Since July of 2020, the FDA has issued more than 100 voluntary recalls for hand sanitizers due to the presence of toxic components or deficient alcohol levels to be effective.

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In March of 2020, the coronavirus outbreak forced the World Health Organization to declare it a pandemic. Safety measures to prevent the spread started by limiting gatherings, closing schools, canceling sports events, etc. The rapid spread and subsequent lockdowns generated panic among the population causing essential household items to be purchased at levels never seen before and creating a shortage that lasted for several weeks or even months. The deficit affected essential cleaning supplies, including chlorine-based products, disinfectants, and alcohol-based hand sanitizer.

According to the WSJ, hand sanitizers sales jumped 600% in 2021. The explosive demand sparked a potential for business opportunity among new manufacturers who decided to produce this new hot commodity. Unfortunately, in many cases, the process lacked quality control and adherence to regulations, forcing the FDA to issue voluntary recalls of hand sanitizers – as early as July of 2020 – due to the presence of toxic chemicals such as methanol/1-propanol or because the alcohol levels were too low to be effective.

As of January of 2021, the FDA established a new policy for testing Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, including during the COVID-19 public health emergency.

The guidance requires for drug manufacturers and compounders to test alcohol and isopropyl alcohol for methanol contamination before end-use production, including medicinal and hand sanitizer products. According to the policy, methanol is not an acceptable ingredient or substitute due to its toxic effects. The guidance applies to all pharmaceutical alcohol used as an active or inactive ingredient in a drug, including hand sanitizer under the FDA's temporary policies for preparing alcohol-based hand sanitizer during the COVID-19 pandemic.

Due to increased demand for alcohol-based hand sanitizers and quality issues detected in productions as of July of 2020, there is a need for a fast and efficient method to quantify the percentage of alcohol in hand sanitizer, accurately. In addition, it is crucial to make sure that the raw material alcohol used in sanitizer manufacturing meets safety requirements for impurities.

Detecting and Analyzing Alcohols in Hand Sanitizer and Impurities in Alcohol

Alcohol-based hand sanitizers are used daily to kill microorganisms, including bacteria. Alcohol-based sanitizers generally contain over 60% of alcohol because if the alcohols are not at the right concentrations, it becomes ineffective at disinfecting. It is essential to ensure that the raw material alcohol used in sanitizer manufacturing meets the safety requirement for impurities. Thus, quantitative estimation of alcohol % in hand sanitizer via GC-FID is an important analysis for identifying and quantifying the alcohols and content in hand sanitizer for quality and branding purposes. In addition, the quality of alcohol used as

raw material is equally important to avoid adverse effects. In this application note, we have developed a GC-FID method for ascertaining the purity of raw material alcohol for impurity levels and a quantitative method for % alcohol in hand sanitizer using a single method on a Zebron™ ZB-624*PLUS* GC column.

Figures 1 to 4 show the various impurities that are possible in alcohol raw material. The method for analysis utilizes a modified USP method that is still within allowable adjustments. The method provides identification and quantification of impurities that can be present in alcohol. The same method parameters were extended to the analysis of alcohol-based sanitizer.

GC-FID Conditions

GC Column: Zebron ZB-624*PLUS*

Dimension: 30-meter x 0.32 mm x 1.80 µm

Part No.: 7HM-G040-31

Injection: Split 20:1 @ 200 °C, 1 µL

Recommended Liner: Zebron PLUS Z-Liner™ (Compatible with Agilent® & Thermo® GC instrument)

Liner Part No.: AG2-0A03-05

Carrier Gas: Helium @ 25 cm/sec (Constant Flow)

