

Starch 1500® Partially Pregelatinized Maize Starch

Technical Bulletin

Starch 1500® partially pregelatinized maize starch results in partial solubility, increased particle size, improved flow properties and good compactibility compared to native starch.

Functions as binder and disintegrant. Provides excellent stability for moisture sensitive drugs and cost effective content uniformity as a carrier for low dose APIs.

StarCap® superior flow maize starch is a mix of globally accepted excipients (corn starch and pregelatinized starch) designed for use in capsules and tablets.

Functions as a diluent with excellent disintegration and dissolution properties independent of media pH. Inert and free flowing, processed to provide good compactibility, especially for dry processes.

Composition

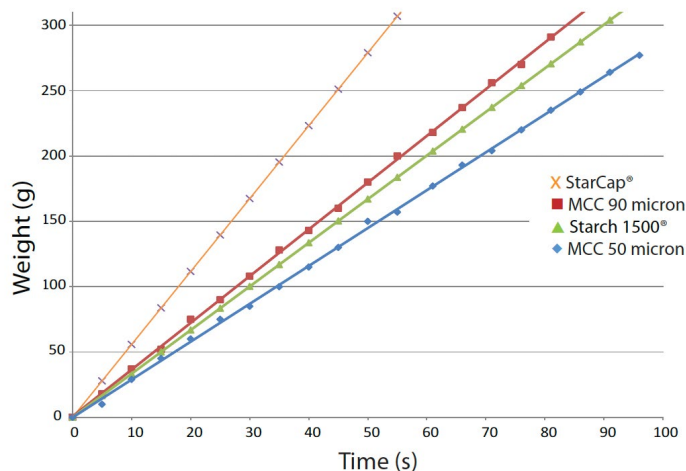
- Amylopectin ~ 73% water soluble polymer providing binding properties when released from starch grain (gelatinization)
- Amylose ~ 27% insoluble polymer swells when wetted providing disintegrant properties in the ungelatinized starch grains



Typical Properties

	Starch 1500	StarCap
Gelatinization Level (%)	~20	~2
Particle Size (micron)	~65	~90
Bulk Density (g/ cc)	0.61	0.42
Tapped Density (g/ cc)	0.82	0.58
Carr's Comp. Index (%)	26	28
Flow Rate (g/ sec)	3.3	5.7
Moisture (%)	7.2	9.1
Water Activity	0.33	0.41
Typical Use Levels	5-20% (range 1-50%)	1-99%

Flow Properties



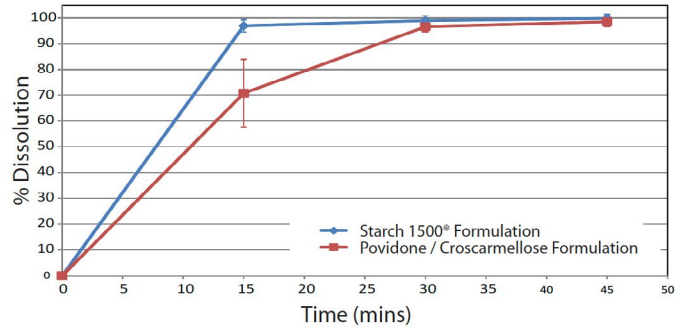
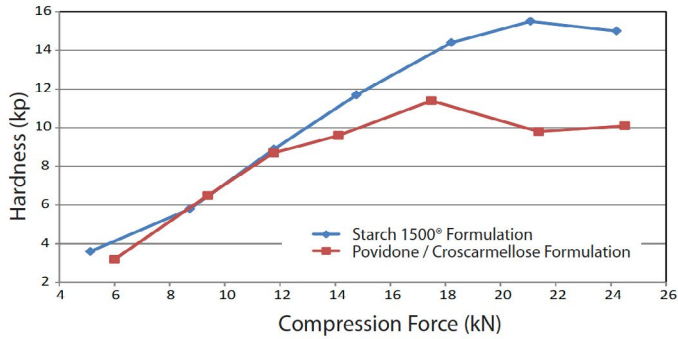
The shape and size of StarCap results in improved flow over similarly sized MCC. Consistency of shape and particle size distribution means good flowability and less need for additional glidant.

Starch 1500®

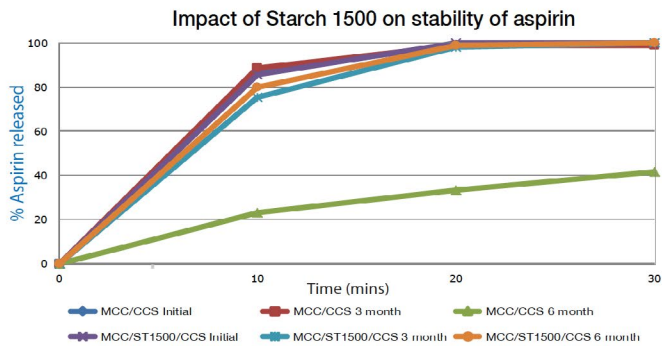
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Comparison of Starch 1500 to PVP and Croscarmellose Sodium

