

## PHARMACEUTICAL AREAS OF EXPERTISE

We can develop and validate methods using headspace, Gas MS, GC, GC-MS, and GC-MS-MS on product containers, internal gas components, the API and the actual Drug Substance.

### Multi-Compendial Gas Testing

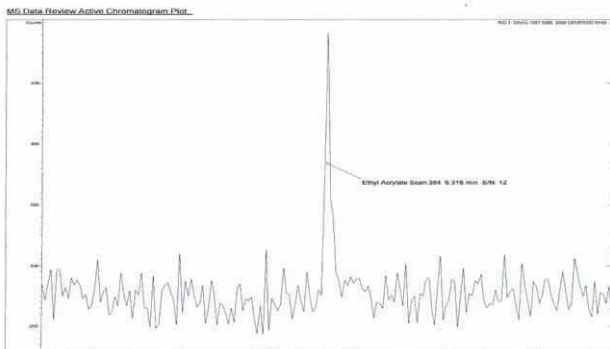
We routinely test gases by USP/NF, EP and even JP criteria. We have demonstrated the analytical validity for a 20ppm limit of Oxygen in NF Nitrogen by MS as an improvement to USP/NF's GC-TCD methodology while establishing a method quantitation limit of 10ppm Oxygen in Nitrogen. This provides a choice to assay USP/NF Nitrogen using either GC-TCD or Gas MS.

### Headspace GC Analysis

With the amount of testing required by the FDA on the API, Drug Substance, and the packaging it is contained in little testing, if any, is being performed on the volume of gas between the product and the container. This is where our expertise in headspace assays is outstanding, and can be used to understand side reactions in short and long-term stability studies.

### Residual Solvent and Genotoxin Quantitation

These reagents are currently attracting the interest of regulatory authorities in Europe and the United States. Although guidelines have not yet been established for all solvents and toxins, contaminant concentrations are generally limited to values in the low ppm ( $\mu\text{g/g}$ ) range, but information in the low ppb ( $\text{ng/g}$ ) is highly desirable. We are capable of developing and validating methods to cGMP standards for these low ppb LOQ's of unwanted residual compounds.



## Pharmaceutical Gas Mass Spectrometry

Our Pharmaceutical Gas Mass Spectrometry Analysis extends the scope and capabilities of traditional Military Standards methodology to achieve the best testing conditions for specific client applications. Headspace testing can be used with pharmaceutical products, devices, packaging and delivery systems to verify that the interior atmosphere is properly blanketing the drug substance. We can identify standard air components and all non-condensable gases that may be present in the headspace of sealed product containers, biopharma lyophilized vials, delivery devices, syringes, blister packs, etc.

### Audits & Approvals

- *US Food and Drug Administration (US-FDA)*
- *Defense Supply Center Columbus (DSCC)*
  - *Coca-Cola™*
  - *Pepsi™*

### Contact Information

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## Atlantic Analytical Laboratory



### The Gas and Volatile Testing Experts

Outsourced science has become indispensable for companies of every size. However, for outsourcing to be effective the expertise, commitment, efficiency and service must be impeccable, which is why the major gas and pharmaceutical companies work with **Atlantic Analytical Laboratory**.

Our knowledge and experience in gas and volatile testing is extensive with expertise in Gas Mass Spectrometry (Gas-MS), Gas Chromatography (GC) and Fourier Transform Infra Red (FTIR) methodology for high purity gas analysis; cryogenic impurity determination for Liquid Nitrogen (LiN), Liquid Oxygen (LOx), Liquid Argon (LAr); Residual Gas Analysis (RGA) for semiconductors and integrated circuits by Mil-Std-883 Test Method 1018; Gas-MS for headspace pharma and biopharma container and leak testing; pharmaceutical applications such as USP/NF, EP and JP grade gases; GC/MS for headspace analysis; full BTU workup for natural and synthetic fuel gases; high-purity analysis for Helium, Hydrogen and HyCO gases; full ISBT testing for beverage grade Carbon Dioxide; and full CGA testing for Compressed Air samples.

We also offer both on-site sampling and testing programs. We are rated as a "Suitable" laboratory for the Defense Supply Center Columbus (DSCC), an "Approved" laboratory for Coca-Cola and Pepsi-Cola, and have recently undergone a FDA inspection without a 483 being issued.

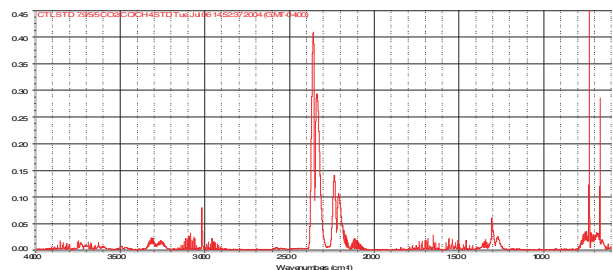
## INDUSTRIAL AREAS OF EXPERTISE

### High Purity Gases

Commodity and Specialty gases such as Nitrogen, Oxygen, Argon, Hydrogen, Helium, Carbon Dioxide, Nitrous Oxide, and specialty gas mixtures are commercially available in a range of purity grades. The proper grade for a given application depends on regulatory agencies such as USP/NF, EP, JP, NFPA, or OEM specifications. The analytical programs that Atlantic Analytical recommends to each client are designed to detect and quantify the critical contaminants associated with the selected grade of gas. A well-designed analysis strategy ensures that all undesirable contaminants have been identified, and that key gas components in specialty gas mixtures are present at their required concentrations.

