Traditional Moisture Analysis Of Lyophilized Materials Comes With Many Problems

It is expensive, complicated and requires hazardous materials. There are also several interferences that can bias test results including mercaptans, ketones, high pH materials and various functional additives.

Figure 1: Computrac® Vapor Pro® XL

The solution is an automatic moisture analyser with a built in relative humidity (RH) sensor as the signal source for the determination of moisture content

Like Karl Fischer titration, the system is moisture specific; other evolved volatiles will not affect the analysis. This instrument offers tangible advantages over traditional methods, such as Karl Fischer (KF) titration or loss-on-drying (LOD). The primary advantage of the RH sensor analyser over KF titration is that the RH Sensor analyser does not require the removal of a sample from its vial. This eliminates exposure of the material to ambient humidity, which can lead to biased test results when testing hygroscopic samples.

The system also does not require the use of hazardous chemical reagents, so consumables and environmental impact are minimized. The rugged design and absence of fragile glass components allow the instrument to be used outside of a controlled lab environment. The fundamental unit of measurement for the system is µg water, making it ideal for testing low moisture samples as well as materials for which a larger sample size, needed for accurate LOD testing, would be economically prohibitive.

The RH sensor analyser uses a thermoset polymer capacitance relative humidity sensor to detect changes in the relative humidity of the temperature controlled sensor chamber caused by thermal evolution of sample moisture.

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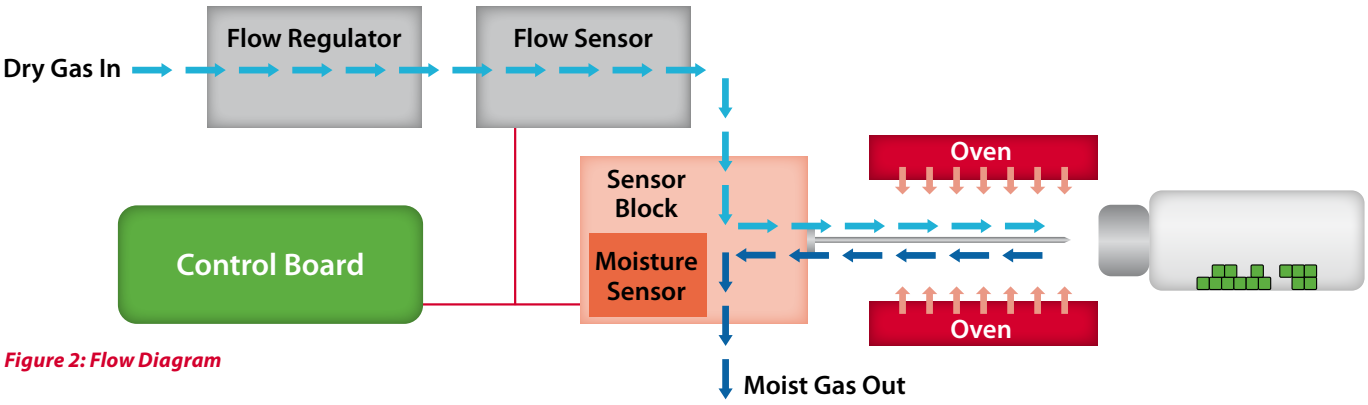


Figure 2: Flow Diagram

The analyte is heated in a sealed temperature controlled oven. The thermally evolved gasses are transported by a dry inert gas stream to a temperature controlled sensor chamber housing the RH sensor.

Samples were tested concurrently on a Computrac® Vapor Pro® instrument, and a Mitsubishi CA-06 volumetric Karl Fischer titration system

Ten (10) tests for each of six (6) materials were conducted and the average test result reported. Test parameters were determined using the following procedures:

- Karl Fischer analysis was carried out using the method described in **USP Standard 921–Ia, Water Determination**
- Optimal Vapor Pro® test temperatures determined using stepped test procedure described in Appendix X2, **ASTM Standard D–7191, 2010, Standard Test Method for Determination of Moisture in Plastics by Relative Humidity Sensor**

The Computrac® Vapor Pro® line of instruments offers a viable alternative to Karl Fischer analysis for lyophilized samples.

In the six materials presented in this study, the Vapor Pro® correlated well with Karl Fischer and exhibited excellent precision over a wide moisture range. The differences between the two result sets were statistically insignificant.

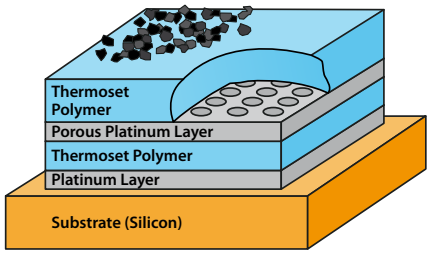
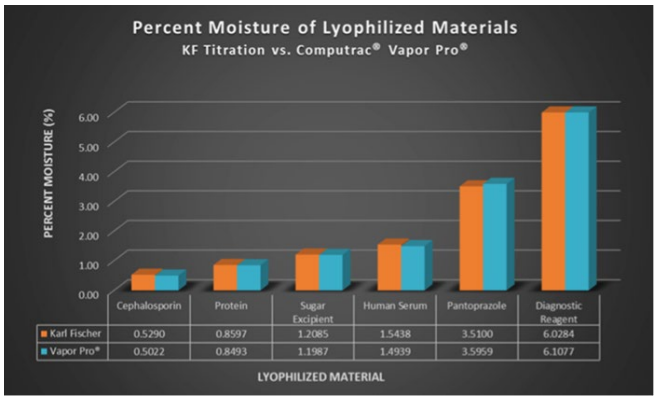


Figure 3: Polymer Capacitance RH Sensor

The RH sensor based technology provides accurate and precise analysis of materials within the lyophilisation vials (sizes 2R to 30R), limiting exposure to atmospheric moisture. It is significantly easier and more intuitive to use, allowing for more repeatable results among tests performed by different users. It is also more cost efficient than Karl Fischer due to the lack of chemical reagents and expensive, breakable glassware.



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