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Summary

This application note describes the analysis an anesthetic agent by gas chromatography-mass spectroscopy (GC-MS) to quantitatively determine the concentration of a suspected contaminant or impurity.

Background

Many drugs used for the induction and maintenance of general anesthesia are volatile organic compounds that are delivered to the patient via inhalation. The low boiling point and high volatility of these compounds make them ideally suited for analysis by GC-MS (for example, as part of an in-process or QC check for material purity). Unfortunately, most commonly employed chromatographic methods are often unable to detect the presence of trace impurities due to limited instrument sensitivity. However, often the manufacturer is aware of the potential impurities or contaminants that may be present in a given anesthetic agent, and in such cases a targeted GC-MS method may be developed which maximizes sensitivity to these compounds. Cambridge Polymer Group has developed such chromatographic methods that can detect and quantify suspected contaminants at levels in the parts per billion range.

Procedure and Results

The anesthetic agent is analyzed by GC-MS—the gas chromatography column serves to separate the compounds in injected material, which are subsequently ionized and analyzed by mass spectroscopy. Most compounds have a characteristic fragmentation pattern and the resulting mass spectrum may be compared against a spectral library for unknown compound identification (see Figure 1). A calibration curve (see Figure 2) is prepared of the suspected contaminant or impurity and is used to determine the limit of detection, limit of quantitation, and uncertainty of the analytical method. A spiked sample (*i.e.* anesthetic agent with a known amount of contaminant deliberately added) is prepared to determine the percent recovery from the sample matrix and correct for any matrix interference effects (see Figure 3).

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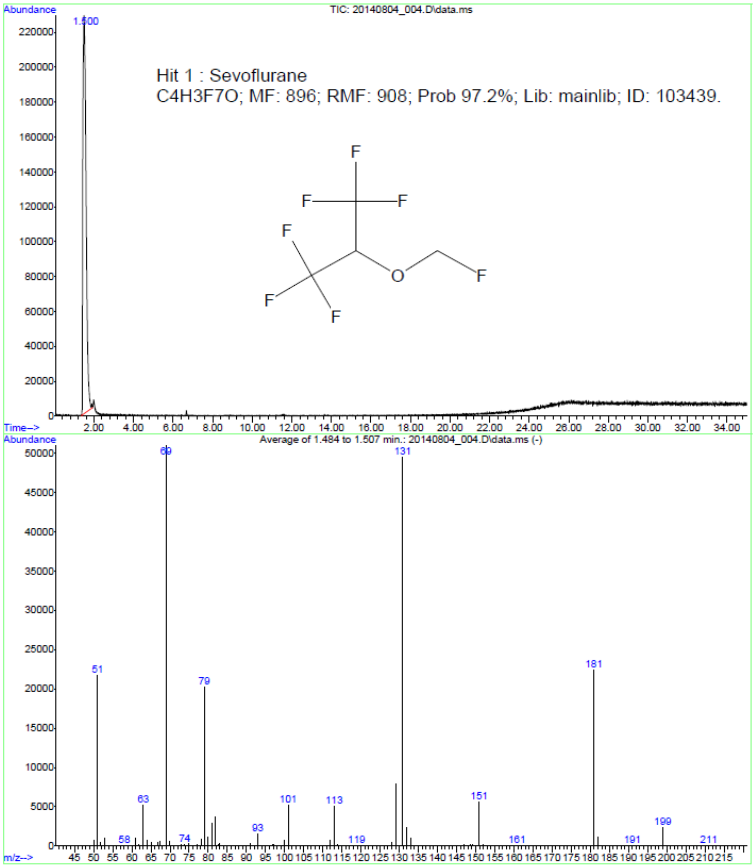

Figure 1: Typical total ion chromatogram for an anesthetic agent (top chart) and measured mass spectrum of the peak centered at 1.90 min (bottom chart) The peak was identified as sevoflurane, a commonly used general anesthetic agent.

