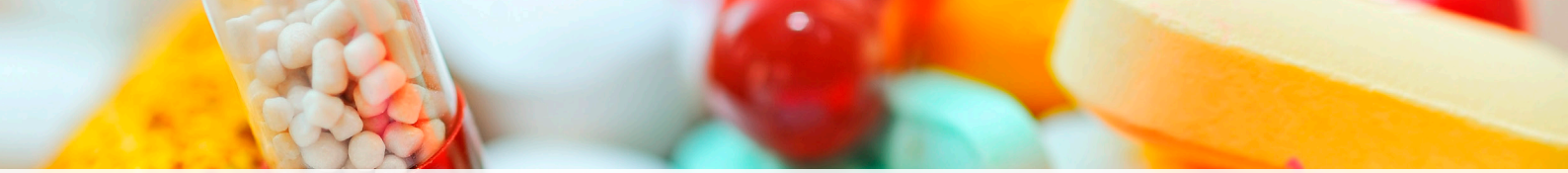
PHARMACEUTICAL APPLICATIONS

SYFT TECHNOLOGIES

syft™ Technologies



PHARMACEUTICAL INDUSTRY APPLICATIONS OF SIFT-MS

Volatile organic compounds (VOCs) are widely utilized in various pharmaceutical manufacturing processes and in other parts of the supply chain (e.g. polymer manufacture and packaging). Many VOCs have adverse health effects and unfortunately find their way into the pharmaceuticals themselves. At unsafe levels, they can result in product recalls, brand damage, and lawsuits.

Selected ion flow tube mass spectrometry (SIFT-MS) is a robust analytical technique that both simplifies testing of challenging compounds (e.g., formaldehyde) and facilitates more frequent component and product testing through greatly enhanced sample throughput. SIFT-MS quantifies VOCs directly in real time to sub-part-per-billion (ppb) concentrations, so that product issues are detected earlier and resolved immediately, delivering economic benefits to all stakeholders.

SIFT-MS represents a major breakthrough for the pharmaceutical industry. This brochure outlines several SIFT-MS-based pharmaceutical applications.

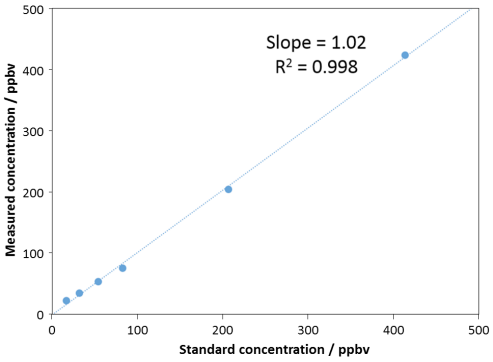
SIMPLE ANALYSIS OF SMALL POLAR COMPOUNDS

Analysis of polar and reactive species – such as formaldehyde, acetaldehyde, and formic acid – is slow and complicated when using conventional chromatographic methods.

SIFT-MS simplifies detection of small polar species by analyzing them directly from gas or headspace to sub-ppbv concentrations without requiring derivatization or preconcentration.

Applications of SIFT-MS for analysis of challenging compounds include:

- Residual monomers and byproducts
- Residual solvents in pharmaceuticals
- Packaging impurities.



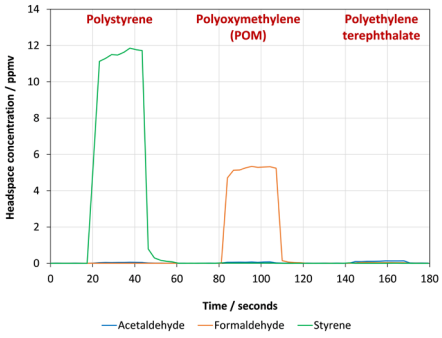
Linear detection of formaldehyde in the ppbv range.

RESIDUAL MONOMER ANALYSIS IN DRUG DELIVERY DEVICES

SIFT-MS provides a very rapid and highly sensitive solution for the detection of residual monomers and other impurities in diverse drug delivery devices, including orally inhaled and nasal drug products (OINDPs) and parenteral and ophthalmic drug products (PODPs).

Benefits of SIFT-MS:

- Very high throughput screening through elimination of chromatographic separation, delivering greatly reduced cost of analysis.
- High selectivity and comprehensive analysis provided by eight rapidly switchable reagent ions.
- High sensitivity, providing rapid warning of quality issues.
- Wide linear and dynamic ranges enable one instrument to be applied readily to multiple analytical tasks.



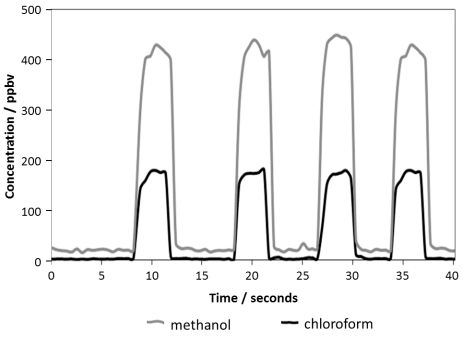
Simple residual monomer analysis of different ground polymers, including formaldehyde from POM polymer.

RAPID RESIDUAL SOLVENT ANALYSIS

A wide variety of solvents are used during manufacture of pharmaceuticals, but regulations strictly control permissible concentrations in the finished product. SIFT-MS provides a very rapid and highly sensitive solution to the detection of VOC residues in pharmaceuticals that are not easily monitored by other technologies.

