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Application News

UV-2600i UV-Vis Spectrophotometer

Spectral Transmission Measurement of Pharmaceutical Containers

Zhen Hao Lee, Ai Ming Chua
Centre for Application Solutions, Shimadzu (Asia Pacific) Pte Ltd, Singapore

User Benefits

- UV-2600i with ISR-2600plus enables spectral transmission measurement of pharmaceutical containers.
- Spectral evaluation function enables automatic pass/fail judgements based on evaluation criteria specified by user.

■ Introduction

Pharmaceutical containers are used to store medicinal agents such as capsules, tablets, etc. It should provide sufficient protection from factors that can cause a degradation in the quality of the medicinal agents over its shelf life. Some common causes of such degradation include exposure to light and reactive gases, absorption of water vapor and microbial contamination [1].

For light sensitive medicinal agents, it is necessary for the container to have light protection properties. This can be achieved by using light-resistant container that reduces light transmission and protect the agent from photochemical deterioration. To evaluate the light transmission properties of a light-resistant container, a spectral transmission measurement can be carried out with UV-Vis spectroscopy according to United State Pharmacopeia (USP) chapter <661.2> Plastic Packaging Systems for Pharmaceutical Uses [2].

This application news describes the use of UV-2600i UV-Vis spectrophotometer equipped with ISR-2600plus integrating sphere accessory to perform spectral transmission measurement for various pharmaceutical containers according to USP chapter <661.2>.

■ Experimental

Three pharmaceutical containers with different sizes and materials were selected for transmission measurement (Fig. 1). One of the containers was transparent amber (Sample 1), while the other two containers were opaque white (Samples 2 and 3). A circular section was cut from each container. These sections were then washed and left to dry, taking care to avoid scratching the surfaces.

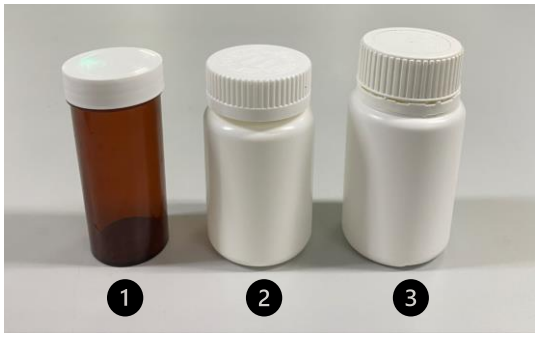

Fig. 1 Pharmaceutical Containers

The UV-2600i UV-Vis spectrophotometer (Fig. 2) was used for spectrum measurement. As the sections from the pharmaceutical containers have curved surfaces, it would result in light scattering and inaccurate result might be obtained if direct transmission measurement is used. Thus, an integrating sphere accessory (ISR-2600plus) is used to measure the spectral transmission of samples more accurately. Table 1 lists the instrument and analytical conditions.

Fig. 2 UV-2600i UV-Vis spectrophotometer

Table 1 Instrument and Analytical Conditions

Instruments	: UV-2600i, ISR-2600plus
Measurement Wavelength Range	: 290 – 450 nm
Data Interval	: 1.0 nm
Scan Speed	: Medium speed
Slit Width	: 5.0 nm
Light Source Switching Wavelength	: 340 nm

The sections from the pharmaceutical container were mounted onto ISR-2600plus integrating sphere accessory. The film holder to hold the sample in position is shown in Fig. 3.

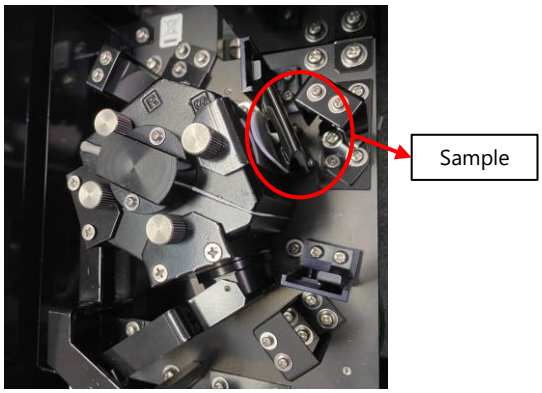

Fig. 3 Mounting of Sample in ISR-2600plus

■ Results and Discussion

The transmission spectra of the three pharmaceutical containers are displayed in Fig. 4.

