Summary - Water Activity - What Is It and How Does It Apply to Pharmaceutical Manufacturing

Water activity (a_w) is defined as the ratio of product vapour pressure to pure water vapour pressure. It is a measure of the water available for chemical or microbiological activity within a product. Water activity is significant to the pharmaceutical industry in that it affects the quality of ingredients and finished product through their chemical stability, a reduced need for chemical preservatives, and a potential reduction in the need for microbial limits testing.

Microbial growth requires water. Water dissolves solutes within a viable cell and is required for metabolic function. When an (a_w) value is associated with a micro-organism it serves as an indication of potential metabolic activity. While organism proliferation ceases below certain water activity levels, some species have the ability to adapt slightly and continue to grow at levels below their optimum range.

Molds can tolerate a_w levels down to about 0.80. Microbiological growth at any level ceases at a_w values of about 0.60. Thus, by controlling the water activity of products, the growth of microorganisms, when present, can be controlled as well.

The a_w also has an effect on the chemical processes within a product or formulation. Lowering the a_w may increase chemical stability. Freezing, freeze drying, salting, syruping, and drying are preservation methods that take advantage of lowering a_w. These methods either bind or eliminate the available water in a product. Ideally, water activity should be evaluated early in the product development process.

Low a_w can be achieved by limiting the amount of water added to a product during formulation, driving off water, or binding remaining water.

Water is often used to dissolve product constituents. Different solutes provide different a_w results.

The a_w of a product may also be examined over time to support product stability. If water activity levels can be achieved and maintained below predetermined levels known to support growth, microbiological and chemical stability of products can be maximized and the potential exists for a reduction in routine microbiological testing.

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