

## Application News

# No. A572

### Spectrophotometric Analysis

## Instrumental Validation of UV-Visible Spectrophotometer Compliant with JP, EP and USP – Application of Instrumental Validation Functions of UV-1900 –

UV-Visible spectroscopy is adopted in the pharmacopoeia published in many countries. However, the differences of the instrumental validation items and their maximum tolerance required for a UV-visible spectrophotometer are seen among them. The newly developed UV-1900 UV-VIS spectrophotometer has the instrumental validation functions compliant with three major pharmacopoeias of Japanese Pharmacopoeia (JP), European Pharmacopoeia (EP) and United States Pharmacopoeia (USP), and the instrumental validation based on them can be easily performed. The instrumental validation compliant with JP, EP and USP using the UV-1900 are described in this report.

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### ■ Instrumental Validation Functions of UV-1900

The external appearance of the UV-1900 is shown in Fig. 1. The UV-1900 is a small-footprint spectrophotometer (450(W) × 501(D) × 244(H) mm) and its hardware design is done based on ergonomics. The UV-1900 uses a color touch panel as a control panel and features the easy-to-navigate user interface which can grasp the current status and operating procedures at a glance. Fig. 2 shows a screen of instrumental validation functions in its maintenance function. The test items compliant with JP, EP and USP are included in the UV-1900. Those compliant with Japanese Industrial Standards (JIS) are also included in it and they can be automatically performed. The semi-automatic tests have items which need inspection tools and the automatic tests are performed using a deuterium lamp mounted in the UV-1900 as an inspection tool.



Fig. 1 External Appearance of UV-1900

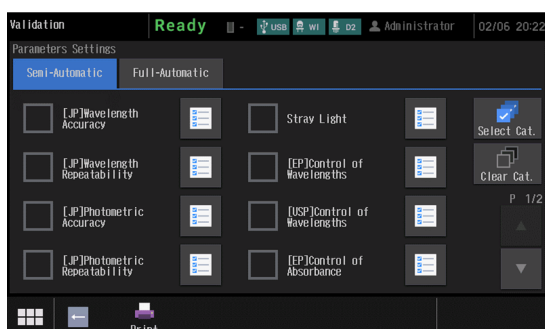


Fig. 2 Screen of Instrumental Validation (Semin-automatic operation)

### ■ Instrumental Validation Compliant with JP

The instrumental validation compliant with JP requires the tests of wavelength accuracy, wavelength repeatability, photometric accuracy and photometric repeatability.

The wavelength accuracy is verified using an optical filter for wavelength calibration. The difference between its certified value and the measured value must be within the tolerance. The emission lines of a deuterium discharge lamp or a low-pressure mercury lamp also can be used for the test of the wavelength accuracy.

The wavelength repeatability is also verified using them. When the optical filter or the emission lines of those lamps are measured three times, the difference between the value measured at the given wavelength and its mean value of the three measurements must be within the tolerance.

The photometric accuracy is verified using an optical filter for photometric calibration. The difference between its certified value at the given wavelength and the measured value must be within the tolerance.

The photometric repeatability is also verified using the optical filter for photometric calibration. The difference between the absorbance value measured at the given wavelength and its mean value of the three measurements must be within the tolerance.

The tolerance for each test item depends on the used inspection tools. The default values set in the UV-1900 are the recommended values for them. Fig. 3 and 4 show the test conditions of the wavelength repeatability and the measured results, respectively.

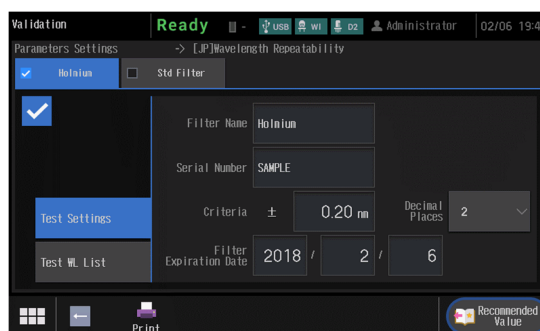


Fig. 3 Conditions for Test of Wavelength Repeatability

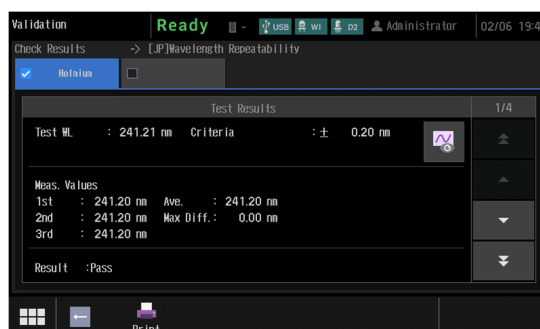


Fig. 4 Results for Test of Wavelength Repeatability

## ■ Instrumental Validation Compliant with USP

The instrumental validation compliant with USP requires control of wavelengths, control of absorbance, limit of stray light and resolution.

The wavelength accuracy and precision are verified using the absorption maxima of rare earth oxide solutions such as the holmium oxide solution and the didymium solution or the emission lines of a deuterium discharge lamp or the emission lines of a low-pressure mercury lamp. They are measured at least six times. For wavelength accuracy, the difference of the mean measured value to the certified value of them must be within the tolerance. For wavelength precision, the standard deviation of the measured values must not exceed the tolerance.

