

The Extrel® MAX300™ series of quadrupole mass spectrometers can provide an accurate and quantitative measurement of organic solvents used in pharmaceutical drying processes.

With its dual detector and dynamic autoranging capabilities, the MAX300 has a detection range of 100% to 10 parts per billion.

In order to reduce costs and improve product quality, a recent trend in pharmaceutical drying applications is to accurately identify the end point of the drying process. To achieve this, pharmaceutical manufacturers are installing gas analyzers to monitor the headspace or dryer exhaust for the presence of organic solvent vapors. Low cost analyzers such as Residual Gas Analyzers (RGA), NIR Photometers and less sensitive quadrupole mass spectrometers are not able to achieve parts per billion (ppb) detection limits.



Therefore, a high performance process mass spectrometer, such as the Extrel MAX300, is becoming the analyzer of choice for solvent drying processes.

Typical Analysis Data

In a solvent drying process, the Extrel MAX300 high performance quadrupole process mass spectrometer is used to monitor the atmospheric composition of the headspace above the drying material. This composition is in close relationship with the concentration of solvents in the material. By analyzing the concentration profiles of solvents in the vapor phase, the true drying process end point can be determined. With high precision of the MAX300, each batch can be dried to the same specification, thus improving the rejection rate when the final product is tested.

The MAX300's detection capabilities are beneficial for dynamic processes such as solvent drying, in which it is desirable to analyze a component over a large concentration range. Figure 1 illustrates the dynamic range, accuracy and response time of the Extrel MAX300 over a complete drying process. During the drying process, the Ethyl Acetate concentration starts near zero then spikes to 62.5%, after which it slowly decreases to 8.6 parts per million (ppm).

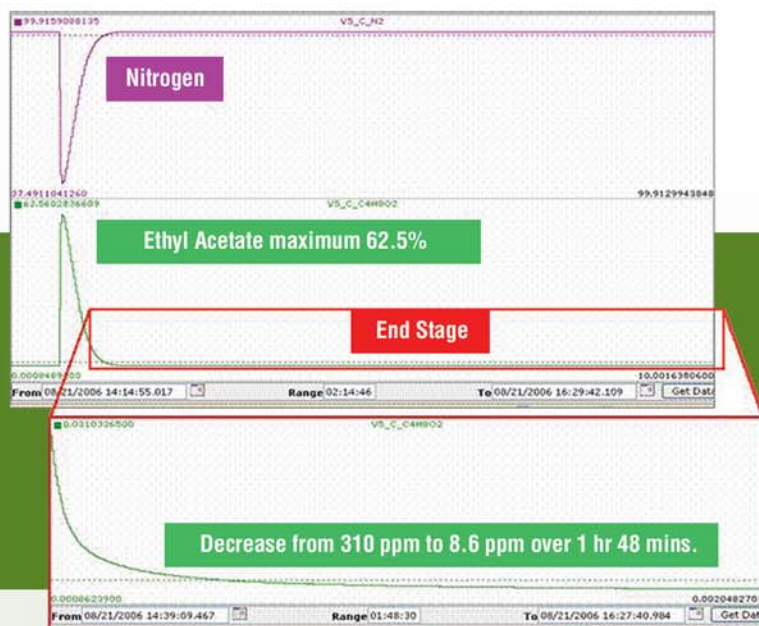


Figure 1: MAX300 Data of Ethyl Acetate Drying Process

As you can see, in order to profile the full drying process, the analyzer must be capable of accurately measuring from 100% down to low ppm levels. In particular, note the downward trend near the end stage in which the Ethyl Acetate concentration decreases from 310 ppm to 8.6 ppm, over a time frame of 1 hour and 48 minutes.

PHARMA SOLVENT DRYING

Figure 2 is a graph containing concentration data obtained during a simulated vacuum drying process measuring Isopropanol (IPA). The data was supplied by an Extrel pharmaceutical customer who performed a series of tests evaluating the performance of the MAX300.

The graph plots the concentration of IPA in ppm over time. The graph is formatted in a logarithmic scale in order to better observe the low level ppm data.

As expected, initially the IPA comes off quickly, spiking to levels near 1000 ppm before beginning a downward trend to its end value near zero. At the end stage of the drying process, when the concentration is 0.10 ppm, Extrel's peak to peak noise is on the order of 0.01 units. This accuracy at low ppm concentrations enables the MAX300 user to determine the end point of the solvent drying process with a high level of confidence.

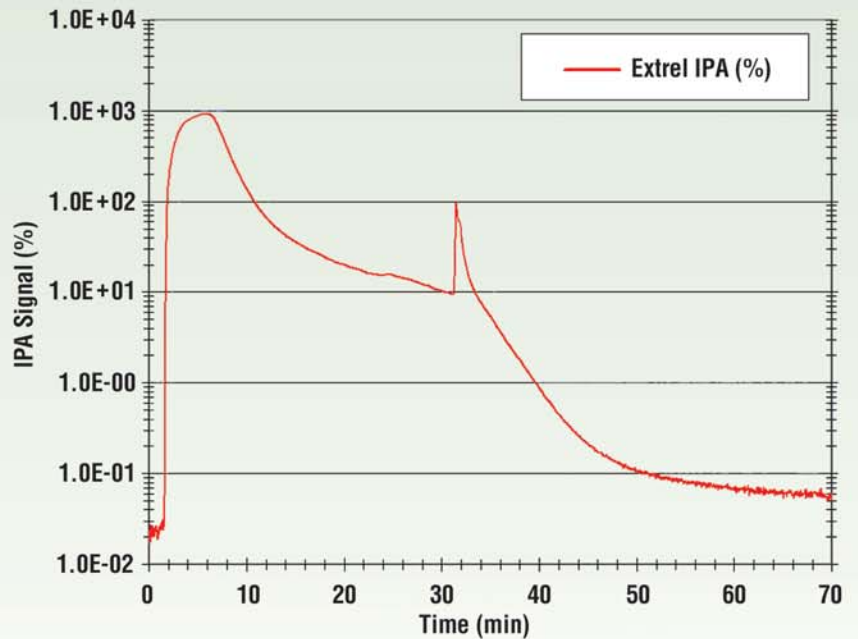


Figure 2: Extrel MAX300 Data from a Simulated IPA Drying Application

Key Application Facts

- The Dual Faraday and Electron Multiplier Detector and its Autoranging capabilities enable the MAX300 to achieve a continuous dynamic range of 100% down to 10 parts per billion.
- The flexibility of the MAX300 process mass spectrometer lends itself to batch processing with its ability to quickly and easily change the analysis method in order to monitor different solvents.
- The Extrel MAX300 has the capability to analyze one or more dryers and is able to analyze different solvents on each dryer.
- An Actively Controlled Sample System (ACSS) has been developed by Extrel for use with vacuum dryers.
- Extrel's Questor 5 web-based user interface has the capabilities to meet 21 CFR Part 11 requirements.



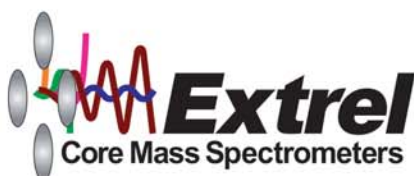
MAX300-LG



MAX300-IG

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