CTech™ SoloVPE® PLUS System Comparability Study

Abstract

The CTech™ SoloVPE® PLUS System is a new instrument for at-line concentration measurement. The system utilizes variable pathlength technology and the Beer-Lambert law to enable the Slope Spectroscopy® method, a powerful tool for measuring concentrations of bioprocessing samples.

The SoloVPE PLUS System was designed based on the CTech™ SoloVPE® platform, with enhanced capabilities to increase the dynamic range and reduce measurement time, while maintaining excellent accuracy and precision.

This study discusses the enhanced capabilities of the SoloVPE PLUS System and demonstrates its comparability to established UV-Vis analytical instruments, including a fixed-pathlength spectrophotometer and the variable pathlength CTech SoloVPE System.

Introduction

The CTech SoloVPE System is an at-line analytical instrument for measuring biological product concentrations via UV-Vis absorbance spectroscopy. The operating principle is based on the Beer-Lambert law:

$$A = \varepsilon\, c\, l$$

Where A is the absorbance through the sample, ε is the extinction coefficient, c is the concentration, and l is the pathlength. Unlike traditional UV-Vis spectroscopy, which uses a fixed pathlength to measure absorbance, the SoloVPE System uses variable pathlength technology (VPT) and takes multiple absorbance measurements at several different pathlengths. Variable pathlength spectroscopy, or the Slope Spectroscopy method, uses a variation of the Beer-Lambert law:

$$m = \varepsilon\, c$$

Where m is the change in absorbance per unit pathlength, also called the slope. Slope-based measurements enable higher concentration readings without the need for dilution, as the SoloVPE instrument adjusts the pathlength to keep the absorbance within the detector's linear measurement range. In addition, because the slope is calculated from the change in absorbance and change in pathlength, rather than an absolute absorbance measurement, it eliminates the need for baseline correction.

The CTech SoloVPE PLUS System, built on the SoloVPE platform, features enhanced measurement capabilities for at-line UV-Vis analytics, including a finer pathlength resolution and a higher maximum concentration. The SoloVPE PLUS device also has a faster motor speed, further reducing the time to obtain measurements compared to the SoloVPE System.

Here we present two studies to demonstrate comparability between the new SoloVPE PLUS System and established analytical instruments: the SoloVPE System and a traditional, fixed-pathlength UV-Vis spectrophotometer.

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Materials and Methods

- CTech SoloVPE PLUS System (SYS-VPE-SOLO-P)

- CTech SoloVPE System (SYS-VPE-SOLO5)

- Fibrette Optical Components (OF0002-P50)

- SoloVPE vessels (OC0009-1-P50) and vessel holders (HM0178)

- Traditional (fixed-pathlength) UV Spectrophotometer

- Monoclonal antibody (mAb) samples

- CTech™ ConfiRM® Certified Slope Reference Materials (MRM-01-P10, MRM-05-P10, MRM-08-P10)

SoloVPE PLUS versus Traditional UV

The SoloVPE PLUS System and the fixed-pathlength spectrophotometer were used to measure four mAb samples at 280 nm with an extinction coefficient of 1.5 mL/(mg*cm) and concentrations ranging from 29 to 228 mg/mL.

Measurements were evaluated for each sample using Equation 1. Each concentration measurement on the SoloVPE PLUS instrument was determined by taking the average of three repeat readings. Relative standard deviation (%RSD) was calculated for the triplicate readings in order to assess the instrument's repeatability.

$$\text{Eq. 1} \quad \%Difference = \frac{ABS(PLUS - UV)}{UV} \times 100\%$$

PLUS: SoloVPE PLUS concentration

UV: Traditional spectrophotometer concentration

SoloVPE PLUS versus SoloVPE System

The SoloVPE and SoloVPE PLUS Systems were first assessed using ConfiRM certified slope reference standards. Three concentration (slope) levels were measured using one SoloVPE instrument and three separate SoloVPE PLUS instruments. Percent difference was calculated for each ConfiRM standard using Equation 2. Each concentration measurement on the SoloVPE PLUS was determined by taking the average of three repeat readings. Relative standard deviation (%RSD) was calculated for the triplicate readings in order to assess the instrument's repeatability. Intermediate precision was assessed by calculating %RSD using all nine readings taken by the three SoloVPE PLUS instruments at each slope value.