Oven Program: 36 °C for 12 min, 260 °C @ 10 °C/min for 15 min

Detector: FID

Detector Temperature: 280 °C

Figure 1. 50 ppm Acetaldehyde and 50 ppm Methanol in 99.5% ethanol

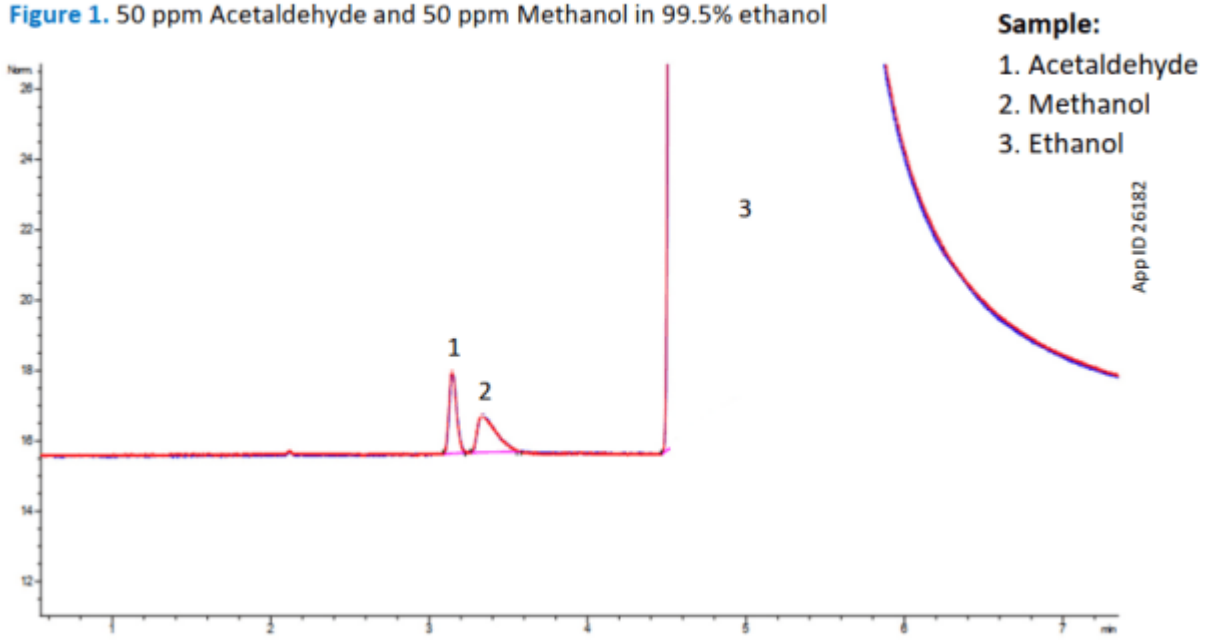


