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APPLICATION NOTE

No. AN53158

Spectral transmission testing of pharmaceutical containers

Using an Evolution Spectrophotometer with an ISA-220 Integrating Sphere Accessory for testing according to USP <671> and USP <661.2>

Introduction

Ensuring adequate quality and safety standards of plastic materials used for pharmaceutical containers is of the utmost importance. To that end, The United States Pharmacopeia Convention has established requirements for containers which are described in The United States Pharmacopeia/ National Formulary (USP/NF) general chapters. These requirements generally relate to the design characteristics of the container and their materials of construction. One parameter that is measured is the amount of light resistance by plastic materials used for pharmaceutical containers. This light is measured as the spectral transmission through the plastic container as described in USP <671> Containers – Performance Testing and USP <661.2> Plastic Packaging Systems for Pharmaceutical Use.[1,2]

Both the plastic bottle material and the curvature of the walls of the bottles can result in the scattering of light. Because of this, an integrating sphere is needed to compensate for the scattering in order to accurately measure the total light transmittance of the sample over the wavelength range required. In this note, the spectral transmission of light through various pharmaceutical bottles is evaluated using a Thermo Scientific™ Evolution™ 260 Bio Spectrophotometer equipped with an ISA-220 Integrating Sphere Accessory.

Figure 1. Pharmaceutical bottles selected for testing: bottle 1 – amber translucent container, bottle 2 – large white opaque container, bottle 3 – natural translucent container, bottle 4 – small white opaque container.

Experimental

Four different pharmaceutical bottles of various sizes and compositions were selected for analysis. Two of the bottles were made of white opaque material, one bottle was natural translucent, and one was amber translucent (Figure 1). Large circular sections were cut out of the side of each bottle, and were washed and dried with care taken to avoid scratching the surfaces.

An Evolution 260 Bio Spectrophotometer was utilized for this experiment due to its compatibility with the ISA-220 Integrating Sphere Accessory.* The integrating sphere fits into the sample compartment of the spectrophotometer and expands the capabilities of the instrument to measure the reflectance and transmittance of diffuse or scattering materials. The ISA-220 Accessory is equipped with its own silicon photodiode detector and is capable of obtaining spectral data between 220 nm and 1100 nm. With the integrating sphere in transmittance mode, the circular bottle sections were mounted to the sphere using the spring-steel clips to hold the sample in place (Figure 2). The % Transmittance was measured at two different locations of each cutout section to ensure the results reflect a general assessment of the material.

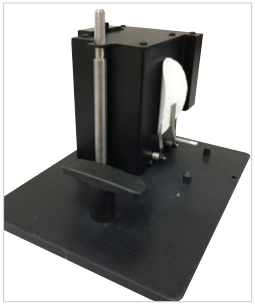

Figure 2. ISA-220 setup for transmission measurements with plastic sample mounted.

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* The Thermo Scientific™ Evolution™ 220 UV-Vis Spectrophotometer is also compatible with the ISA-220 Accessory.

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Results

The % Transmittance of the bottle sections between 290 nm – 450 nm using air as a reference was measured with the Scan method using Thermo Scientific™ INSIGHT™ Software. The high-energy Materials Bandwidth setting was selected for this measurement as it was designed specifically for use with the ISA-220 and delivers outstanding sensitivity, particularly with low transmittance samples. The % Transmittance data from the four plastic bottles tested is summarized in Figure 3.

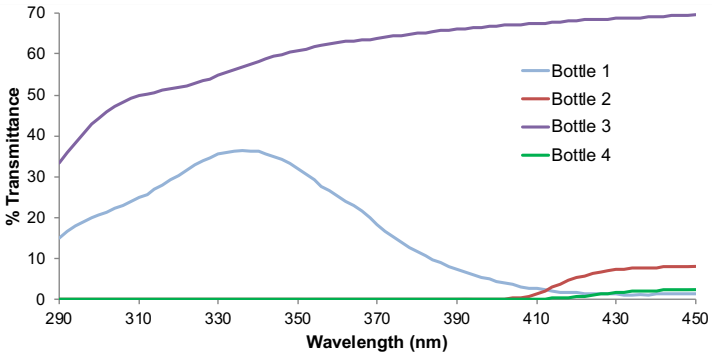

Figure 3. % Transmittance data of four plastic bottles.

According to the USP standard for both <661.2> and <671>, the observed spectral transmission for plastic containers used for products intended for oral or topical use should not exceed 10% at any wavelength in the range of 290 – 450 nm. More specific limits for maximum spectral transmission based on container size must be considered if the container is intended for parenteral use.

When examining the maximum transmittance data in Table 1, two of the four bottles exceeded the 10% spectral transmission limit for containers intended to contain products for oral use. Bottle 3, which was a natural translucent container, transmitted 33% – 70% of light between the wavelengths tested. Bottle 1, which was an amber translucent container, exhibited less spectral transmission than Bottle 3 but still exhibited between 1% – 37% light transmission over the wavelength range.

Bottles 1 and 3 exceeded 10% spectral transmission at any point between 290 nm – 450 nm due to the material's translucent properties. These bottles would not be acceptable for containing pharmaceutical products for oral use. Bottles 2 and 4, which were a white opaque material, did not exceed the 10% limit, therefore, met the USP requirement for spectral transmission.

Table 1. Maximum transmittance of bottles

Sample	Limit of Transmittance (%)	Measured Maximum Transmittance (%)
Bottle 1	10	37
Bottle 2	10	8
Bottle 3	10	70
Bottle 4	10	2

Conclusion

The spectral transmission of plastic pharmaceutical containers can easily be measured using an Evolution 260 Bio Spectrophotometer with an ISA-220 Integrating Sphere Accessory. The Integrating Sphere enables the instrument to measure the total transmittance of scattering materials. This experimental setup was used to measure the spectral transmission of four plastic bottles of various size and composition. It was determined that only two of the four bottles met the USP specification for spectral transmittance which shows the importance of this testing for confirming the packaging system meets the requirements to be used as a pharmaceutical container.

References

1. United States Pharmacopeia and National Formulary (USP 42-NF 37), General Chapter <661.2>, Plastic Packaging Systems for Pharmaceutical Use
2. United States Pharmacopeia and National Formulary (USP 42-NF 37), General Chapter <671>, Containers – Performance Testing

Notes

1. The Spectral Transmission section has previously been proposed to be deleted from USP <671> and to be relocated in USP <661.2> in PF 42(4). A Spectral Transmission section is now found in USP <661.2> however as of the most recent update in PF 44(3), the Spectral Transmission section has not been removed from USP <671>.

Description	Part number
Evolution 220 Spectrophotometer	840-210600
Evolution 260 Bio Spectrophotometer	840-211000
ISA-220 Integrating Sphere for Evolution Spectrophotometers	222-269400

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