Moisture Determination of Lyophilized Materials by Relative Humidity Sensor Analyzer
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Purpose
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, keytones, high pH materials and various functional additives. The solution is an automatic moisture analyzer 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. The analyzer 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.

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 analyzer over KF titration is that the RH Sensor analyzer 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 is solventless, so consumables and environmental impact are minimized. The rugged design, particularly the absence of fragile glass components, allows 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 the larger sample size needed for accurate LOD testing would be economically prohibitive.

Methods
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:

Results
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.

Conclusion
The Computrac® Vapor Pro® offers a viable alternative to Karl Fischer analysis for lyophilized samples. The RH sensor based technology provides accurate and precise analysis of materials within the lyophilization vials while limiting exposure to atmospheric moisture. It is significantly easier and more intuitive to operate and the solventless design greatly reduces the environmental footprint of the analysis.