Document Title: Description, AN, Understanding water activity for reduced microbial testing using USP method 1112		Part # and Rev. 13428-01	
		Release Date:	
Rev.	Description	Revision By	Date

Production Filename: 13428 (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

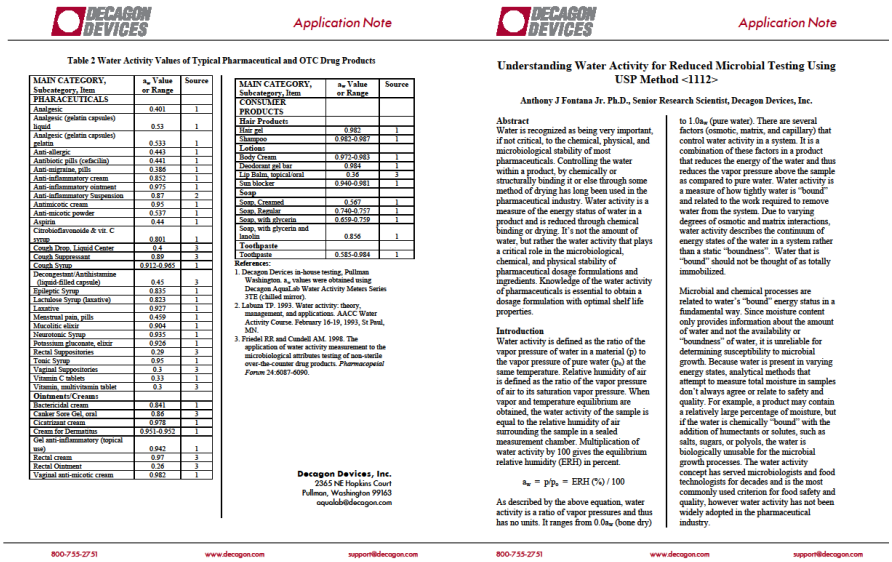
Colors: Color Print on White

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

Table 2 Water Activity Values of Typical Pharmaceutical and OTC Drug Products

MAIN CATEGORY, Subcategory, Item	a_w Value or Range	Source
PHARACEUTICALS		
Analgesic	0.401	1
Analgesic (gelatin capsules) liquid	0.53	1
Analgesic (gelatin capsules) gelatin	0.533	1
Anti-allergic	0.443	1
Antibiotic pills (cefaclin)	0.441	1
Anti-migraine, pills	0.386	1
Anti-inflammatory cream	0.852	1
Anti-inflammatory ointment	0.975	1
Anti-inflammatory Suspension	0.87	2
Antimicotic cream	0.95	1
Anti-micotic powder	0.537	1
Aspirin	0.44	1
Citrobioflavonoide & vit. C syrup	0.801	1
Cough Drop, Liquid Center	0.4	3
Cough Suppressant	0.88	3
Cough Syrup	0.912-0.965	1
Decongestant/Antihistamine (liquid-filled capsule)	0.45	3
Epileptic Syrup	0.835	1
Lactulose Syrup (laxative)	0.823	1
Laxative	0.927	1
Menstrual pain, pills	0.459	1
Mucolitic elixir	0.904	1
Neurotonic Syrup	0.935	1
Potassium gluconate, elixir	0.926	1
Rectal Suppositories	0.29	3
Tonic Syrup	0.95	1
Vaginal Suppositories	0.3	3
Vitamin C tablets	0.33	1
Vitamin, multivitamin tablet	0.3	3
Ointment/Creams		
Bactericidal cream	0.841	1
Canker Sore Gel, oral	0.86	3
Cicatrizant cream	0.975	1
Cream for Dermatitus	0.951-0.952	1
Gel anti-inflammatory (topical use)	0.942	1
Rectal cream	0.97	3
Rectal Ointment	0.26	3
Vaginal anti-micotic cream	0.982	1