### Air Separation Products: LiN, LOx, LAR

We maintain a fully validated set of analytical equipment for low-level impurity analysis of cryogenic gases. A typical FTIR gas spectrum is illustrated below showing spectral characteristics for a Certified gas standard, with quantitation limits extending into the low ppb range.



### Semiconductors/Integrated Circuits

One area that Atlantic Analytical specializes in is Residual Gas Analysis (RGA), for both leak testing applications and outgassing studies for a wide range of industries, including our military. All analyses are performed using our custom mass spectrometer sample inlet systems, which were designed and developed by Atlantic Analytical.

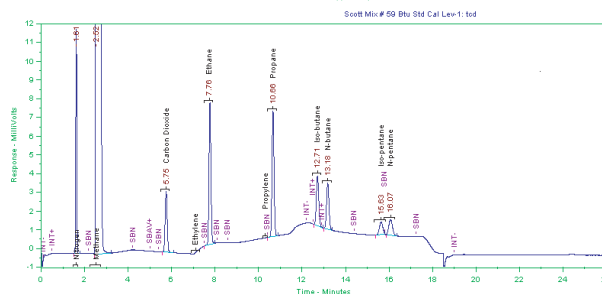
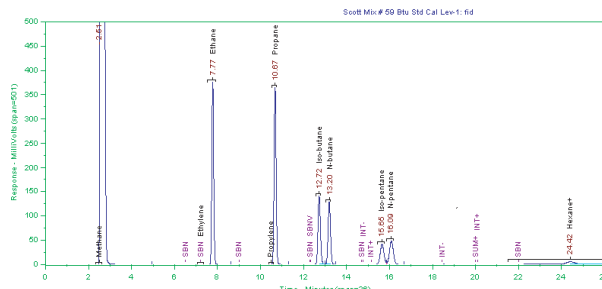
We are currently the only commercial RGA lab that can claim uninterrupted "Suitability" for the Defense Supply Center Columbus (DSCC) for over 18 years.

## Natural and Fuel Gases

The chemical composition and heating value (BTU content) of natural gases varies with the reservoir source, processing / conditioning steps, and delivery method.

Fuel gas analysis is used to determine turbine efficiency, evaluate commercial suppliers, ensure fuel quality, satisfy emissions requirements, and establish fuel pricing.

Below is a typical GC-FID (top)/TCD (bottom) analysis for a natural fuel gas.



## Manufactured Fuel Gases

Several classes of gaseous fuels are commercially produced from solid or liquid precursors. Common examples include: Reformed (Catalytic) Gas, Refinery Gas, Coke Oven (Coal) Gas, Producer Gas, Water (Blue) Gas, Oil Gas, Blast Furnace Gas, Liquefied Gas (LG), Ethylene, Propylene, Butylene, Butadiene, Propane-Propylene grades, Butane-Propane (B-P) mixtures and Butane-Butylene grades.

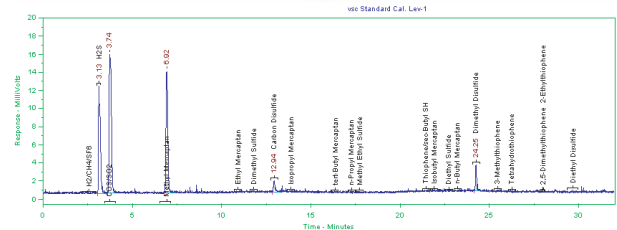
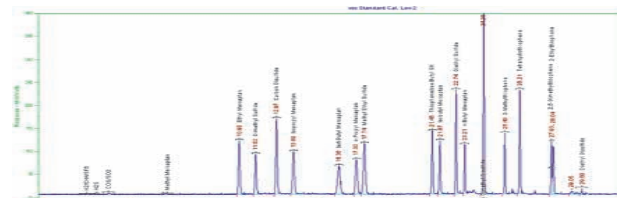
## Hydrogen & HyCO Gases

Hydrogen is one of the materials now being considered as an alternative fuel because it is abundant, efficient, renewable and unlike other alternatives, produces zero emissions. Many believe that this versatile element will

become a primary fuel and energy carrier of the future, used in both Internal Combustion Engines and Fuel Cells. To ensure the purity of hydrogen fuel gases, we can perform sample analysis with up to five 9's purity if necessary (99.999%).

## Beverage Grade Carbon Dioxide

Carbon Dioxide (CO2) is commercially produced from a wide range of feed gas sources. Each CO2 feed gas source and industrial purification process involves a unique set of analytical challenges that must be met in order to ensure CO2 product quality. Pictured below are two levels of standards that have been analyzed on a GC dedicated for Sulfur Speciation using a Sulfur Chemiluminescence Detector (SCD). Not only can we determine total sulfur, but we go one step further, and determine which sulfurs are present and at what concentration down to very low ppb Minimum Quantitation Limits.



## Compressed Air

Compressed air has many applications including Self-Contained Breathing Apparatus (SCBA), Self-Contained Underwater Breathing Apparatus (SCUBA) and pharmaceutical processing applications. We routinely perform complete CGA grade analyses to identify possible air contamination from compressor equipment malfunctions, poor maintenance or operational practices and environmental sources.