Demonstrating improvements in binding and disintegration properties, while reducing cost of excipient by 60% (guaifenesin study)

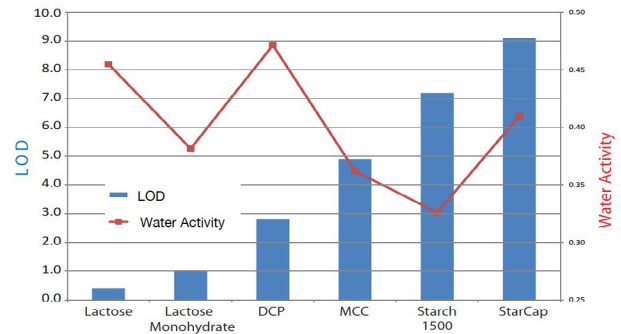


Improved Stability for Moisture Sensitive Actives



Moisture scavenging properties of Starch 1500 makes it an excellent diluent to enhance stability of moisture sensitive drugs.

Comparison of Water Activity vs Loss on Drying (LOD)

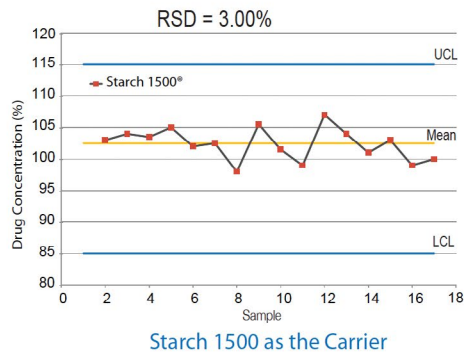
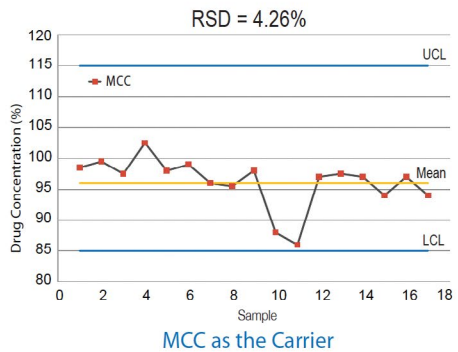
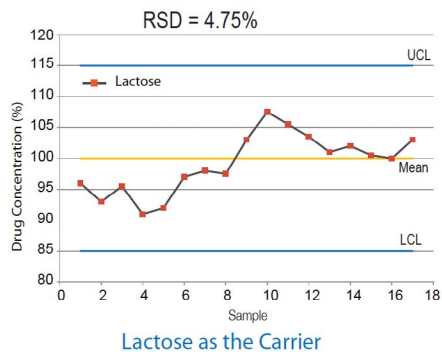


While Starch 1500 has a high moisture content, it has low water activity, this gives better stability to moisture sensitive actives. Moisture is bound compared to free, as in other excipients.

Starch 1500[®]

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Starch 1500 Low Dose Uniformity

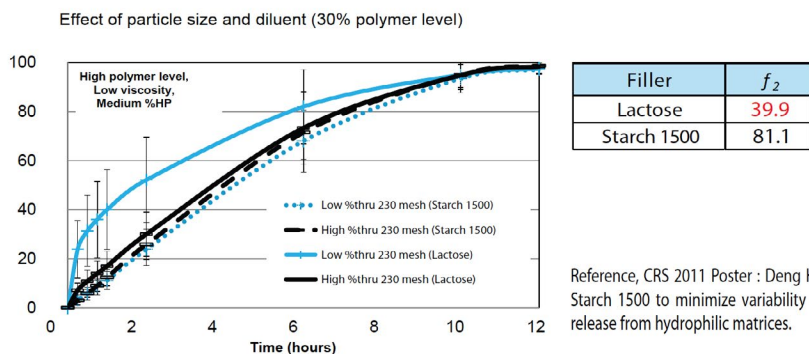


- Reduction in cost and complexity
- Eliminates wet granulation step
- Improves content uniformity

Reference: Hashim Ahmed, Ph.D. and Navnit Shah, Ph.D.
Formulation of Low Dose Medicine- Theory and Practice.
Amer Pharm Review, Vol 3, Issue 3 (2000).

Dose Uniformity

Starch 1500 as diluent in matrix formulations can minimize differences in drug release ($f_2 > 50$) despite variations in properties of hypromellose (METHOCEL[™] K100LV). Replacing lactose with Starch 1500 as diluent, results in more robust formulations. Recent studies have highlighted that similar combinations can be used to reduce the variability that may be associated with hydrophilic matrices through Quality by Design (QbD).



Colorcon has negotiated exclusive rights for customers using pregelatinized starch and hydrophilic polymers (including, but not limited to METHOCEL[™] premium cellulose ethers), covered under patent by Janssen (US Patent No 6,667,060).

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