Flexible UV-Vis spectrophotometer is designed for routine, flexible use while delivering research-grade performance. It is a double-beam instrument equipped with a powerful xenon flash lamp, eliminating daily warmup. The lamp comes with a 10-year warranty (for Cary 3500 instruments purchased from Agilent or participating partners), which drastically reduces the frequency and cost of lamp replacement, for ultimate peace of mind. The Cary 3500 Flexible UV-Vis spectrophotometer has a large sample compartment to facilitate sample manipulation and user access, yet it maintains a small footprint. It can be equipped with solid-sample and thin-film holders, catering to various sample types and sizes.

The Cary 3500 Flexible UV-Vis spectrophotometer is used with the Cary UV Workstation software, which offers streamlined methods for wavelength reads, scanning, concentration, and kinetics. The software includes on-demand help and training with the built-in Help and Learning Center, which provides intuitive, easy-to-follow video tutorials for all users. Cary UV Workstation software is compatible with the Agilent OpenLab software suite. OpenLab software provides technical controls to securely acquire and store data in laboratories that must comply with FDA 21 CFR Part 11, EU Annex 11, GAMP5, ISO/IEC 17025, and the EPA's 40 CFR Part 160 (and similar regulations in other countries). These controls include access control and secure data, electronic signature workflows, and advanced audit trail review.

Experimental

Select accessories suitable for the analysis

Pharmaceutical packaging systems come in different shapes and sizes. The solid-sample holder accessory kit (G9854A) offers a range of accessories, providing greater flexibility for the analysis. Depending on the size, thickness, and type of sample, the solid-sample holder accessory kit can support sampling needs for the analysis. Features include:

- The option to select the aperture size. The aperture plates come in three different aperture sizes (Figure 1A)
- The ability to adjust the height of the sample holder using the appropriate screw positions on the aperture plate (Figure 1B)
- The option to select V-mounts and spacers for the different sample thicknesses (Figures 1C and 1D)
- The unique design of the magnetic thin-film holder for measuring thin films (Figure 1E)

Once the solid-sample holder is fitted with the preferred configuration, the holder should be realigned.

