

Document Title: Description, AN, Water Activity Best Testing Practices Guide.pdf		Part # and Rev. 14518-01	
		Release Date: 2-15-12	
Rev.	Description	Revision By	Date

Production Filename: 14518-01, Water Activity Best Testing Practices Guide.pdf

Path to Published Files: decadoc/Application Notes/Published - To print on Plain paper/PTT/14518-01, Solid Dosage Tablet Water Activity Testing Guide.pdf

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 5550

Finish: None

Adhesive: None

Special Notes: Illustrations are Ref Only ** Not to Scale ** (Page 1 of 6)

	Application Note	
Water Activity Best Testing Practices Product 2. Solid Dosage Tablets		
<p>Introduction The AquaLab research and development team now has water activity best testing practices available for solid dosage tablets. The objectives of this study were to:</p> <ol style="list-style-type: none"> 1. Observe the impact of ambient humidity on water activity testing results when using normal testing practices. 2. Compare the water activity average values, test time and repeatability across several water activity instruments. 3. Determine if an advantage in precision is gained by extending read times up to an hour when using dewpoint instruments instead of using the initial value provided in the normal ~5 minute test time. 4. Identify the optimal settings for the custom mode testing option in Series 4 instruments. 5. Observe the impact of test temperature on water activity test results. <p>Materials and Methods The water activity instruments used for testing included 1 AquaLab Series 3TE Chilled Mirror Water Activity Instrument and 2 AquaLab Series 4TEV Chilled Mirror Water Activity Instruments. Each instrument was verified daily using unsaturated salt solutions at 0.25 a_w, 0.5 a_w, 0.76 a_w, and 1.00 a_w. All testing was conducted on 3 replicates taken from 3 independent samples. Humidity was controlled using a glove box and all sampling and testing was conducted in the glove box. Humidity in the glove box was constantly monitored. Sampling was done as quickly as possible with the sample exposed for no more than 5 seconds during sampling. The ambient humidities included in the study were 10% RH, 30% RH, and 70% RH. At each humidity, testing was conducted in 3 parts. A description of each part follows.</p>	<p>Part 1 consisted of tests accomplished using just the AquaLab instruments. An initial water activity reading was recorded when the first test ended as indicated by the instrument, but then the instrument was set to continue taking measurements up to approximately 1 hour. The initial and final mean water activity and standard deviation across the 3 samples were compared using ANOVA to see if a significant advantage is gained in the AquaLab instruments by extending the test time. All tests in Part 1 were done at 25°C.</p> <p>Part 2 consisted of comparing the results in Part 1 for tablets tested whole and tablets crushed before testing. The tablets were crushed using mortar and pestle inside the glove box at each humidity. Tablets were crushed, but not pulverized to a powder. Sample preparation was investigated as a significant source of variation again using ANOVA.</p> <p>Part 3 consisted of utilizing the custom feature in the AquaLab Series 4 instruments. This mode allows setting stability specifications for ending a test, which consists of identifying a water activity range that must be met by a specified number of tests. For example, the custom setting could be 3 tests and 0.003 a_w. Once started, the instrument will then continue taking tests until 3 results are within +/- 0.003 a_w of each other. To determine the preferred custom mode to achieve the highest combination of repeatability and speed, 4 custom mode settings were compared including: 3 tests within +/- 0.001 a_w, 5 tests within +/- 0.001 a_w, 3 tests within +/- 0.003 a_w, and 5 tests within +/- 0.003 a_w. Testing was conducted using 1 Series 4TEV instrument on 3 replicates from 3 samples. The mean water activity and standard deviation across all 3 samples was then compared using ANOVA to determine if one custom mode setting provides significantly better performance than another</p>	
800-755-2751	www.aqualab.com	support@aqualab.com