MAIN CATEGORY, Subcategory, Item	a_w Value or Range	Source
CONSUMER PRODUCTS		
Hair Products		
Hair gel	0.982	1
Shampoo	0.982-0.987	1
Lotions		
Body Cream	0.972-0.983	1
Deodorant gel bar	0.984	1
Lip Balm, topical/oral	0.36	3
Sun blocker	0.940-0.981	1
Soap		
Soap, Creamed	0.567	1
Soap, Remilar	0.740-0.757	1
Soap, with glycerin	0.659-0.759	1
Soap, with glycerin and lanolin	0.856	1
Toothpaste		
Toothpaste	0.585-0.984	1

References:

1. Decagon Devices in-house testing, Pullman Washington. a_w values were obtained using Decagon AquaLab Water Activity Meters Series 3TE (chilled mirror).
2. Labuza TP. 1993. Water activity: theory, management, and applications. AACC Water Activity Course. Feburary 16-19, 1993, St Paul, MN.
3. Friedel RR and Cundell AM. 1998. The application of water activity measurement to the microbiological attributes testing of non-sterile over-the-counter drug products. *Pharmacopeial Forum* 24:6087-6090.

Decagon Devices, Inc.
2365 NE Hopkins Court
Pullman, Washington 99163
aqualab@decagon.com

DECAGON DEVICES Application Note

Understanding Water Activity for Reduced Microbial Testing Using USP Method <1112>

Anthony J Fontana Jr. Ph.D., Senior Research Scientist, Decagon Devices, Inc.

Abstract

Water is recognized as being very important, if not critical, to the chemical, physical, and microbiological stability of most pharmaceuticals. Controlling the water within a product, by chemically or structurally binding it or else through some method of drying has long been used in the pharmaceutical industry. Water activity is a measure of the energy status of water in a product and is reduced through chemical binding or drying. It's not the amount of water, but rather the water activity that plays a critical role in the microbiological, chemical, and physical stability of pharmaceutical dosage formulations and ingredients. Knowledge of the water activity of pharmaceuticals is essential to obtain a dosage formulation with optimal shelf life properties.

Introduction

Water activity is defined as the ratio of the vapor pressure of water in a material (p) to the vapor pressure of pure water (p_o) at the same temperature. Relative humidity of air is defined as the ratio of the vapor pressure of air to its saturation vapor pressure. When vapor and temperature equilibrium are obtained, the water activity of the sample is equal to the relative humidity of air surrounding the sample in a sealed measurement chamber. Multiplication of water activity by 100 gives the equilibrium relative humidity (ERH) in percent.

$$a_w = p/p_o = ERH\ (\%) / 100$$

As described by the above equation, water activity is a ratio of vapor pressures and thus has no units. It ranges from 0.0a_w (bone dry) to 1.0a_w (pure water). There are several factors (osmotic, matrix, and capillary) that control water activity in a system. It is a combination of these factors in a product that reduces the energy of the water and thus reduces the vapor pressure above the sample as compared to pure water. Water activity is a measure of how tightly water is "bound" and related to the work required to remove water from the system. Due to varying degrees of osmotic and matrix interactions, water activity describes the continuum of energy states of the water in a system rather than a static "boundness". Water that is "bound" should not be thought of as totally immobilized.

Microbial and chemical processes are related to water's "bound" energy status in a fundamental way. Since moisture content only provides information about the amount of water and not the availability or "boundness" of water, it is unreliable for determining susceptibility to microbial growth. Because water is present in varying energy states, analytical methods that attempt to measure total moisture in samples don't always agree or relate to safety and quality. For example, a product may contain a relatively large percentage of moisture, but if the water is chemically "bound" with the addition of humectants or solutes, such as salts, sugars, or polyols, the water is biologically unusable for the microbial growth processes. The water activity concept has served microbiologists and food technologists for decades and is the most commonly used criterion for food safety and quality, however water activity has not been widely adopted in the pharmaceutical industry.

800-755-2751 www.decagon.com support@decagon.com