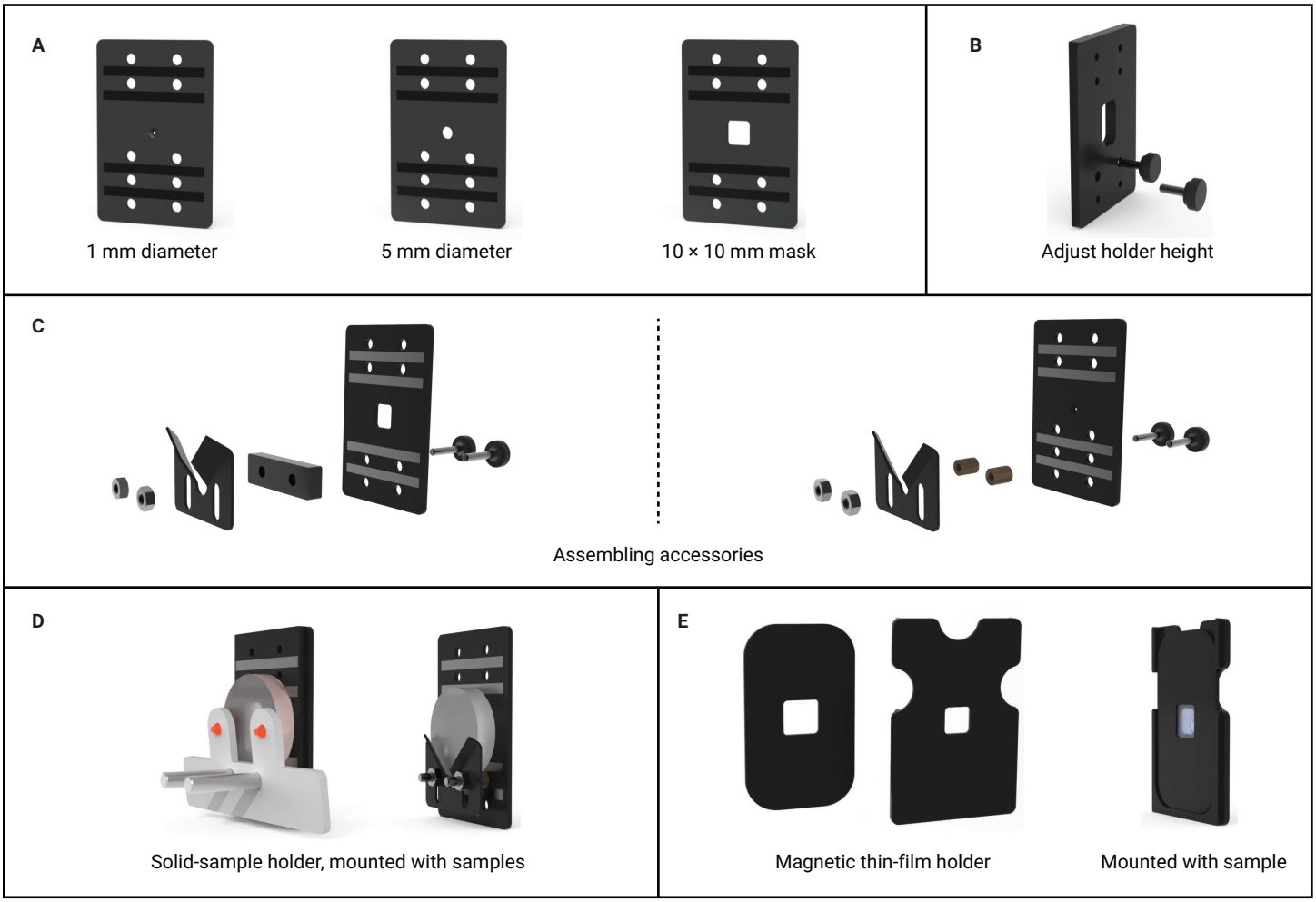

Figure 1. The Agilent solid-sample holder accessory kit includes a range of accessories that cater for various sample types and sizes. (A) The solid-sample holder can be fitted with the aperture plate with different aperture sizes including 1 and 5 mm diameters and a 10 × 10 mm mask. (B) Adjust the height of the sample holder. (C) Assembling accessories (V-mounts, spacers, and aperture plates) to meet sampling requirements. (D) Solid-sample holder fitted with samples. (E) The magnetic thin-film holder.

Sample analysis

Spectral transmission measurements of two different plastic pharmaceutical packaging systems used for oral administration (liquids and tablets) were selected for the study. Sections representing the average thickness were cut from three areas of each plastic packaging system. Each specimen was washed and dried using lint-free tissues and mounted on the aperture plate with a 5 mm aperture size. Mounting the sample is quick and simple, requiring no tools. **Note:** wipe the specimen with lint-free tissues to avoid leaving fingerprints or other marks on the surface that light passes through. The solid-sample holder was placed in the Cary 3500 Flexible UV-Vis spectrophotometer, and spectral transmission measurement of the specimen was collected using Cary UV Workstation software (version 1.4). The parameters indicated in Table 1 were used to create a data acquisition method. As part of the method, the Y Max function was set to the range of 290 to 450 nm (Figure 2). The Y Max function determines the highest Y-value within the specified wavelength range.

Once the data are collected, a results table is generated automatically by the software, which includes the maximum value for Y and the wavelength value at which the highest Y-value occurs. The Y Max function drastically reduces operator interaction when analyzing data. The ability to save calculations within a method increases laboratory productivity while enhancing technical control in regulated environments. The same experimental procedure was followed to collect the transmission spectra of each specimen.

Table 1. Experimental parameters for the Agilent Cary 3500 Flexible UV-Vis spectrophotometer as specified in USP <671>.

