



# STARCH 1500<sup>®</sup>

PARTIALLY PREGELATINIZED MAIZE STARCH

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

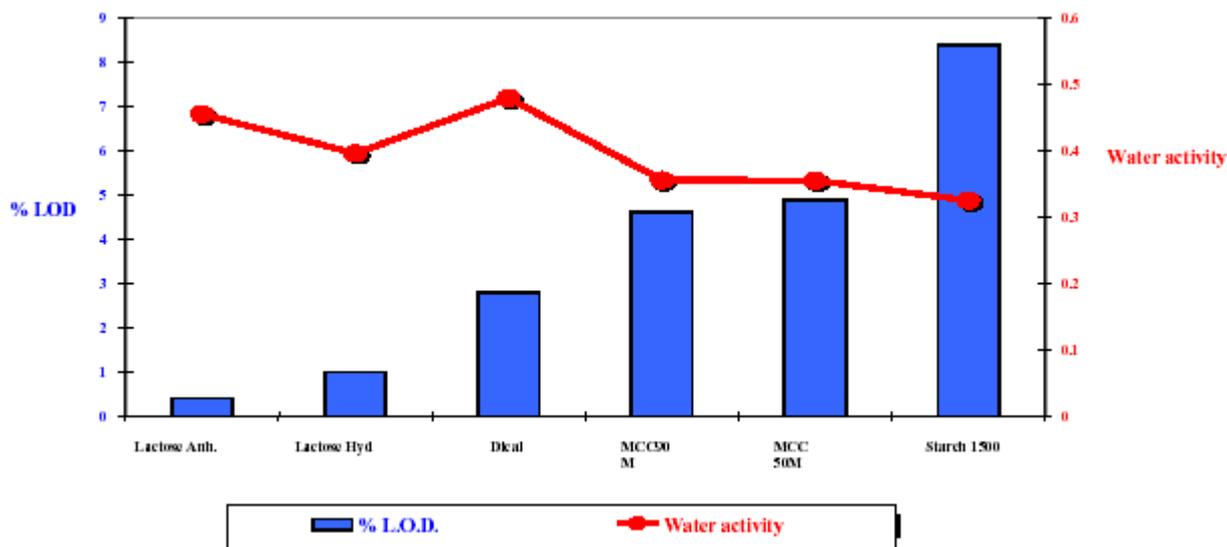
Loss on drying (LOD) or total moisture content of pharmaceutical products can include both bound (e.g. water of hydration) and free water. It is the free water that is responsible for degradation of moisture sensitive materials resulting in poor stability profiles.

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<sup>1</sup> 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.

---

**World Headquarters**

Colorcon  
415 Moyer Blvd., P.O. Box 24, West Point, PA 19486-0024  
Tel: 215-699-7733 Fax: 215-661-2605 Web Site @<http://www.colorcon.com>

---

<b>Locations</b>	<b>Telephone</b>	<b>Facsimile</b>	<b>Locations</b>	<b>Telephone</b>	<b>Facsimile</b>
<i>United States</i>			<i>Asia/Pacific</i>		
Santa Ana, California	714-549-0631	714-549-4921	Singapore	65-6438-0318	65-6438-0178
Indianapolis, Indiana	317-545-6211	317-545-6218	Fuji-gun, Shizuoka, Japan	81-5-4465-2711	81-5-4465-2730
Humacao, Puerto Rico	787-852-3815	787-852-0030	Shanghai, China	86-21-5442-2222	86-21-5442-2229
			Goa, India	91-0832-2883434	91-0832-2883440
<i>Europe</i>			Seoul, Korea	822-2057-2173	822-2057-2179
Dartford, Kent, England	44-1322-293000	44-1322-627200			
Bougival, France	33-1-3082-1582	33-1-3082-7879	<i>Latin America</i>		
Idstein, Germany	49-6126-9961-0	49-6126-9961-11	Buenos Aires, Argentina	54-11-4552-1565	54-11-4552-3997
Gallarate, Italy	39-0331-776932	39-0331-776831	Cotia, Brasil	55-11-4612-4262	55-11-4612-3307
Budapest, Hungary	36-1-200-8000	36-1-200-8010	Bogota, Colombia	571-418-1202	571-418-1257
Istanbul, Turkey	90-216-465-0360	90-216-465-0361	Caracas, Venezuela	58-212-793-3459	58-212-781-2619
Barcelona, Spain	34-9-3589-3756	34-9-3589-3792	Santa Fe, Mexico	52-55-5292-1611	52-55-5292-1750

The information contained herein, to the best of our knowledge is true and accurate. Any recommendations or suggestions are made without warranty or guarantee, since the conditions of use are beyond our control. Any information contained herein is intended as a recommendation for use of our products so as not to infringe on any patent.

©2003 Colorcon. The information contained in this document is proprietary to Colorcon and may not be used or disseminated inappropriately.

Starch 1500® is a trademark of BPSI Holdings, Inc.  
EX/Istarch1500\_wateractivity\_vs\_LOD\_rev1\_0703