

UV-Vis

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Spectral Transmission of Pharmaceutical Containers in Accordance with USP <671>

Introduction

All medicinal products need to be protected and packaged in containers which conform to prescribed standards. The quality of pharmaceutical packaging

can have a significant impact on the performance of pharmaceutical products and can reduce shelf-life if the improper packaging is used. Packaging must:¹

- Protect against all adverse external influences (e.g. moisture, light, oxygen and temperature variation) which may affect quality or potency of the product
- Protect against biological contamination
- Protect against physical damage
- Carry the correct product identification and information

The USP chapter, <671>, "Containers – Performance Testing" provides standards for the functional properties of packaging systems used for solid and liquid oral dosage forms for pharmaceuticals and dietary supplements. The test methods detailed in this chapter determine the water vapor permeation rate and spectral transmission of plastic containers.²

The previously proposed changes to USP <671> involved moving the Spectral Transmission section into Plastic Packaging Systems for Pharmaceutical Use <661.2> in Pharmacopeial Forum (PF) 42(4) [July-Aug. 2016]. However, this change was not introduced and may be postponed until chapters <661.1> and <661.2> fully apply (May 1, 2020).^{3,4}

This application note demonstrates the determination of spectral transmission of plastic pharmaceutical containers using the LAMBDA™ 1050+ UV/Vis/NIR spectrophotometer, in accordance with USP <671>.

Method

Sections, representing the average wall thickness, were cut from three areas of an oral tablet medicine container obtained from a pharmacy. Each specimen was washed using a soft cloth dampened with methanol and the surfaces left to dry.

Samples were individually mounted, after wiping with lens tissue, in a LAMBDA 1050+ UV/Vis/NIR spectrophotometer with a 150 mm InGaAs integrating sphere accessory (Figure 1). The LAMBDA 1050+ was used because it allows other applications to be performed in the NIR region. However, if there is no NIR requirement, the LAMBDA 850+ UV/Vis spectrophotometer is highly suited to this application. Additionally, this method allows for the use of different integrating sphere sizes. The 150 mm integrating sphere meets all international measurement guidelines, such as those set by ASTM, DIN and CIE, offering flexibility for other applications such as haze (ASTM D 1003) and high accuracy color measurements (ASTM D 308).

The sample section was clamped on the external port of the integrating sphere such that its cylindrical axis was parallel to the plane of the slit and approximately centred with respect to the slit (Figure 2). If the specimen is too small to cover the opening of the integrating sphere, the uncovered portion can be masked with opaque paper or masking tape, providing the length of the specimen is greater than the slit in the spectrophotometer. Alternatively, a small spot kit can be used to reduce the beam size.

UVWinLab™ software was used to take the measurements in transmission, with the instrument parameter settings shown in Figure 3. The software allows the users to set limits. In this case, a 10 % transmittance limit was set in accordance with USP <671>.



Figure 2. Integrating sphere accessory with (right) and without (left) pharmaceutical container sample mounted.



Figure 1. LAMBDA 1050+ UV/Vis/NIR spectrophotometer with 150 mm integrating sphere accessory.

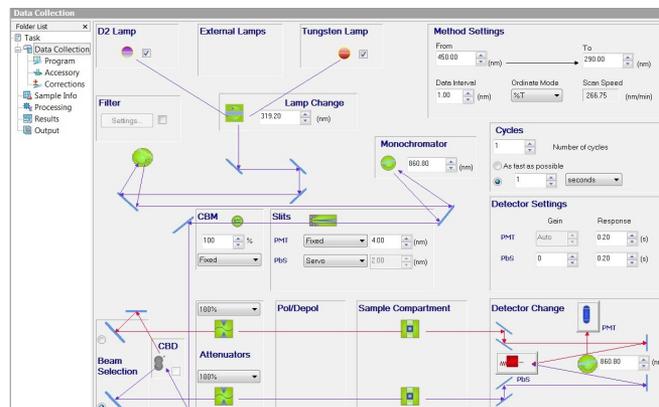


Figure 3. UVWinLab instrument parameter settings.

Results

As stated in USP <671>, the observed spectral transmission should not exceed the limits given in Table 1 for containers intended for parenteral use. Plastic containers intended for oral or topical administration, on the other hand, should not exceed 10 % spectral transmission at any wavelength in the range 290 – 450 nm.

Table 1. Spectral transmission limits for plastic containers, as stated in USP <671>.

Nominal Size (in mL)	Maximum Percentage of Spectral Transmission at Any Wavelength Between 290 and 450 nm (%)
1	50
2	45
5	40
10	35
20	30
50	15

Note: For containers larger than 50 mL, the limits for 50 mL apply.

In this application, the medicine container used was designed for oral administration and, therefore, the 10 % limit applies. The spectra of the three sections of the medicine container are shown in Figure 4. The maximum transmittance for all three sections was under 10 % (Table 2), and thus within the spectral transmission limit specified in USP <671>.

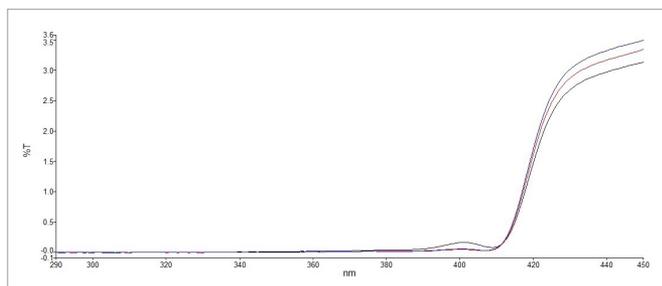


Figure 4. Overlaid scans of 3 sections of a medicine container.

Table 2. Maximum transmittance, between 290 – 450 nm, of three sections of a pharmaceutical container.

Sample ID	Limit (%T)	Max Transmittance (290 - 450 nm)
Sample 1	10	3.1
Sample 2	10	3.3
Sample 3	10	3.5

Conclusion

The determination of spectral transmission of plastic pharmaceutical containers was performed using the LAMBDA 1050+ UV/Vis/NIR spectrophotometer and UVWinLab software, in accordance with USP <671>. The LAMBDA 850+ UV/Vis spectrophotometer, however, is highly suited for this method when the user does not require the NIR region for other applications. Analysis was simple and the ability to set up limits and calculations for maximum transmittance within the software allows for rapid results to be obtained.

References

1. World Health Organization, *Guidelines on packaging for pharmaceutical products (Annex 9)*, WHO Technical Report Series, No. 902, 2002.
2. United States Pharmacopeia and National Formulary (USP 41-NF 36), General Chapter <671>, Containers – Performance Testing.
3. <https://www.gmp-compliance.org/gmp-news/revised-usp-chapter-671-containers-performance-testing-adopted>. Date accessed: September 2018.
4. <https://www.gmp-compliance.org/gmp-news/draft-usp-chapter-671-containers-performance-testing>. Date accessed: September 2018.