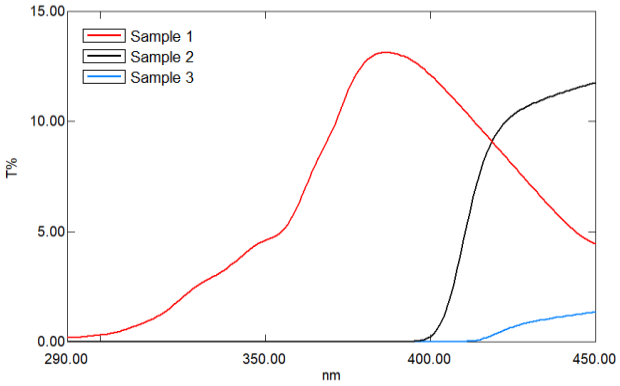

Fig. 4 Transmission spectra of three pharmaceutical containers

As stated in USP chapter <661.2>, the observed spectral transmission for plastic container used for products intended for oral or topical administration should not exceed 10 % at any wavelength in the 290 – 450 nm range. If the plastic container is intended for parenteral use, different maximum spectral transmission limits are applied based on the container size. For this analysis, all three pharmaceutical containers were intended for oral administration. Thus, the 10 % limit would apply.

Based on the transmission spectra in Fig. 4, it is observed that Samples 1 and 2 have transmittance values exceeding the 10 % limit. Sample 1 has transmitted light throughout the measured wavelength range, with an absorption peak around 380 nm. Whereas the transmittance value for Sample 2 started decreasing at around 420 nm, and almost no light was transmitted in the UV region. The spectra also shows only Sample 3 has transmittance value below the 10 % limit. Therefore, Sample 3 is able to meet the USP requirement for spectral transmission.

■ Pass/Fail Judgement using Spectral Evaluation Function

The spectra evaluation function in LabSolutions™ UV-Vis software can be used to perform pass/fail judgement on the measured spectra of pharmaceutical containers. By specifying spectral transmission limit of 10 % as the evaluation criteria, spectra judgement can be made automatically. Fig. 5 shows the detailed settings window of spectral evaluation function.

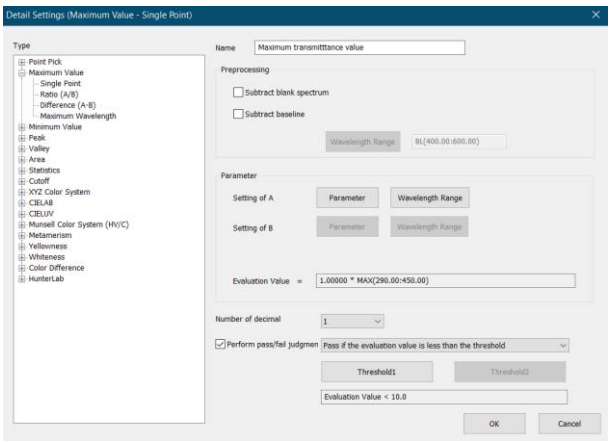

Fig. 5 Window Settings of Spectral Evaluation Function

Fig. 6 shows the spectral evaluation results for the three pharmaceutical container sections. "PASS" is indicated for Sample 3 as the maximum transmittance value measured is 1.4 %, which is within the requirement of <10 %. However, Samples 1 and 2 received a "FAIL" since the maximum transmittance value obtained were 13.1 % and 11.8 % respectively. The failed results are also indicated with a red colored row. This allows quick determination for the measurement results to have passed or failed at a glance.

			Maximum transmitttance value	
	Legend	File Name	Value	Judgment
1	☑	Sample 1.vspd	13.1	FAIL
2	☑	Sample 2.vspd	11.8	FAIL
3	☑	Sample 3.vspd	1.4	PASS

Fig. 6 Spectral Evaluation results of three pharmaceutical bottle

■ Conclusion

The spectral transmission measurement of pharmaceutical containers can be obtained using UV-2600i UV-Vis spectrophotometer and ISR-2600plus integrating sphere accessory. As the spectral evaluation function in LabSolutions UV-Vis software can perform pass/fail judgement automatically based on pre-set evaluation criteria, the quality inspection procedure is simplified, and high efficiency can be achieved.

■ Reference

1. FDA Guidance for Industry on the Container Closure Systems for Packaging Human Drugs and Biologics (July 1999)
2. United States Pharmacopeia and National Formulary (USP 44-NF 39), General Chapter <661.2>, Plastic Packaging Systems for Pharmaceutical Use.

Note:
The Spectral Transmission section has previously been proposed to be relocated from USP chapter <671> to USP chapter <661.2> in Pharmaceutical Forum (PF) 42(4). However, the change was not introduced and may be postponed until chapter <661.2> is fully apply (December 1, 2025)

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Shimadzu Corporation
www.shimadzu.com/an/

SHIMADZU (Asia Pacific) Pte. Ltd,
www.shimadzu.com.sg