Benefits of SIFT-MS:

- Direct analysis through elimination of chromatographic separation, which is ideal for detection of volatile solvents.
- High selectivity via multiple rapidly switchable reagent ions.
- Very high throughput VOC screening coupled with high sensitivity provides rapid warning of quality issues and greatly reduces the test cost per analysis.
- Wide linear and dynamic ranges allows one instrument to be applied to multiple analytical tasks.



Rapid analysis for residual solvents using SIFT-MS.

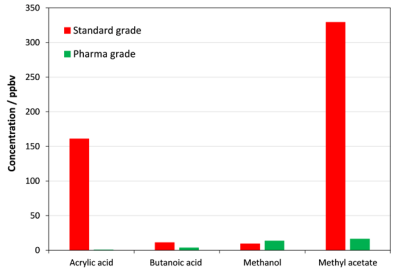
ENHANCED PACKAGING TESTING

With its ability to analyze a very wide range of compounds rapidly, SIFT-MS revolutionizes packaging testing across diverse materials including:

- Polymers
- Adhesives
- Print products
- Laminates.

Benefits of SIFT-MS:

- Increased product testing through faster analysis, provides early warning of quality issues in packaging materials.
- Multiple packaging applications are conveniently and simply tackled by one instrument.
- High selectivity from eight rapidly switchable reagent ions.
- High robustness to humidity, greatly simplifying testing procedures for high moisture systems.



Simple quality assurance testing of polypropylene feedstock for packaging production.

SUMMARY

SIFT-MS represents a major breakthrough for the pharmaceutical industry due to its ability to comprehensively analyze diverse VOC and inorganic gas impurities with very high sample throughput. When coupled with autosampler technology, SIFT-MS delivers unparalleled sample throughputs.

By delivering rapid results and facilitating wider scale testing, Syft instruments provide a unique opportunity for on-line product quality decisions to be made, which reduce the risks of product loss and brand damage.

Syft Technologies is committed to its customers' success, delivering simplicity of operation, fully integrated solutions, user-friendly software, product reliability, and extensive after-sales support.

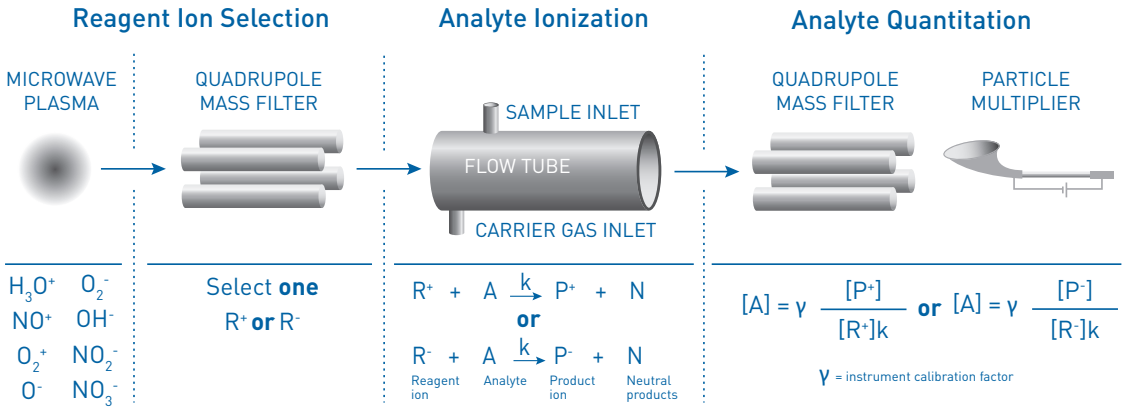
SELECTED ION FLOW TUBE MASS SPECTROMETRY (SIFT-MS)

SIFT-MS is the leading real-time analytical technique for comprehensive gas analysis to ultra-trace levels.

SIFT-MS uses ultra-soft, precisely controlled chemical ionization coupled with mass spectrometric detection to rapidly quantify VOCs and permanent gases to low part-per-trillion concentrations by volume (pptv). Eight chemical ionization agents (reagent ions) are applied in Syft instruments: H_3O^+, NO^+, O_2^+, O^-, O_2^-, OH^-, NO_2^-, and NO_3^-.

These eight reagent ions react with VOCs and inorganic gases in very well controlled ion-molecule reactions but they do not react with the major components of air (N_2, O_2, and Ar). This enables SIFT-MS to analyze air at trace and ultra-trace levels without preconcentration.

Rapid switching of eight reagent ions provides unsurpassed selectivity among direct MS techniques.



BENEFITS OF SYFT SIFT-MS INSTRUMENTS

- Instantaneous identification and quantitation of VOCs and inorganic gases using a fully integrated, extensive chemical ionization library
- Real-time gas analysis to low part-per-trillion by volume (pptv) concentrations with class-leading selectivity, no preconcentration, and high robustness to humidity
- Analysis of diverse compounds in a single analysis (e.g. ammonia, formaldehyde, formic acid, and organosulfur compounds)
- Ease of operation with push-button simplicity, no sample preparation, and comprehensive LabSyft data analysis software
- Designed and engineered for use in demanding environments, with easy integration into sample delivery systems (including autosamplers) and IT infrastructure
- Reliable, low maintenance instruments and accessories, with market-leading after-sales support

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