The absorbance accuracy and precision are verified using potassium dichromate solutions or gray glass filters. The absorbance accuracy must be within the tolerance. The absorbance precision can be verified as the standard deviation of at least six replicate measurements at two or more absorbance levels over the operational range. The standard deviation must not exceed the tolerance.

Stray light can be detected at a given wavelength with a suitable solution like the potassium iodide aqueous solution (10 g/L). The absorbance at a given wavelength must be more than 0.7<sup>\*1</sup>.

The resolution is verified by measuring the ratio of the absorbance of a 0.020 % (v/v) solution of toluene in hexane at the maximum and minimum at about 269 and 266 nm, respectively.

The tolerance for each test item depends on the used inspection tools. The default values set in the UV-1900 are the recommended values for them. Fig. 5 and 6 show the test conditions of the absorbance accuracy and precision, and the measured results, respectively.

\*1 A cell of 5 mm in length filled with the solvent is used as the reference. Aceton and the aqueous solution of potassium chloride (12 g/L) and sodium nitrite (50 g/L) are used as the test solution, depending on the tested wavelength.

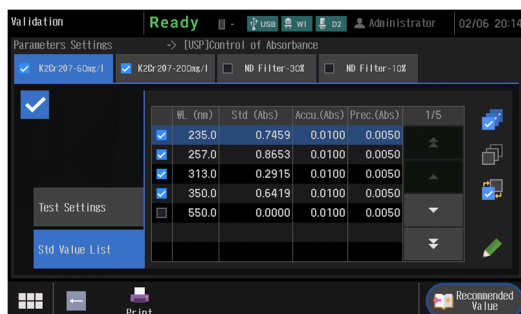


Fig. 5 Conditions for Control of Absorbance

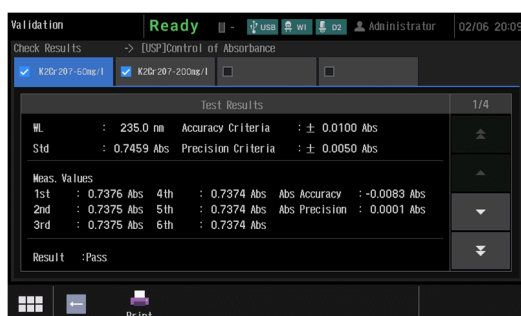


Fig. 6 Results for Control of Absorbance

## ■ Instrumental Validation Compliant with EP

The instrumental validation compliant with EP requires control of wavelengths, control of absorbance, limit of stray light and resolution, whose tests are a little different from those of USP.

The wavelength accuracy is verified using the absorption maxima of the holmium perchlorate solution or the emission line of a deuterium discharge lamp or the emission lines of a low-pressure mercury lamp. When it is measured based on the given measurement conditions, the difference between its certified value and the measured value must be within the tolerance. The tolerance depends on the used inspection tools and the given wavelength for the test.

The absorbance accuracy is verified using suitable filters or a solution of potassium dichromate. The measured absorbance value at the given wavelength must be within the tolerance (absorbance of  $\pm 0.01$ ).

Stray light is detected at 198 nm with a 12 g/L aqueous solution of potassium chloride<sup>\*2</sup>. The measured absorbance value must be greater than 2.0.

The resolution is verified by measuring the ratio of the absorbance of a 0.020 % (v/v) solution of toluene in hexane at the maximum and minimum at about 269 and 266 nm, respectively.

The default values set in the UV-1900 are the recommended values for them. Fig. 7 and 8 show the test conditions of the stray light and the measured result, respectively.

\*2 The limit of stray light is referenced as an example in this report.

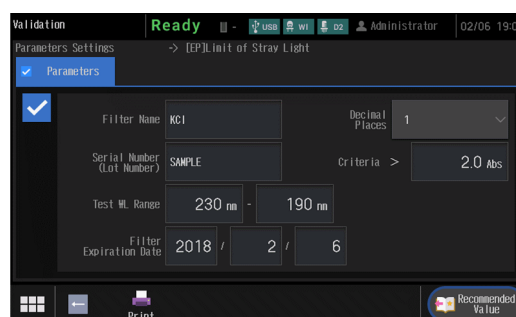


Fig. 7 Conditions for Limit of Stray Light

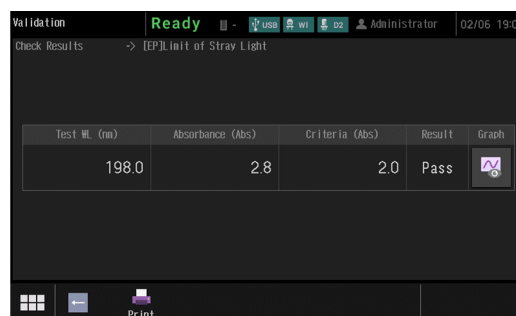


Fig. 8 Results for Limit of Stray Light

## ■ Conclusion

The instrumental validation functions compliant with JP, USP and EP included in the UV-1900 can facilitate their tests comprised of several items.



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