

# Application News

## No. A626

### Spectrophotometric Analysis

## Measurement of Impurities in Ethanol Using UV-Vis Spectrophotometer

At present, demand for ethanol for disinfection is increasing sharply as preventive measure for an infectious disease. When ethanol is to be used as a medical product, identification testing and purity testing conforming to the applicable Pharmacopoeias in each country are necessary. Ultraviolet-visible (UV-Vis) spectrophotometry is used in these tests as one technique for determining whether impurities are present in ethanol.

In the experiment introduced here, measurement of "Other impurities (absorbance)" in ethanols, which is described in the Japanese Pharmacopoeia, European Pharmacopoeia, and United States Pharmacopoeia, was conducted using a Shimadzu UV-1900i UV-Vis spectrophotometer, and absorbance, which is specified as an acceptance standard in the Pharmacopoeias, was judged automatically by using the evaluation function of LabSolutions™ UV-Vis.

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### Test Method for Ethanols

The Japanese Pharmacopoeia (JP) describes the five items "Clarity and color of solution," "Acidity or alkalinity," "Volatile impurities," "Other impurities (absorbance)," and "Residue on evaporation" under "Purity" testing of ethanol, anhydrous ethanol and ethanol for disinfection. Among these, "Other impurities (absorbance)" is measured in order to determine the presence/absence of impurities contained in ethanol based on absorption in the ultraviolet (UV) region.

The European Pharmacopoeia (EP) includes "Absorbance" as one item in "TESTS" and describes similar testing using UV-Vis spectrophotometry.

The United States Pharmacopoeia (USP) specifies "ULTRAVIOLET ABSORPTION" in "SPECIFIC TESTS" and also describes testing by UV-Vis spectrophotometry.

The measurement method for "Other impurities" is the same in the three Pharmacopoeias. The absorption spectrum of the sample is measured using a cell with an optical path length of 5 cm and water as a blank, and judgment of acceptability is based on absorbance.

Specifically, the Pharmacopoeias provide that the absorbances at 240 nm, between 250 and 260 nm, and between 270 and 340 nm are not more than 0.40, 0.30, and 0.10, respectively, when the absorption spectrum is measured in the 235 to 340 nm wavelength region. The provision also specifies that the absorption spectrum should be smooth and "show a steadily descending curve with no observable peaks or shoulders."

### Measurement of Anhydrous Ethanol

Anhydrous ethanol was measured with the UV-1900i UV-Vis spectrophotometer shown in Fig. 1, using a Shimadzu square long-path absorption cell holder and a 50 mm square cell. Table 1 shows the measurement conditions.

Fig. 2 shows the results of spectrum measurement.



Fig. 1 UV-1900i UV-Vis Spectrophotometer

Table 1 Measurement Conditions

Instrument	: UV-1900i
Software	: LabSolutions UV-Vis
Measurement wavelength range	: 235 - 340 nm
Scan speed	: Medium
Sampling pitch	: 0.5 nm
Slit width	: 1 nm (fixed)

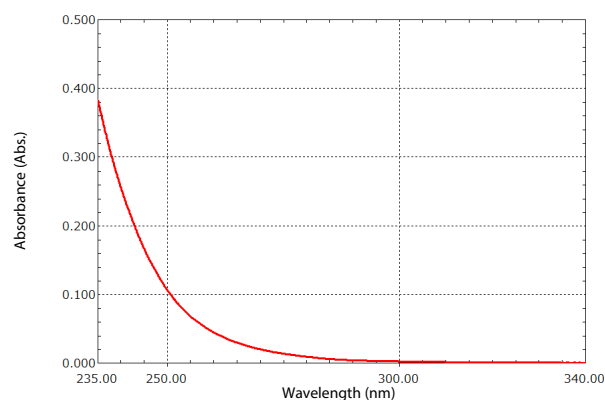


Fig. 2 Result of Measurement of Anhydrous Ethanol

In Fig. 2, it can be confirmed that absorbance is not more than 0.40 at 240 nm, not more than 0.30 between 250 and 260 nm, and not more than 0.10 between 270 and 340 nm, and there are no clear peaks or remarkable shoulders in the absorption spectrum curve.

### Pass/Fail Judgment Using LabSolutions UV-Vis

The provisions for "Other impurities (absorbance)" of anhydrous ethanol specify that the absorbances at 240 nm, between 250 and 260 nm, and between 270 and 340 nm are not more than 0.40, 0.30, and 0.10, respectively. However, reading the absorbances of all the measured samples is time-consuming work and judgments must be made carefully, as human error is also possible. The time required for this work can be reduced by the spectral evaluation function of LabSolutions UV-Vis.

The spectral evaluation function features 8 pass/fail criteria and 33 standard evaluation methods, including point pick, maximum value, minimum value, peak, valley, area, statistics, and cutoff, as well as a pass/fail judgment function. Here, a pass/fail judgment for anhydrous ethanol was made using the pass/fail judgment function.

