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Production Filename: 13457 (In Product Library)

Path to Working Files: DecaDoc\Application Notes\Master

Dimensions: 8.5 inch wide, 11 inch tall

Material: Paper, 92 Bright White or better, 75g/m² or heavier

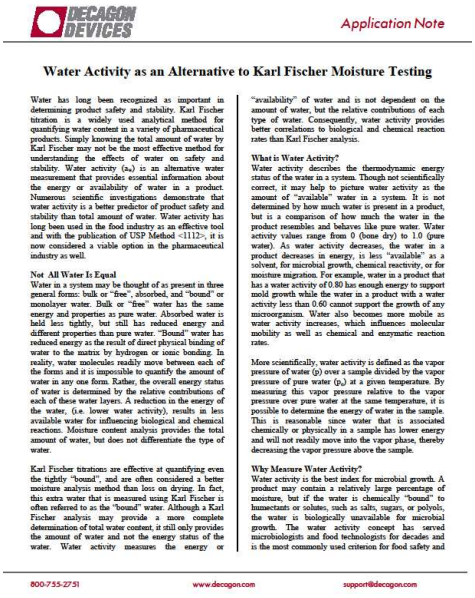
Colors: Color Print on White

Printer: HP Color LaserJet 8550-PS

Finish: None

Adhesive: None

Special Notes: Illustrations are Ref Only ** Not to Scale ** (Shown page 1 of 2)



DECAGON DEVICES Application Note

Water Activity as an Alternative to Karl Fischer Moisture Testing

Water has long been recognized as important in determining product safety and stability. Karl Fischer titration is a widely used analytical method for quantifying water content in a variety of pharmaceutical products. Simply knowing the total amount of water by Karl Fischer may not be the most effective method for understanding the effects of water on safety and stability. Water activity (a_w) is an alternative water measurement that provides essential information about the energy or availability of water in a product. Numerous scientific investigations demonstrate that water activity is a better predictor of product safety and stability than total amount of water. Water activity has long been used in the food industry as an effective tool and with the publication of USP Method <1112>, it is now considered a viable option in the pharmaceutical industry as well.

Not All Water Is Equal

Water in a system may be thought of as present in three general forms: bulk or "free", absorbed, and "bound" or monolayer water. Bulk or "free" water has the same energy and properties as pure water. Absorbed water is held less tightly, but still has reduced energy and different properties than pure water. "Bound" water has reduced energy as the result of direct physical binding of water to the matrix by hydrogen or ionic bonding. In reality, water molecules readily move between each of the forms and it is impossible to quantify the amount of water in any one form. Rather, the overall energy status of water is determined by the relative contributions of each of these water layers. A reduction in the energy of the water, (i.e. lower water activity), results in less available water for influencing biological and chemical reactions. Moisture content analysis provides the total amount of water, but does not differentiate the type of water.

Karl Fischer titrations are effective at quantifying even the tightly "bound", and are often considered a better moisture analysis method than loss on drying. In fact, this extra water that is measured using Karl Fischer is often referred to as the "bound" water. Although a Karl Fischer analysis may provide a more complete determination of total water content, it still only provides the amount of water and not the energy status of the water. Water activity measures the energy or "availability" of water and is not dependent on the amount of water, but the relative contributions of each type of water. Consequently, water activity provides better correlations to biological and chemical reaction rates than Karl Fischer analysis.

What is Water Activity?

Water activity describes the thermodynamic energy status of the water in a system. Though not scientifically correct, it may help to picture water activity as the amount of "available" water in a system. It is not determined by how much water is present in a product, but is a comparison of how much the water in the product resembles and behaves like pure water. Water activity values range from 0 (bone dry) to 1.0 (pure water). As water activity decreases, the water in a product decreases in energy, is less "available" as a solvent, for microbial growth, chemical reactivity, or for moisture migration. For example, water in a product that has a water activity of 0.80 has enough energy to support mold growth while the water in a product with a water activity less than 0.60 cannot support the growth of any microorganism. Water also becomes more mobile as water activity increases, which influences molecular mobility as well as chemical and enzymatic reaction rates.

More scientifically, water activity is defined as the vapor pressure of water (p) over a sample divided by the vapor pressure of pure water (p_o) at a given temperature. By measuring this vapor pressure relative to the vapor pressure over pure water at the same temperature, it is possible to determine the energy of water in the sample. This is reasonable since water that is associated chemically or physically in a sample has lower energy and will not readily move into the vapor phase, thereby decreasing the vapor pressure above the sample.

Why Measure Water Activity?

Water activity is the best index for microbial growth. A product may contain a relatively large percentage of moisture, but if the water is chemically "bound" to humectants or solutes, such as salts, sugars, or polyols, the water is biologically unavailable for microbial growth. The water activity concept has served microbiologists and food technologists for decades and is the most commonly used criterion for food safety and

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