Parameter	Setting
Wavelength Range	290 to 450 nm
Spectral Bandwidth	2 nm
Baseline	Air
Aperture Size	5 mm

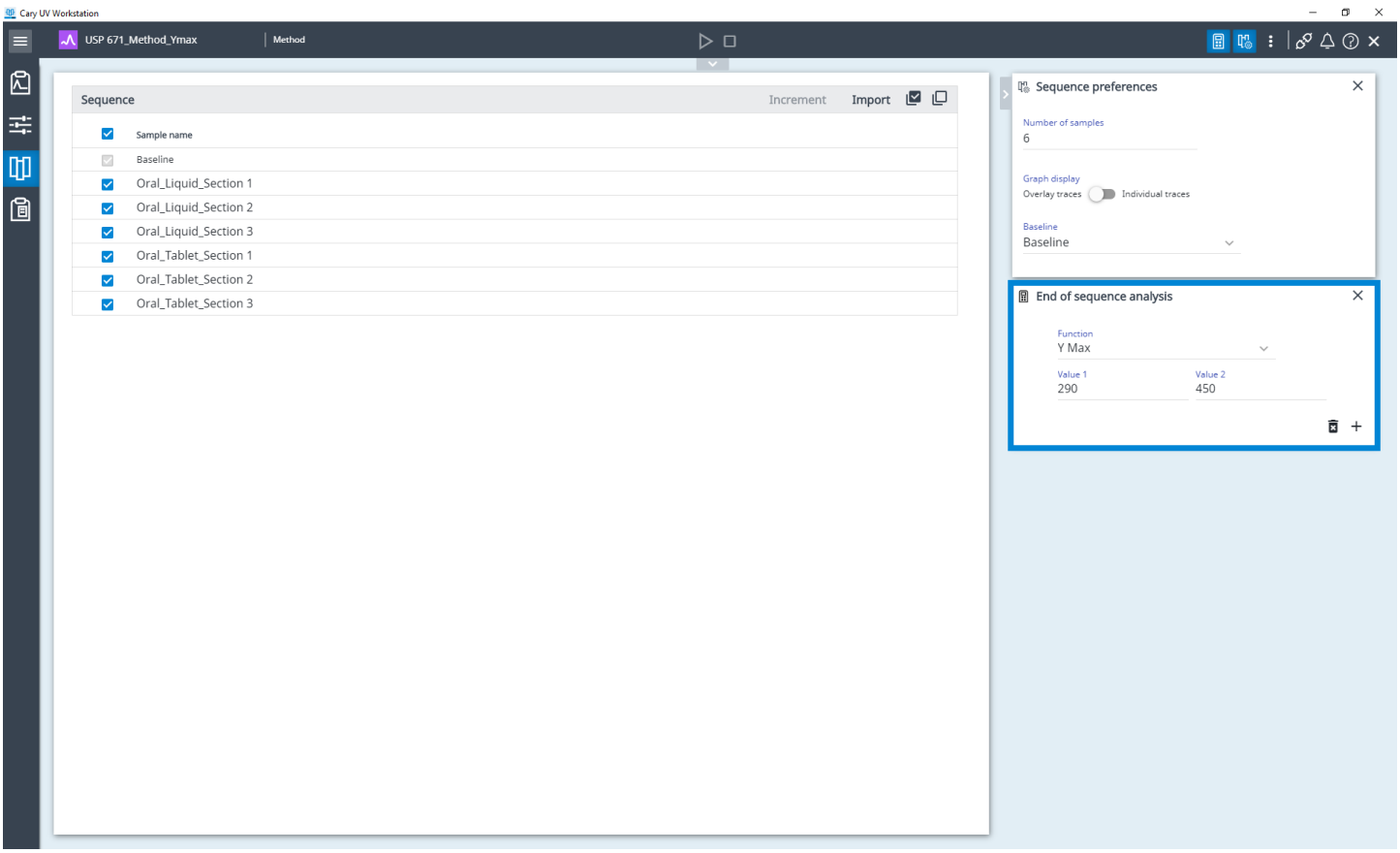

Figure 2. Agilent Cary UV Workstation software with the Y Max function set in the End of sequence analysis section. The End of sequence analysis function will be executed automatically at the end of data collection.