$$\text{Eq. 2} \quad \%Difference = \frac{ABS(VPE - CoA)}{CoA} \times 100\%$$

VPE: SoloVPE or SoloVPE PLUS slope reading

CoA: Certificate of Analysis slope value

The SoloVPE and SoloVPE PLUS Systems were then used to measure nine mAb samples at 280 nm. The samples had extinction coefficients ranging from 1.3 to 1.6 mL/(mg*cm) and concentrations from 10 to 320 mg/mL. Select samples were diluted with water or a 0.9% NaCl solution before measurement with the SoloVPE System, in accordance with the testing laboratory's standard operating procedure; the SoloVPE PLUS System measured the samples before dilution.

Percent difference was calculated for each sample using Equation 3. Each concentration measurement on the SoloVPE PLUS System was determined by taking the average of three repeat readings. Relative standard deviation (%RSD) was calculated for the triplicate readings in order to assess the instrument's repeatability.

$$\text{Eq. 3} \quad \%Difference = \frac{ABS(PLUS - SOLO)}{SOLO} \times 100\%$$

PLUS: SoloVPE PLUS concentration

Solo: SoloVPE concentration

The SoloVPE and SoloVPE PLUS Systems were also evaluated for speed. Each system was configured to adjust the pathlength through the following steps:

1. Home position
2. Zero position
3. Collect 1 slope reading using 10 datapoints
4. Home position

Results

Data are presented in Tables 1–5. In all tests, the SoloVPE PLUS System demonstrated excellent precision, achieving less than 2.0% RSD across all triplicate measurements.

When compared against the traditional, fixed-pathlength spectrophotometer, SoloVPE PLUS measurements differed by less than 2.0% for all samples tested. When compared against the SoloVPE System, SoloVPE PLUS measurements differed by less than 2.0% for the majority of the samples tested.

In the speed test, the SoloVPE instrument completed the cycle in 2 minutes and 7 seconds, while the SoloVPE PLUS instrument completed it in 59 seconds.

Table 1. SoloVPE PLUS versus Traditional UV Spectrophotometer: mAb concentration

Sample	Extinction Coefficient (mL/(mg*cm))	Concentration, Traditional UV (mg/mL)	Concentration, SoloVPE PLUS (mg/mL)	%Difference	%RSD, SoloVPE PLUS
mAb-1	1.5	29.41	29.78	1.3%	0.30%
mAb-2	1.5	104.8	104.1	0.7%	0.31%
mAb-3	1.5	185.3	187.4	1.1%	0.85%
mAb-4	1.5	228.4	228.1	0.1%	1.07%

Table 2. SoloVPE versus SoloVPE PLUS: ConfiRM Standard Accuracy

ConfiRM Standard	CoA Value		SoloVPE		SoloVPE PLUS #1		SoloVPE PLUS #2		SoloVPE PLUS #3	
	Slope*	Uncertainty	Slope*	%Diff.	Slope*	%Diff.	Slope*	%Diff.	Slope*	%Diff.
Low	0.107	±4.0%	0.106	0.9%	0.107	0.2%	0.106	0.6%	0.107	0.0%
High	22.868	±4.5%	22.681	0.8%	22.525	1.5%	22.495	1.6%	22.751	0.5%
Ultra High	45.633	±4.5%	45.117	1.1%	44.731	2.0%	44.612	2.2%	45.569	0.1%

Slope values are in units of Abs/mm.

Table 3. SoloVPE versus SoloVPE PLUS: ConfiRM Standard Precision

ConfiRM Standard	SoloVPE		SoloVPE PLUS #1		SoloVPE PLUS #2		SoloVPE PLUS #3		Overall SoloVPE PLUS
	Slope*	%RSD	Slope*	%RSD	Slope*	%RSD	Slope*	%RSD	%RSD (n = 9)
Low	0.106	0.24%	0.107	0.11%	0.106	0.10%	0.107	0.56%	0.41%
High	22.681	0.07%	22.525	0.61%	22.495	1.28%	22.751	0.96%	1.11%
Ultra High	45.117	0.08%	44.731	0.60%	44.612	0.83%	45.569	1.06%	1.28%

Slope values are in units of Abs/mm.

