Quality Control of Hand Sanitizers

Fast and reagent-free ethanol content determination

Summary

In 2020, the demand for hand sanitizer skyrocketed due to the COVID-19 pandemic. Many companies shifted gears, streamlining their operations to produce hand sanitizer in large volumes. As in any product manufacturing process, accurate formulation enables good quality and minimizes waste. The alcohol content in hand sanitizers must be greater than 60% (v/v) to be an effective antiseptic. Reagents commonly used in these solutions are water, alcohol (commonly ethanol or isopropanol), small amounts of emollient (skin softener, e.g. glycerol), and an oxidizing agent (e.g. hydrogen peroxide) to minimize microbial contamination.

A safe and fast way to monitor ethanol content in these sanitizing solutions is with **reagent-free** near-infrared spectroscopy, which provides reliable **results in a few seconds**, quickly indicating when adjustments in formulation are necessary.



Experimental Equipment



Figure 1. DS2500 Liquid Analyzer and a sample filled in a disposable vial.

Mixtures of ethanol/water standards with a range of ethanol content from 58% to 82% (v/v) were measured in transmission mode with a DS2500 Liquid Analyzer over the full wavelength range (400–2500 nm). Reproducible spectrum acquisition was achieved using the built-in temperature control at 40 °C. For convenience, disposable vials with a path length of 8 mm were used, which made cleaning of the sample vessels unnecessary. The Metrohm software package Vision Air Complete was used for all data acquisition and prediction model development.

Table 1. Hardware and software equipment overview

Equipment	Metrohm number
DS2500 Liquid Analyzer	2.929.0010
DS2500 Holder 8 mm vials	6.7492.020
Disposable vials, 8 mm	6.7402.000
Vision Air 2.0 Complete	6.6072.208



2.929.0010 - DS2500 Liquid Analyzer

Robust near-infrared spectroscopy for quality control, not only in laboratories but also in production environments. The DS2500 Liquid Analyzer is the tried and tested, flexible solution for routine analysis of liquids along the entire production chain. Its robust design makes the DS2500 Liquid Analyzer resistant to dust, moisture and vibrations, which means that it is eminently suited for use in harsh production environments. The DS2500 Liquid Analyzer covers the full spectral range from 400 to 2500 nm, heats samples up to 80°C and is compatible with various disposable vials and quartz cuvettes. The DS2500 Liquid Analyzer is thus adaptable to your individual sample requirements and helps you obtain accurate and reproducible results in less than one minute. The integrated sample holder detection and the self-explanatory Vision Air Software also ensure simple and safe operation by the user. In the case of larger-sized sample quantities, productivity can be considerably increased by using a flow-through cell in combination with a Metrohm sample robot.





6.6072.208 - Vision Air 2.0 Complete

Vision Air - Universal spectroscopy software. Vision Air Complete is a modern and simple-to-operate software solution for use in a regulated environment. Overview of the advantages of Vision Air: Individual software applications with adapted user interfaces ensure intuitive and simple operation; Simple creation and maintenance of operating procedures; SQL database for secure and simple data management; The Vision Air Complete version (66072208) includes all applications for quality assurance using Vis-NIR spectroscopy: Application for instrument and data management; Application for method development; Application for routine analysis; Additional Vision Air Complete solutions: 66072207 (Vision Air Network Complete); 66072209 (Vision Air Pharma Complete); 66072210 (Vision Air Pharma Network Complete);



6.7402.000 - Disposable vials, 8 mm diameter, transmission

250 lockable disposable glass vials (borosilicate) with a diameter of 8 mm for analyses of liquid samples in transmission mode. Suitable for the following Analyzers:NIRS XDS RapidLiquid Analyzer NIRS XDS VialHeater + NIRS XDS Transmission OptiProbe Analyzer



6.7492.020 - DS2500 Holder 8 mm vials

Intelligent holder for disposable glass vials with 8 mm diameter

Results

All 13 measured Vis-NIR spectra (**Figure 2**) were used to create a prediction model for quantification of the ethanol content. The quality of the prediction models was evaluated using correlation diagrams, which display a very high correlation between VisNIR prediction and primary method values. The respective figures of merit (FOM) display the expected precision of a prediction during routine analysis.