Figure 2. 100 ppm Acetaldehyde and 100 ppm Methanol in 99.5% ethanol

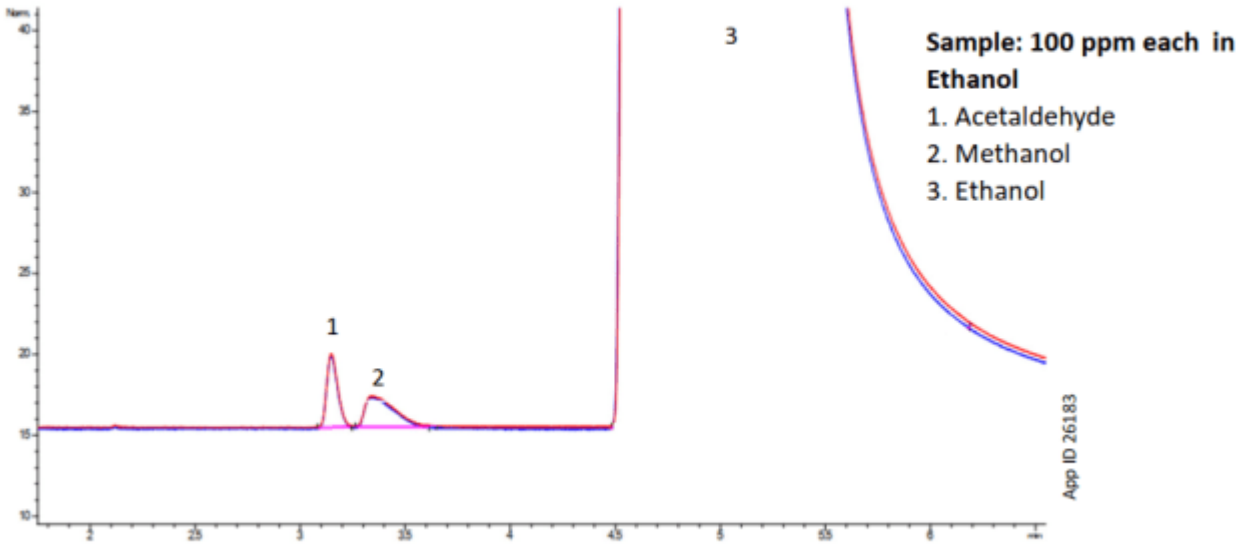


Figure 3. 200 ppm Methanol in 99.5% ethanol

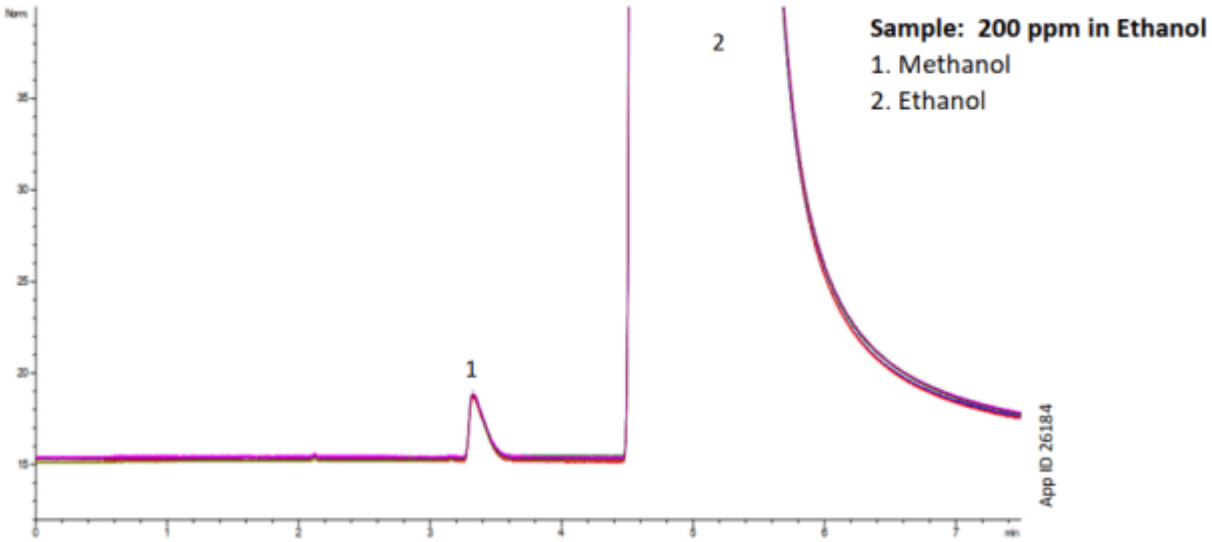
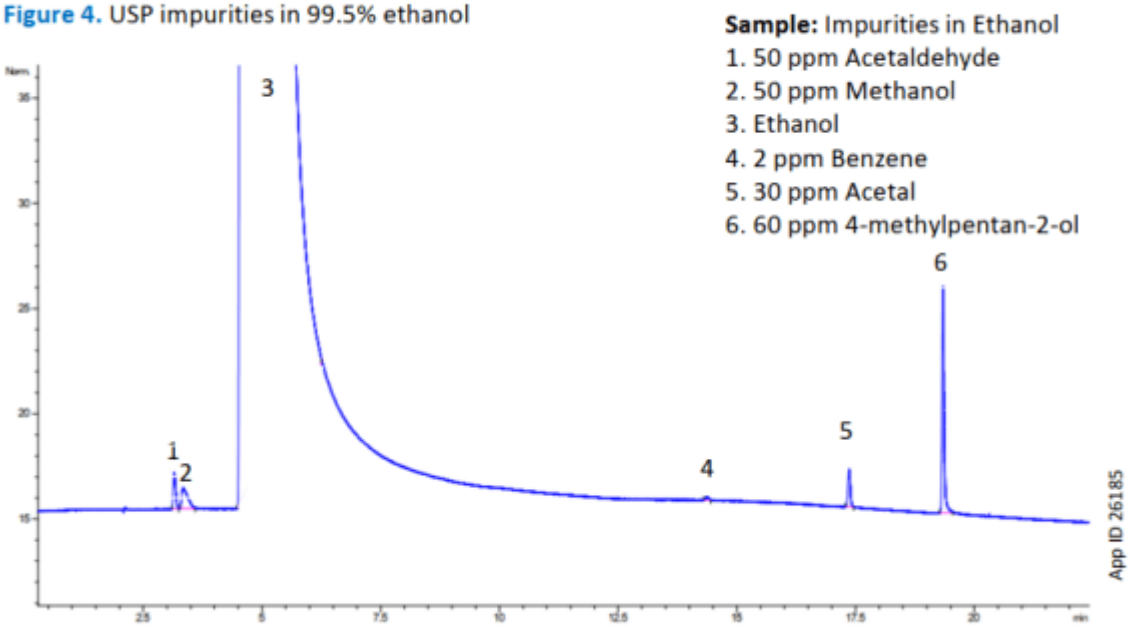
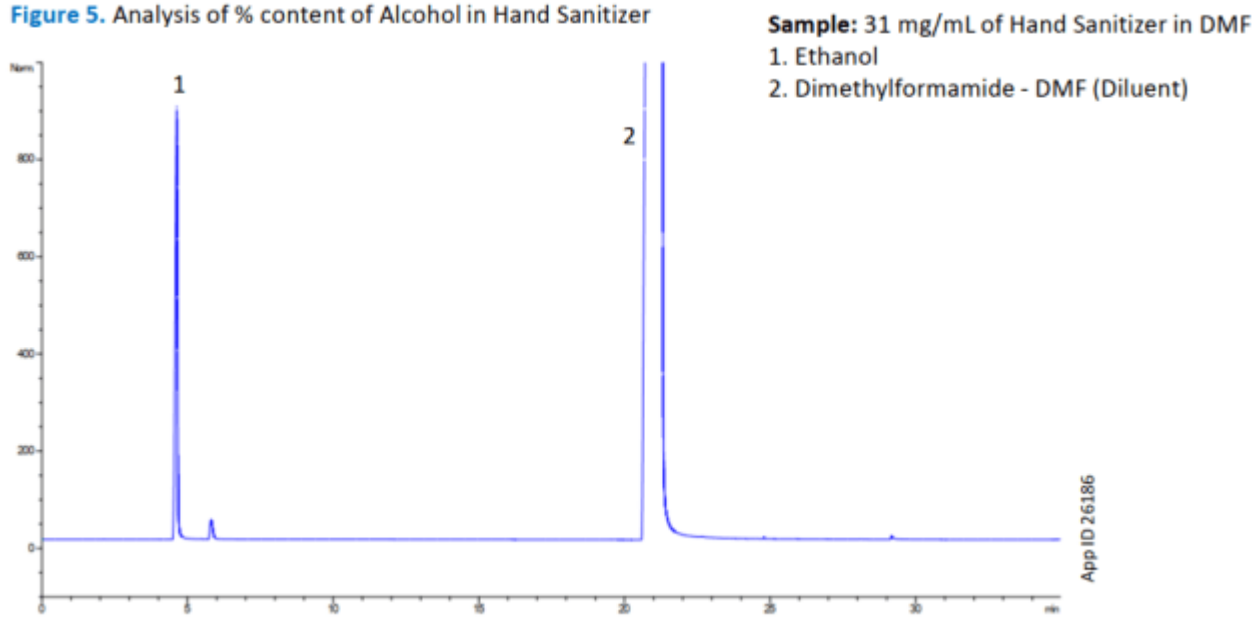


