

Insights on Moisture Scavenging Properties of Starch 1500[®]

Technical Bulletin

Challenge

There is heightened scrutiny by regulators and patient advocacy groups, on the potential presence of impurities and degradants during the shelf-life of medicinal products. It's imperative to manage moisture effectively as it is known to be the main cause of degradation leading to impurities in solid dose formulations.

Starch 1500[®], partially pregelatinized starch, provides superior protection against moisture for sensitive drugs by its ability to tightly bind with water and reduce free moisture in tablet and capsule formulations.

Materials and Methods

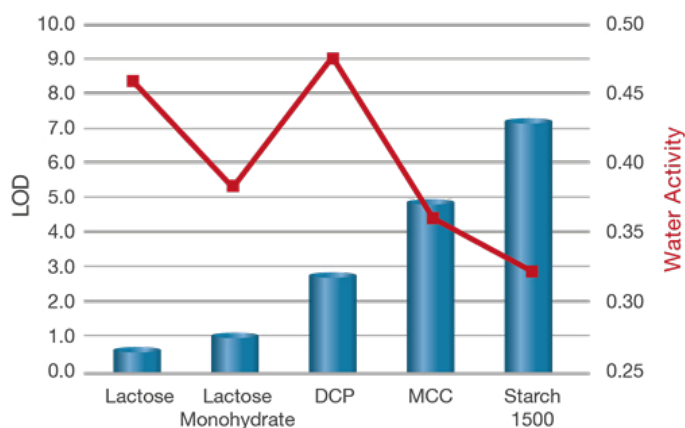
The water activity (a_w) and dynamic vapor sorption (DVS) behavior of Starch 1500 were measured using Aqualab Series 3 (Decagon) and DVS Intrinsic (Surface Measurement Systems) equipment, respectively.

Results

Water Activity

Loss on drying (LOD), shows the amount of water that is held inherently by an ingredient. Compared to other commonly used fillers, Starch 1500 has a higher LOD; however, it has the lowest water activity (a_w) which means it has the highest capacity for binding moisture, not allowing it to interact with the API.

Starch 1500 shows the lowest water activity compared to other excipients

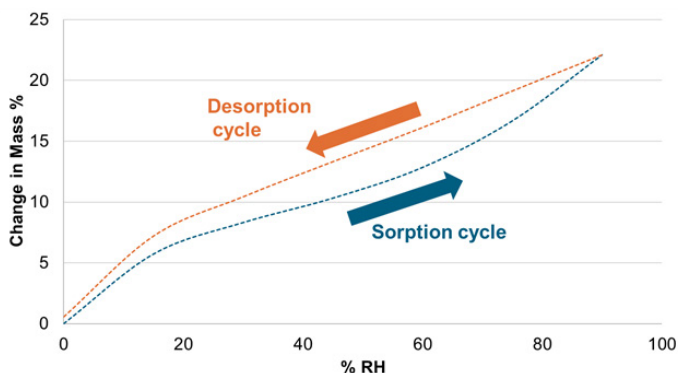


- Water activity (a_w) is a measure of thermodynamic energy or freely available water in a system
- Low level of free water means little or no drug degradation
- Water activity values range from $a_w=0$ (completely dry) to $a_w=1.0$ (pure water)
- Low a_w means water is strongly bound and free water less available for chemical reactions

Dynamic Vapor Sorption (DVS)

- DVS is a gravimetric sorption/desorption technique that measures how quickly and how much water is sorbed or desorbed by a sample at controlled relative humidity (RH) condition.
- Rapidly measures uptake and loss of moisture by flowing a carrier gas at a specified relative humidity over the sample.
- Two cycles of sorption and desorption form a loop called **hysteresis**, which is a fingerprint for a powder, as not all the sorbed water can dissociate during desorption or drying.

DVS analysis shows that Starch 1500 has a greater capacity to bind with water and hold it



Excipients	Hysteresis Area*
Starch 1500	185
MCC	73
Lactose	3

* Area between absorption and desorption curves

Starch 1500®

Partially Pregelatinized Maize Starch

Starch 1500 can retain significantly more tightly bound moisture when compared to MCC or lactose. Studies have shown that formulations with partially pregelatinized starch may enhance drug product stability by preferentially binding to micro-environmental free moisture and decreasing the rate at which the relative humidity reaches equilibrium with the environment.

Conclusion

Starch 1500®, partially pregelatinized starch, demonstrates excellent moisture scavenging properties compared to other commonly used pharmaceutical excipients, making it an excellent excipient for managing moisture.

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