



**STARCAP 1500®**  
CO-PROCESSED STARCH EXCIPIENT

Information Sheet  
STARCAP 1500®  
Properties

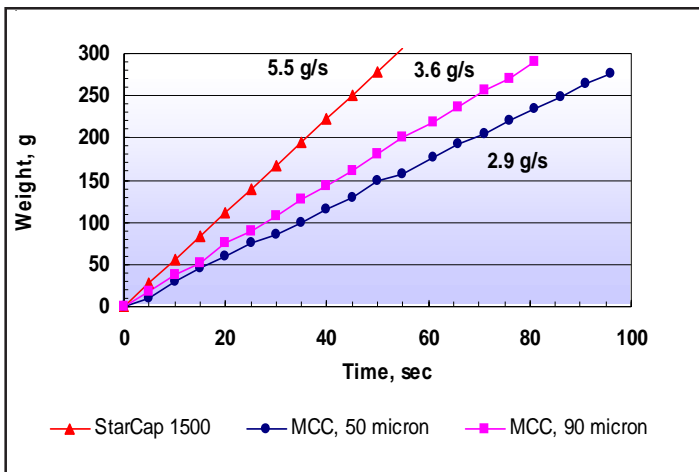
## Why STARCAP 1500® in capsules?

STARCAP 1500 is a unique co-processed mixture of globally accepted excipients, corn starch and pregelatinized starch designed for use in capsules and tablets. STARCAP 1500 is an inert free-flowing, low dust excipient with disintegration and dissolution properties that are independent of media pH.

### Flow

The flow properties of STARCAP 1500 are ideal for capsule filling applications. STARCAP 1500 flows smoothly with minimal dusting or adherence to contact surfaces. This corresponds to a cleaner filling operation with lower variation in capsule weight.

**Figure 1. Flowability of STARCAP 1500 & Microcrystalline Cellulose**

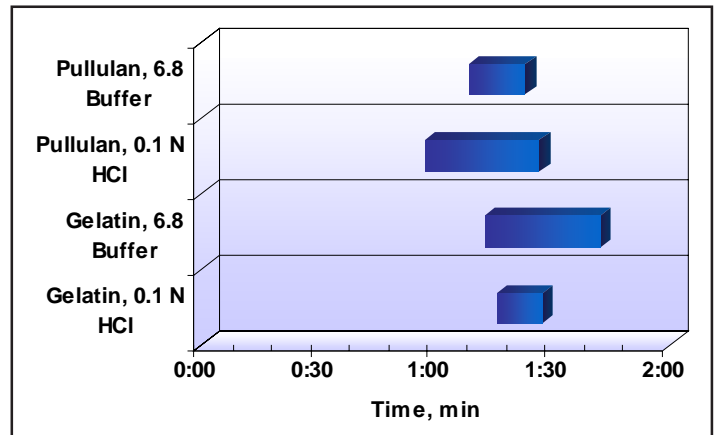


SOTAX FT 300, Vibration Setting: 1.7g (acceleration of gravity)

### Disintegration/Dissolution

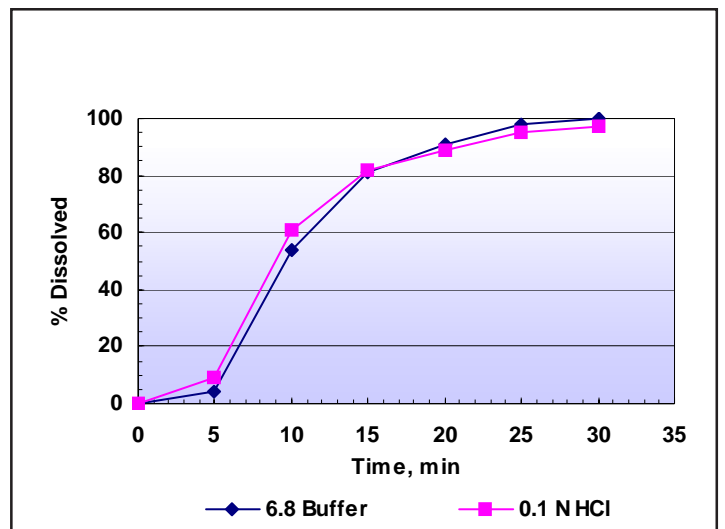
At high (>75%) usage levels of STARCAP 1500 in the formulation, disintegration time and drug dissolution rate are independent of media pH leading to consistent drug release profiles in-vivo.