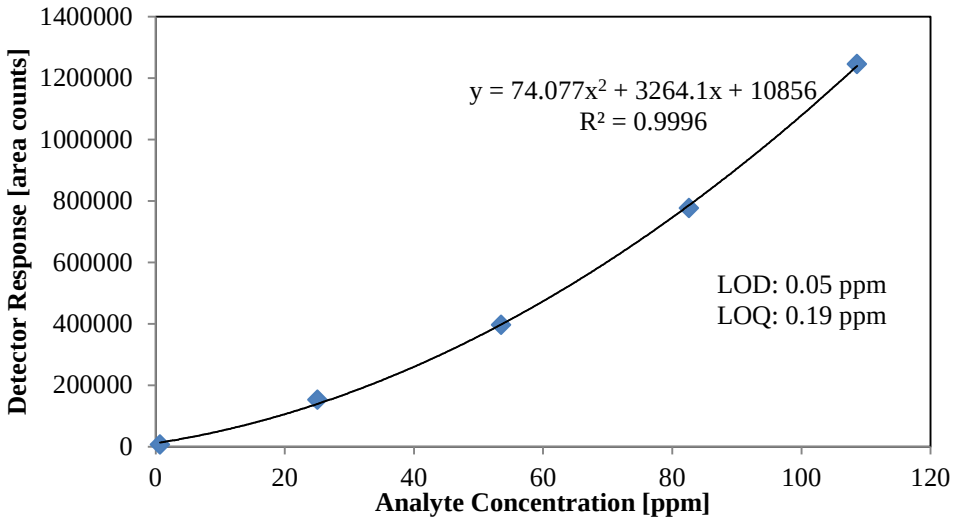

Figure 2: Exemplary calibration curve for a suspected oil contaminant in a general anesthetic agent.

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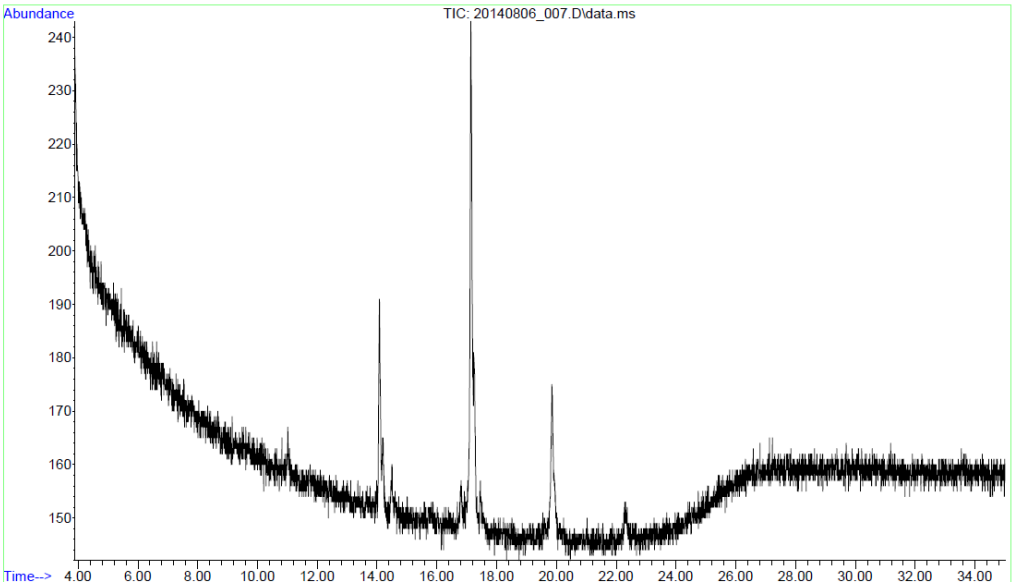

Figure 3: Total ion chromatogram of a 500 ppb spike of a suspected oil contaminant in a general anesthetic agent, analyzed under a targeted GC-MS method.