

MicroNIR[®] OnSite-W for rapid quantification of ethanol in hand sanitizers

Near Infrared Spectroscopy (NIRS) is a powerful tool to quantify ethanol or isopropanol concentration

Hand sanitizers are a crucial element in the fight against disease. The active ingredient in hand sanitizer is alcohol, either ethyl or isopropyl alcohol. It has been shown that alcohol concentrations must be above 60% v/v to be effective. The ideal concentration is approximately 80% for ethyl alcohol (ethanol) and approximately 75% for isopropyl alcohol (isopropanol; see end note). A simple, rapid, and non-destructive test of concentration can help avoid producing or using ineffective hand sanitizer that may increase the risk of disease transmission.



Figure 1 - MicroNIR OnSite-W

Benefits

- Rapid, real-time, non-destructive near-infrared material analysis
- Wireless, compact, rugged, and ergonomic design for one-hand operation
- Multifunction button for one-click data acquisition
- Internal, rechargeable battery with continuous run time greater than 10 hours
- IP65 and IP67 rated for use in wet and dusty environments
- Bluetooth or USB connectivity to tablet or PC
- Compatible with original MicroNIR OnSite accessories
- Powerful MicroNIR Pro model-building and prediction software

NIR Setup and Calibration

The following study demonstrates the feasibility of determining the concentration of ethanol in hand-sanitizer formulations. A stock solution of ethanol (95% v/v) was used to prepare standards at different concentrations, aimed at building a predictive model based on regression analysis. Calibration standards from 15 to 100% (by volume) of ethanol were prepared, and added to a basic hand-sanitizer formulation of glycerol and hydrogen peroxide, present at 1.45% and 0.125 % v/v respectively.

The NIR spectra of the calibration standard were acquired using the MicroNIR OnSite-W in the spectral range from 950 to 1650 nm. The device was equipped with the side view vial holder accessory that works in transmittance with a pathlength of 2 mm. Every spectrum was acquired 3 times to reduce the effect of any inhomogeneity in the mixture. The original MicroNIR absorbance spectra are shown in figure 2a with the corresponding 1st derivative spectra in Figure 2b.

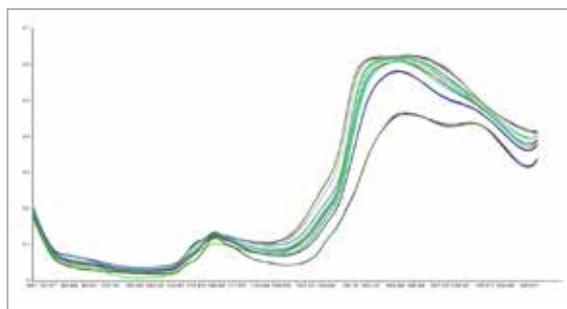


Figure 2a – Original spectra

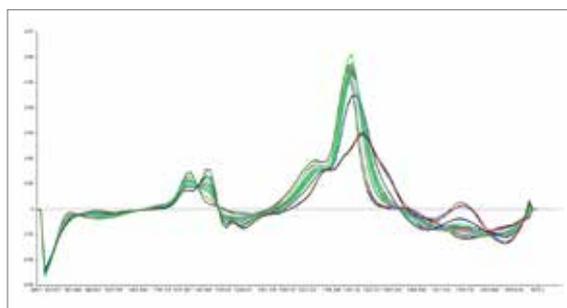


Figure 2b – Transformed spectra

A PLS (Partial Least Squares) regression model was constructed from the NIR spectral features related to the alcohol content variation. The model provided the following results:

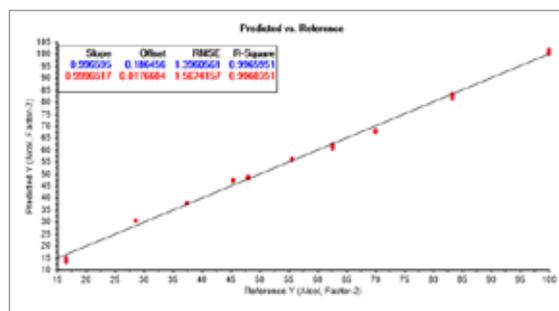


Figure 3 – PLS Prediction vs Reference

From the measured vs predicted line it is possible to estimate the error associated to the model prediction of the alcohol content in hand sanitizers. The calibration error RMSECV is equal to 1.57% with a coefficient of determination R2 close to 100%. To test the model robustness, an external validation was performed:

Expected	NIR	Difference
52.00	52.61	0.61
58.00	58.90	0.90
64.00	64.29	-0.29
70.00	70.50	-0.50
76.00	76.13	-0.13
82.00	81.53	0.47
88.00	88.06	-0.06

Table 1 – New sample predictions

The results in the table are averages over 3 replicates with an RSD of 0.38%.

Conclusion

This feasibility study demonstrates that the MicroNIR OnSite-W is a fast and reliable tool for determining the ethanol concentration in hand sanitizers compounded according to WHO- and FDA-approved formulations. Since ethanol and isopropanol have similar NIR spectral

signatures, we would expect similarly robust results with isopropyl alcohol. This method is readily applicable in the field using the powerful MicroNIR Pro software suite included with the instrument, which provides an intuitive user interface that requires minimum training to operate from a Windows™ tablet or PC.

¹The production of hand sanitizer is regulated by FDA and WHO:

- FDA Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (Accessed 19/03/2020)
- WHO Guidelines on Hand Hygiene in Health Care, Part I, Chapter 12, Page 49
- WHO Guidelines on Hand Hygiene in Health Care, Part I, Chapter 10, Page 28

Based on above guidelines the suggested formulation recommended by the World Health Organization (WHO) is:

- Ethyl alcohol (80 % v/v) or Isopropyl alcohol (75 % v/v)



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