Results and discussion

According to the USP <671>, the observed spectral transmission for plastic containers that contain products intended for oral administration should not exceed 10% at any wavelength in the range of 290 to 450 nm. In this study, the plastic pharmaceutical containers that were used were designed for oral administration; therefore, a 10% spectral transmission limit was applied.

Note: USP chapter <661.1> "Plastic Materials of Construction" and <661.2> "Plastic Packaging Systems for Pharmaceutical Use" become official on December 1, 2025, replacing USP chapter <661> "Plastic Packaging Systems and their Materials of Construction". USP chapter <661.2> includes the identical Spectral Transmission test (including test procedures and acceptance criteria) as specified in USP chapter <671> "Containers – Performance Testing". USP general chapter <659> "Packaging and Storage Requirements" permits the early adoption of chapter USP chapter <661.2>. Therefore, the Spectral Transmission test described in this application note incorporates requirements specified in USP chapter <671> and USP chapter <661.2> (if early adoption of USP chapter <661.2> is implemented).[1-5]

The amount of light transmitted by each plastic pharmaceutical container was measured using the Cary 3500 Flexible UV-Vis spectrophotometer. Following data acquisition, the Results and Analysis page was automatically generated by the Cary UV Workstation software, allowing quick and easy data analysis. The Results and Analysis page can be customized to display the data that are specific to the analysis, and consists of the following (Figures 3 and 4):

- Transmission spectra for each sample and graph legend.
- Results table tabulating the maximum percent transmission value for each scan in the wavelength range of 290 to 450 nm. The X-value (wavelength) where the highest Y-value occurs is also presented.

As shown in Figures 3 and 4, the maximum spectral transmission values for all plastic containers in the wavelength range of 290 to 450 nm are under 10%, thus meeting the requirements in USP <671>.