**Figure 2. Capsule Disintegration Time: 20% Propranolol HCl: 80% STARCAP 1500**



STARCAP 1500 is compatible with two pH independent capsule materials (gelatin and pullulan).

**Figure 3. Capsule Dissolution Rate: Gelatin Capsules, 25% Propranolol HCl : 75% STARCAP 1500**



All capsules were size 1, 95% confidence intervals shown for disintegration time, 6 capsules.



## Encapsulation Properties

Encapsulation trials were run on an IMA Imatic 200 high speed, continuous movement, dosator encapsulation machine. The Imatic was set to produce 100,000 capsules per hour. STARCAP 1500 was the sole component used in filling the capsule shells. The capsule size used in this evaluation was size 1. The filling weight was maximized and resulted in an average fill weight of 380 mg per capsule. Weight variation was monitored over a 30 minute period taking samples approximately every minute.

The range of fill weight produced was 363 - 392 mg. The relative standard deviation of the fill weight was 1.2%. This low variation at high speeds shows STARCAP 1500's excellent encapsulation properties on production scale equipment.

## Stability

Manufactured in a cGMP facility dedicated to the pharmaceutical industry and supported by a team of technical experts, STARCAP 1500 exhibits good physical, chemical, and microbiological stability.

**Table 1.**

Variable	Time Zero	30°C/65% RH			40°C/75% RH		
		1 month	3 months	6 months	1 month	3 months	6 months
Bulk Density (g/cm <sup>2</sup> )	0.47 ± 0.01	0.47 ± 0.01	0.47 ± 0.01	0.45 ± 0.01	0.46 ± 0.01	0.45 ± 0.01	0.44 ± 0.01
Moisture* (%)	8.9 ± 0.3	9.2 ± 0.3	9.5 ± 0.4	9.9 ± 0.5	9.7 ± 0.1	10.6 ± 0.2	11.5 ± 0.2
Flowability* (g/sec)	5.6 ± 0.5	5.6 ± 0.2	5.4 ± 0.5	5.3 ± 0.2	5.1 ± 0.3	4.5 ± 0.3	4.4 ± 0.3
Dispersion pH (20% solids)	5.4 ± 0.3	5.5 ± 0.3	5.4 ± 0.2	5.4 ± 0.3	5.6 ± 0.3	5.4 ± 0.3	5.4 ± 0.3
RVA Peak Viscosity (% Relative to Time Zero)	100 ± 2.0	97 ± 2.0	97 ± 5.0	97 ± 6.0	96 ± 1.0	97 ± 5.0	96 ± 3.0
Microbiological Burden**	Pass	Pass	Pass	Pass	Pass	Pass	Pass

\* Moisture and flowability are related. Moisture uptake can be minimized by keeping product in recommended storage conditions: tightly sealed container, below 30°C (86°F). Moisture uptake is reversible.

\*\* Microbiological burden specification: Aerobic TPC < 100 cfu/g, Combined Mold & Yeast < 100 cfu/g, absence of *E. Coli*, *Coagulase Positive Staphylococcus*, *Pseudomonas aeruginosa*, & *Salmonella* species

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Humacao, Puerto Rico	787-852-3815	787-852-0030	Shanghai, China	86-21-5442-2222	86-21-5442-2229
			Goa, India	91-832-288-3434	91-832-288-3440
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Barcelona, Spain	34-9-3589-3756	34-9-3589-3792	Santa Fe, Mexico	52-55-3000-5700	52-55-3000-5701&02

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