Figure 4. USP impurities in 99.5% ethanol



In this method, the sample alcohol sanitizer was dissolved in Dimethylformamide to quantify % alcohol content, as shown in **Figure 5**. The precision of the method concerning peak retention and peak area are presented in **Table 1**.

Figure 5. Analysis of % content of Alcohol in Hand Sanitizer



In addition to analysis of alcohols, this method provides a way to analyze % alcohol content in hand sanitizer and to quantify impurities on a single method without the necessity to change method parameters and GC column. This is possible due to the optimal selectivity of Zebron ZB-624*PLUS* for volatile compounds like alcohols. In addition, the column has extensive cross-linkage through Engineered Self-Cross Linking™ (ESC™) and thermal stability of 300/320 °C max temperature to bake out contaminants.

Based on the results obtained in this method analysis, we can conclude that the Zebron ZB-624*PLUS* column provides optimal selectivity and reproducibility for analyzing alcohol and alcohol-based sanitizers in a single method.

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Sources

Analysis of Alcohols in Hand Sanitizer and Impurities in Alcohol by GC-FID using Zebron™ ZB-624*PLUS*™ GC Columns Dr. Ramkumar Dhandapani, Zandra Baja, Zara Jalai, and Dr. Bryan Tackett Phenomenex, Inc.

FDA complete hand sanitizer recall list

Grand View Research

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