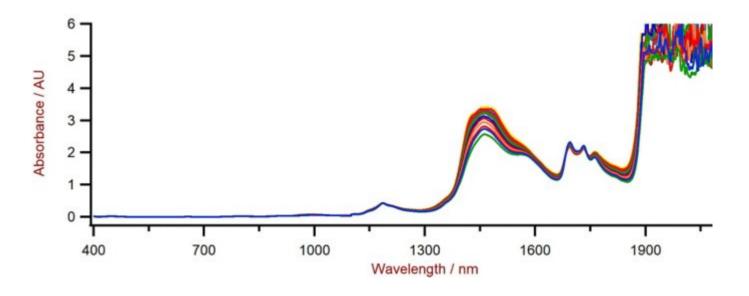


Figure 2. Vis-NIR spectra of hand sanitizers with varying ethanol content measured on a DS2500 Liquid Analyzer.

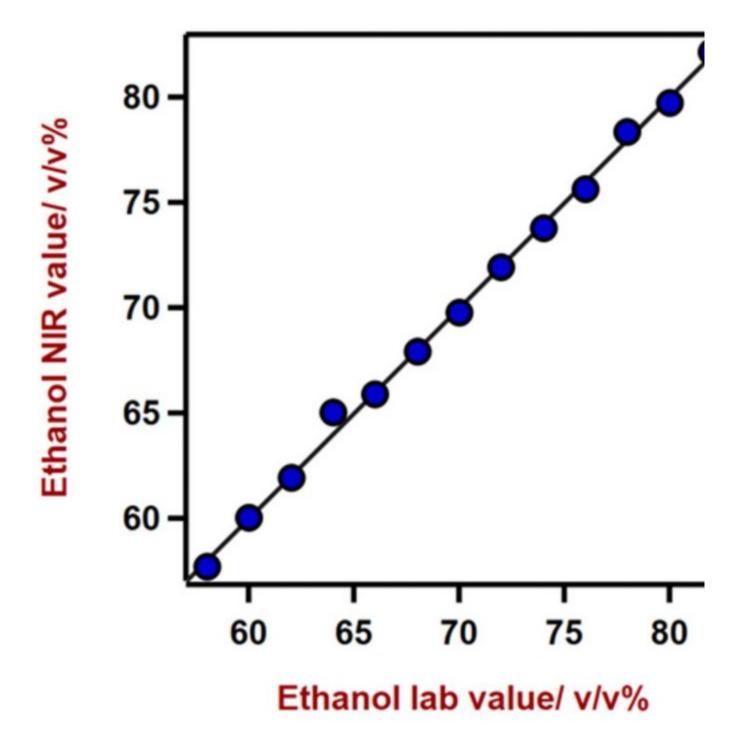


Figure 3. Correlation diagram and the respective figures of merit for the prediction of ethanol content in hand sanitizers using a DS2500 Liquid Analyzer.

Table 2. Figures of merit for the prediction of ethanol content in hand sanitizers using a DS2500 Liquid Analyzer.

Figures of merit	Value
R^2	0.9977
Standard error of calibration	0.41 v/v%
Standard error of cross-validation	0.56 v/v%

Conclusion

This application note demonstrates the feasibility of the DS2500 Liquid Analyzer for the determination of ethanol in hand sanitizer products. Vis-NIR spectroscopy enables a fast determination with high accuracy, and therefore represents a suitable alternative to the standard method.

Table 3. Time to result for the ethanol content determination in hand sanitizers using gas chromatography

Parameter	Method	Time to result and workflow
Ethanol content	GC	5 min (preparation) + 5 min (GC)
Metrohm AG Ionenstrasse 9100 Herisau	mailto:info@metrohm.com	