### Setting of Pass/Fail Judgment Using LabSolutions UV-Vis

Although there are three judgment conditions by absorbance, in analysis of anhydrous ethanol, judgments are made by using [Point Pick – Single Point] and [Maximum Value – Single Point]. [Point Pick – Single Point] reads the absorbance of a fixed wavelength, and [Maximum Value – Single Point] can read the maximum value in a predetermined wavelength range.

First, absorbance of NMT 0.40 ("not more than 0.40") at 240 nm is set. Fig. 3 shows the Detailed Settings screen for evaluation of [Point pick – Single point]. The setting is made from this screen. The wavelength is set at 240 nm, and the pass/fail judgment criterion is set at NMT 0.40.

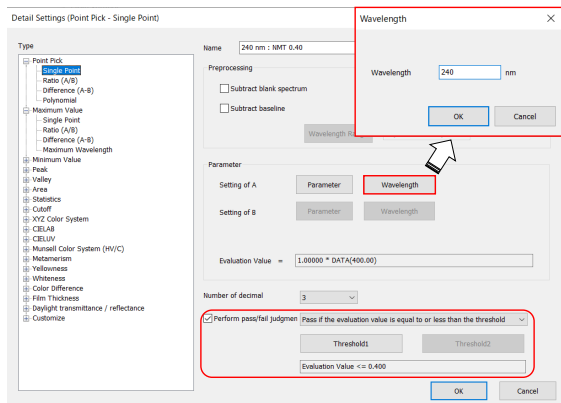


Fig. 3 Detailed Settings Screen for [Point Pick – Single Point] Evaluation

Next, the remaining conditions are set. Fig. 4 shows the Detailed Settings screen for evaluation of [Maximum Value – Single Point]. The wavelength range is designated, and the maximum value of absorbance in that range is read.

Here, two conditions are set. The judgment criteria of NMT 0.30 is set for 250-260 nm, and NMT 0.10 is set for 270-340 nm.

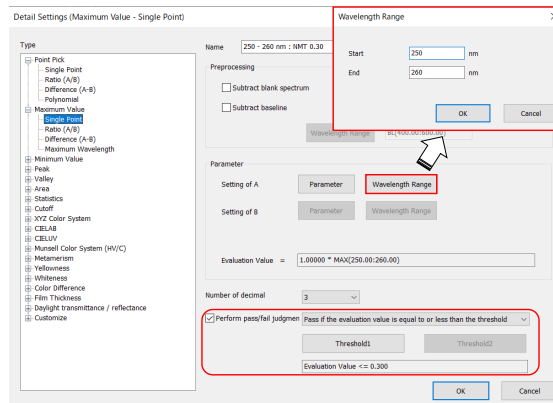


Fig. 4 Detailed Settings Screen for [Maximum Value – Single Point] Evaluation

### Results of Pass/Fail Judgment

Fig. 5 shows the results of the pass/fail judgments for the anhydrous ethanol shown in Fig. 2 and a simulated rejected sample. The absorbance values of the anhydrous ethanol are within the pass range for all three wavelength conditions. On the other hand, in case of failure, the result can be understood at a glance, as the evaluation line is colored red.

Fig. 6 shows an enlarged view of the evaluation table. In pass/fail judgments, the data are added to the evaluation table automatically after spectrum acquisition. Therefore, the judgment can be completed simply by measuring the sample.

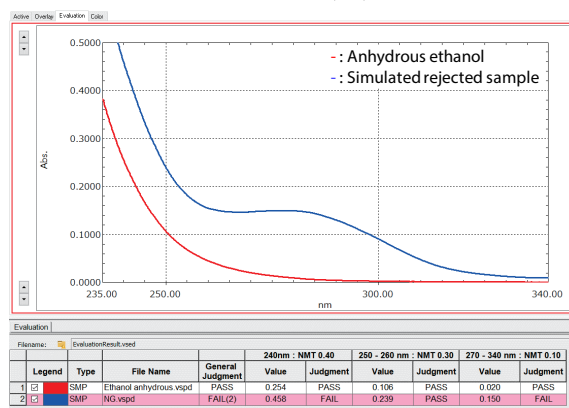


Fig. 5 Results of Pass/Fail Judgment

### Conclusion

In this experiment, measurements of anhydrous ethanol were conducted in accordance with the Japanese Pharmacopoeia, European Pharmacopoeia, and United States Pharmacopoeia using a UV-1900i, and a pass/fail judgment was made using the spectral evaluation function of the LabSolutions UV-Vis software. Analysis time, including judgment work, can be substantially reduced by using the spectral evaluation function.

				240nm : NMT 0.40		250 - 260 nm : NMT 0.30		270 - 340 nm : NMT 0.10	
Legend	Type	File Name	General Judgment	Value	Judgment	Value	Judgment	Value	Judgment
1	SMP	Ethanol anhydrous.vspd	PASS	0.254	PASS	0.106	PASS	0.020	PASS
2	SMP	NG.vspd	FAIL(2)	0.458	FAIL	0.239	PASS	0.150	FAIL

Fig. 6 Enlargement of Evaluation Table

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