Table 4. SoloVPE versus SoloVPE PLUS: mAb Concentration

Sample	Extinction Coefficient (mL/(mg*cm))	Concentration, SoloVPE (mg/mL)	Concentration, SoloVPE PLUS (mg/mL)	%Difference	%RSD, SoloVPE PLUS
mAb-5	1.3	262*	265.1	1.2%	0.86%
mAb-6	1.3	222*	228.0	2.7%	0.60%
mAb-7	1.5	180*	178.8	0.7%	0.70%
mAb-8	1.5	10	10.13	1.3%	0.11%
mAb-9	1.5	180*	180.2	0.1%	0.33%
mAb-10	1.5	50	50.47	0.9%	0.43%
mAb-11	1.6	135*	138.6	2.6%	0.79%
mAb-12	1.5	107*	104.1	2.7%	0.31%
mAb-13	1.5	184*	187.4	1.8%	0.85%
mAb-14	1.5	320*	321.6	0.5%	0.61%

These samples were diluted for measurement using SoloVPE in accordance with the testing laboratory's standard operating procedure. Values reflect the concentration of the original sample based on dilution factor calculations. The SoloVPE PLUS instrument measured the original sample without dilution.

Table 5. SoloVPE versus SoloVPE PLUS: Speed

Procedure	SoloVPE (m:ss)	SoloVPE PLUS (m:ss)
3 readings, 10 datapoints	2:07	0:59

Conclusion

This study demonstrates the SoloVPE PLUS System is comparable in performance to existing UV-Vis spectrophotometers, including the CTech SoloVPE System. The tests provide evidence that the SoloVPE PLUS System's enhanced capabilities yield the same accuracy as the original SoloVPE System with excellent precision as well as improved functionality, such as a higher maximum concentration without dilution and a faster operation speed.

Appendix A provides a complete key feature comparison of the SoloVPE and SoloVPE PLUS Systems for interested parties looking to upgrade their existing at-line VPT system or purchase a new one.

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Appendix A: SoloVPE and SoloVPE PLUS System Comparison

Product Feature	SoloVPE System	SoloVPE PLUS System
Part Number	SYS-VPE-SOLO5	SYS-VPE-SOLO-P
Hardware		
Pathlength Range	0.005 – 15.000 mm	0.002 – 15.000 mm
Typical Measurement Speed (3 repeats)	<2 min	<1 min
Instrument Power Supply	Through Cary 60	Independent Power Supply
Back Panel Ports	Accessory port, Detector port	Detector port, USB, Power
Weight	9 kg (20 lb)	9 kg (20 lb)
Light Source	Cary 60	Cary 60
Software		
Compatible Software	SoloVPE Software (to be discontinued), CTech™ ViPER® ANLYTX Software	CTech™ ViPER® ANLYTX Software
Microsoft Windows Compatibility	SoloVPE Software: Windows 10 ViPER: Windows 10 or Windows 11	Windows 10 or Windows 11
Minimum Computer Requirements	Intel i5 Processor, 250 GB Hard Drive, 8 GB RAM	Intel i5 Processor, 250 GB Hard Drive, 8 GB RAM
Consumables		
Fibrette® Optical Component	●	●
SoloVPE Sample Vessels	●	●
CHEM013 Standard	●	●
ConfiRM® Slope Reference Materials	0.1, 0.14, and 23 Abs/mm Standards	0.1, 0.14, 23, and 46 Abs/mm Standards
Applications		• Protein Concentration • Nucleic Acid Concentration • Oligonucleotide Concentration • AAV Titer Determination • Plasmid (DNA/RNA) Purity Analysis • Polysorbate Solution Analysis • Hemoglobin Analysis • Gold Particle Testing • Colorimetric Assessment **SoloVPE PLUS has extended dynamic range for all applications**