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Dimensions: 8.5 inch wide, 11 inch tall

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

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Finish: None

Adhesive: None

Special Notes: Illustrations are Ref Only ** Not to Scale ** (Shown page 1 of 3)



Application Note

Measuring Moisture Content of Pharmaceutical Products Using Water Activity

Introduction

The terms moisture content and water content are often used interchangeably and represent a measure of the quantity of water in a product. Moisture content provides valuable information about yield and quality, making it important from a financial standpoint. In addition, moisture content provides information about texture since increasing levels of moisture provide water mobility and lower the glass transition temperature.

Water activity represents the energy status of the water in the system. It is equal to the relative humidity of the air in equilibrium with a sample in a sealed chamber. It is defined as the vapor pressure of water in a sample divided by the vapor pressure of pure water at the sample temperature. Water activity provides valuable information about microbial spoilage, chemical stability, and physical stability. Water activity and moisture content together provide a complete moisture analysis.

Moisture content and water activity are currently measured using separate techniques or instruments. Water activity is measured using either a capacitance or chilled mirror water activity instrument while moisture content is measured using any one of the 35 different methods listed in Official Methods of the AOAC (AOAC, 1995). Combining the two analyses in one instrument saves time and labor. Decagon's new AquaLab Series 4TE DUO and AquaSerp Isotherm Generator now make it possible to measure both water activity and moisture content using Decagon's proven water activity measurement technology.

To measure moisture content using water activity requires an understanding of the relationship between the two parameters. This relationship, referred to as the moisture sorption isotherm, is complex and unique to each product type. It must be determined experimentally by measuring water content at several water activity values. This only needs to be done once for a given product. Isotherm analysis can be done manually with saturated salt chambers and desiccators or automatically using an isotherm generator instrument. Decagon's AquaSerp isotherm generator can rapidly generate robust isotherms with unmatched data resolution (Figure 1).

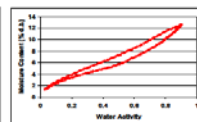


Figure 1. Moisture sorption isotherm for microcrystalline cellulose generated using the AquaSerp Isotherm Generator at 25 °C.

Once an isotherm has been generated, it can be used to indirectly determine moisture content based on a water activity measurement. This is most easily accomplished using a model that characterizes the isotherm. Many different isotherm models have been proposed, but the most commonly used models are the GAB and BET. Decagon has developed another model, called the Double Log Polynomial (DLP) that is superior to the others for modeling complex isotherms. The models are determined empirically using the data collected during isotherm generation and the resulting equation can be used to calculate moisture content using water activity.

Decagon's new AquaLab Series 4TE(V) DUO, a chilled mirror water activity instrument, has been designed to accept isotherm equations. Using the isotherm equation for a specific product, the Series 4 can determine moisture content from the water activity values it generates. Each product to be analyzed for moisture content will have a unique isotherm model that must be selected using the Series 4 system commands prior to writing. A Series 4TE(V) DUO is required because the test must be conducted at the same temperature as the original isotherm to be valid.

Clearly, the accuracy of this moisture content method relies on the quality of the isotherm and the repeatability of the water activity measurement. To further investigate the feasibility of measuring moisture content by water activity, Decagon Devices investigated the process using several different product types.