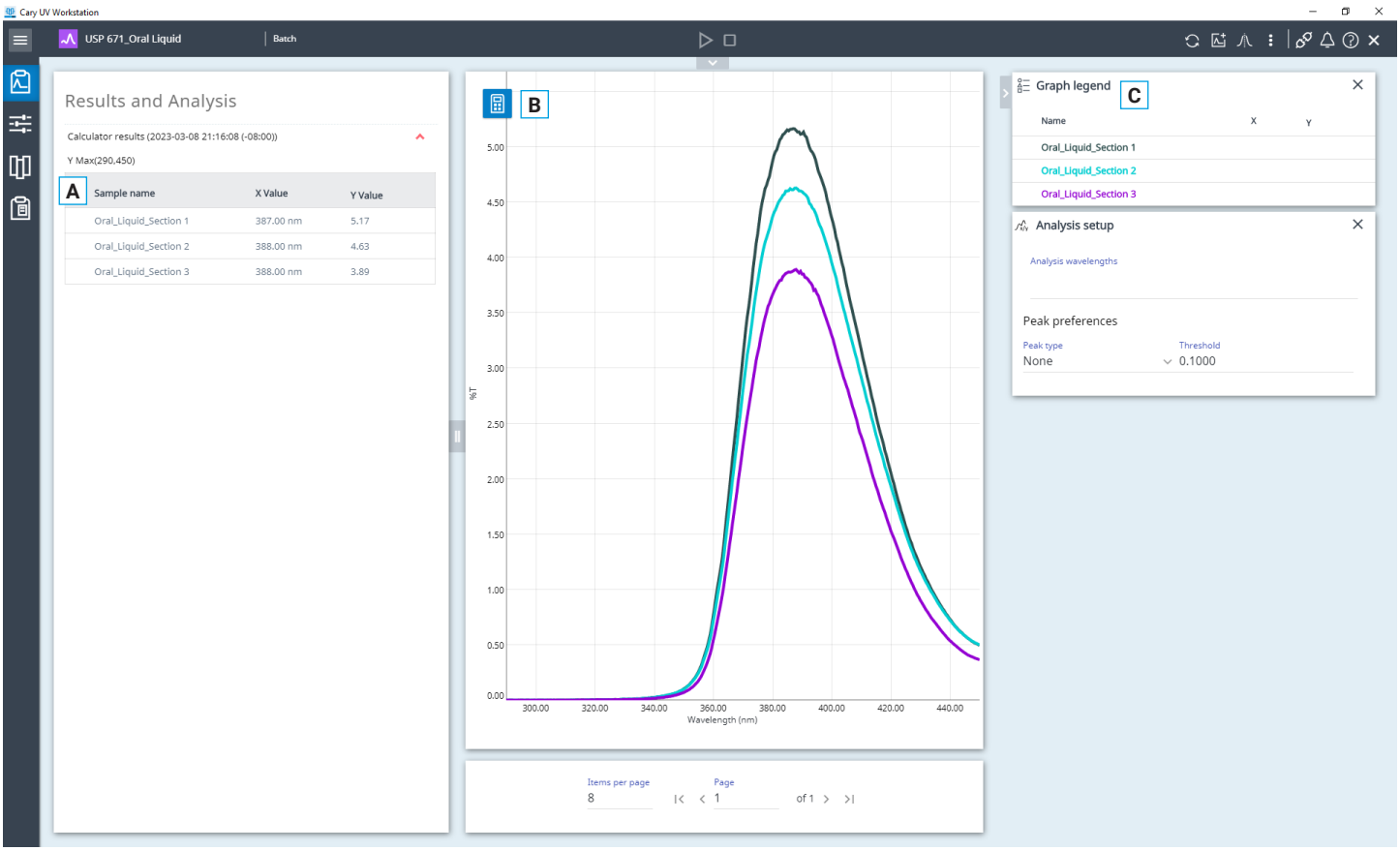

Figure 3. Agilent Cary UV Workstation Results and Analysis page generated for the analysis of plastic pharmaceutical packaging containing oral liquid. The results table (A) presents the Y Max values for each trace, which were calculated automatically using the "End of sequence analysis" section. This page also shows the transmission spectra for each sample (B) and the graph legend (C).

