EXCIPIENTS

STARCH 1500®

PARTIALLY PREGELATINIZED MAIZE STARCH

Technical Data

Water Activity vs LOD

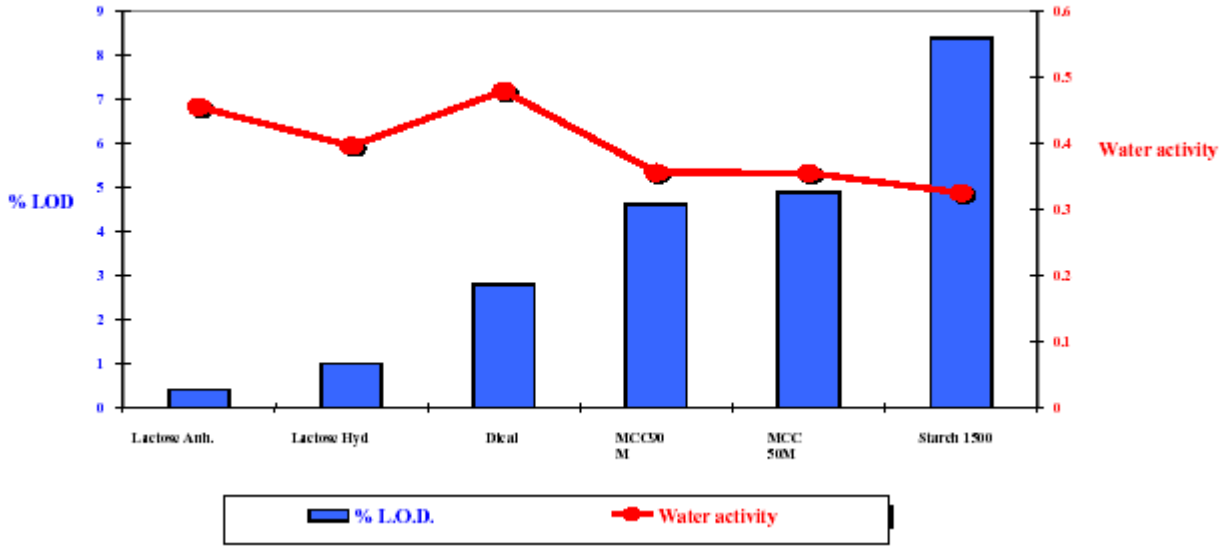
Free and Bound Water in Starch 1500 compared to other commonly used excipients

Loss on drying (LOD) or total moisture content of pharmaceutical products can include both bound (e.g. water of hydration) and free water. It is the free water that is responsible for degradation of moisture sensitive materials resulting in poor stability profiles.

Starch 1500 meets USP, EP and JP LOD specifications of no more than 13-14%. The equilibrium moisture content of Starch 1500 is 8-10%. Even under accelerated storage conditions of 40°C and 75%RH, Starch 1500 remains within its moisture specification.

The quantity of free water in pharmaceutical powders can be measured using a water activity meter. The study summarised below compares LOD and water activity for a number of commonly used excipients. Water Activity was measured using AquaLab Series 3 Model TE Meter Manufactured by Decagon (USA) and LOD using USP method.
Even though Starch 1500 has the highest total moisture content when compared with other commonly used pharmaceutical excipients, it has the lowest quantity of free water which means greater stability of moisture sensitive actives.

Comparison of Water Activity vs. LOD for Commonly used Excipients



Summary

The free water content and therefore degree of water activity provides more valuable information than the total moisture content when considering the stability of moisture sensitive products.
In an Aspirin stability study conducted by Colorcon it was found that although Starch 1500 contained the high total moisture content, this provided the most stable formulation when compared to alternatives containing excipients with significantly lower LOD. The results of the study demonstrated that ultimate stability was not dependent on the total quantity of moisture present, but on its form and relative availability**.**

1 Cunningham, C.R. et al., Formulations of Acetylsalicylic Acid Tablets for Aqueous Enteric Film Coating, *Pharm. Tech. Europe*, May 2001.

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