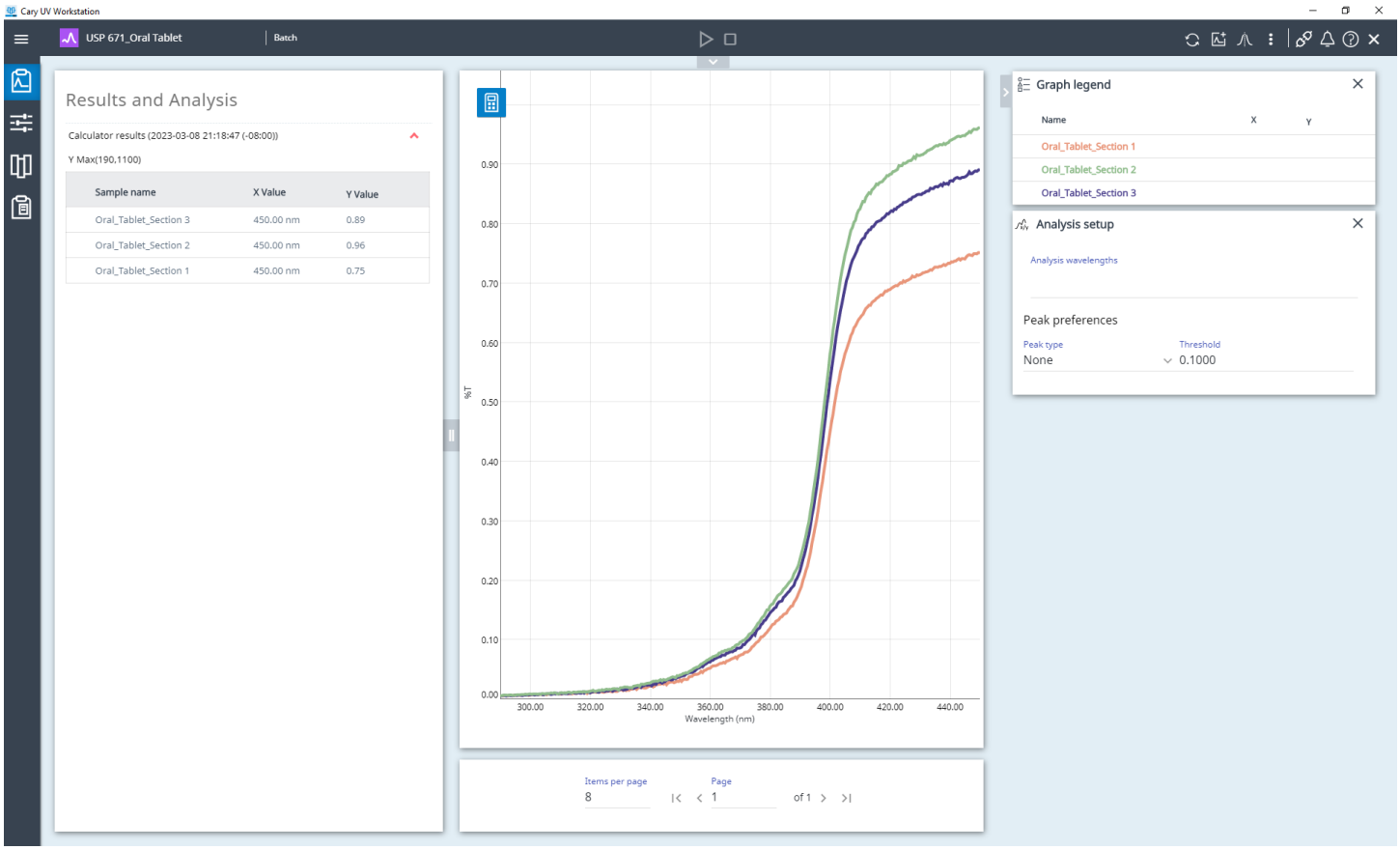

Figure 4. Agilent Cary UV Workstation Results and Analysis page generated for the analysis of plastic pharmaceutical packaging containing oral tablets.

Conclusion

The Agilent Cary 3500 Flexible UV-Vis spectrophotometer equipped with the solid-sample holder was used to measure the spectral transmission measurements of plastic pharmaceutical containers as specified in the USP <671>. The Cary 3500 Flexible UV-Vis spectrophotometer is designed for routine and flexible use while delivering research-grade performance. It is a double-beam instrument equipped with a powerful xenon flash lamp. The xenon lamp has a 10-year warranty, ensuring uninterrupted operation while avoiding expensive and time-consuming lamp replacements. The solid-sample holder accessory kit consists of a range of accessories, which provide greater flexibility to analyze a range of samples. The solid-sample holder can be fitted with an aperture plate with different aperture sizes accommodating a wide variety of sample types and sizes, which is ideal for analyzing pharmaceutical containers. The Cary 3500 Flexible UV-Vis spectrophotometer comes with Cary UV Workstation software, where calculations can be saved within a method to increase laboratory productivity while offering technical control. This software is compatible with the Agilent OpenLab software suite. OpenLab software provides technical controls to securely acquire and store data in a central or local database while being compliant with regulatory requirements.

References

1. United States Pharmacopeia and National Formulary (USP 43-NF 38), General Chapter <671>, Containers–Performance Testing.
2. United States Pharmacopeia and National Formulary (USP 43-NF 38), General Chapter <659>, Packaging and Storage Requirements.
3. United States Pharmacopeia and National Formulary (USP 43-NF 38), General Chapter <661>, Plastic Packaging systems and their Material of Construction
4. United States Pharmacopeia and National Formulary (USP 43-NF 38), General Chapter <661.1>, Plastic Materials of Construction. Chapter will become official on December 1, 2025.
5. United States Pharmacopeia and National Formulary (USP 43-NF 38), General Chapter <661.2>, Plastic Packaging Systems for Pharmaceutical Use. Chapter will become official on December 1, 2025.

Further information

- Agilent Cary 3500 Flexible UV-Vis Spectrophotometer
- Agilent Cary UV Workstation software
- Data Integrity Options for GMP Facilities for the Agilent Cary 3500 UV-Vis Spectrophotometer Series
- UV-Vis Spectroscopy and Spectrophotometer FAQs

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