Evaluation of a Novel Modified Starch Polymer as a Gelatin Replacement in Soft Capsule Shells

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INTRODUCTION

- Gelatin is well known for soft gel capsule formulation.
- However in recent years there was a great interest in developing gelatin free capsules for various technical (crosslinking of gelatin), economical, cultural and health reasons. Furthermore gelatin replacement has a great significance for vegetarians and religious groups.
- To obtain the required rheological film properties suitable for softgel capsules, a non-GMO pregelatinized hydroxypropyl pea starch with an optimum amount of amylose, named LYCOAT® RS780 was tested and compared with HP corn and HP potato starch.
- The film forming formula consists of a combination of starch (pea, corn, potato) with carrageenan, plasticizers and water.
- The combination of the two hydrocolloids leads to a synergistic interaction that produces a gel network resulting in a film suitable for soft capsule encapsulation.

PURPOSE:

1. To compare the influence of different sources starches (pea, corn, potato) functionalities on softgel capsules encapsulation properties.
2. To evaluate the critical parameters required for manufacturing softgel capsules:
   - Solution viscosity,
   - Film strength and elasticity,
   - Capsule attributes.
3. Capsules: Dissolution profile studies.

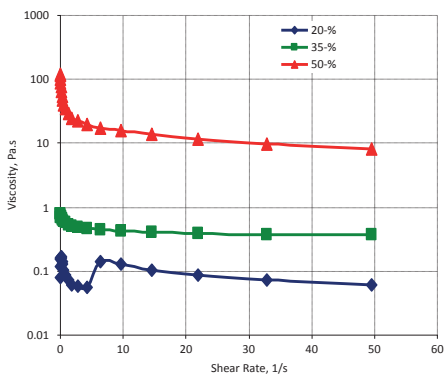
MATERIALS & METHODS

- A full factorial design of experiment (2x2) was employed to evaluate the effects of starch/carrageenan and plasticizers on the functionality of starch films.
- The film forming hydrocolloid mixture was incorporated in the plasticizer solution (Glycerin, Sorbitol syrup) under continuous mixing and then heated (up to 80 °C) →The Gel mass is then cooled and grinded into granules → Gel granules are re-melted and extruded into ribbons and fed into encapsulation machine → After filling and sealing the formulation the resulted capsules are dried at the ambient conditions.
- Rheological and mechanical properties of the film (Young Modulus, Elongation at break and Tensile strength) were measured using a rheometer and a texture analyzer.
- Starch solutions viscosities at various concentrations (20%, 35% and 50%) were evaluated with AR1000 Rheometer (TA Instrument) at 60 °C and 0 – 50 s-1 shear rates.
- Capsule Burst Strength and Elasticity Evaluation:
  - Capsules made with different starches were tested for burst strength using Texture,
  - Analyzer with a 1.0” cylindrical probe,
  - Probe moved at 1.0mm/s until capsules were broken,
  - Maximum force is called burst strength; maximum distance is defined as elasticity.

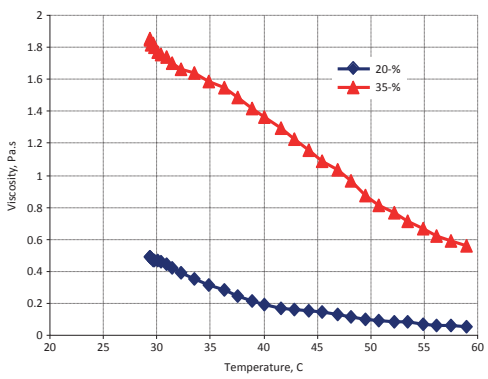
RESULTS & DISCUSSION

Viscosities as Functions of Starch Concentration

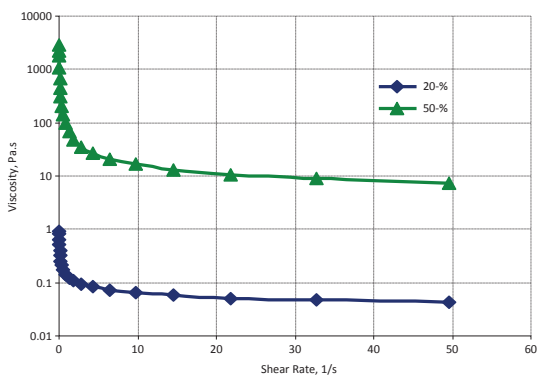
Pea Starch: Viscosity vs. Shear Rate at 60°C.



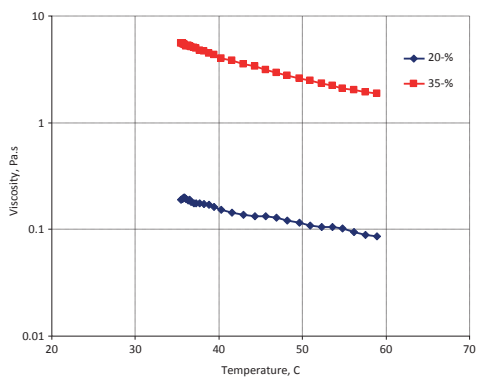
Pea Starch: Viscosity vs. Temperature.



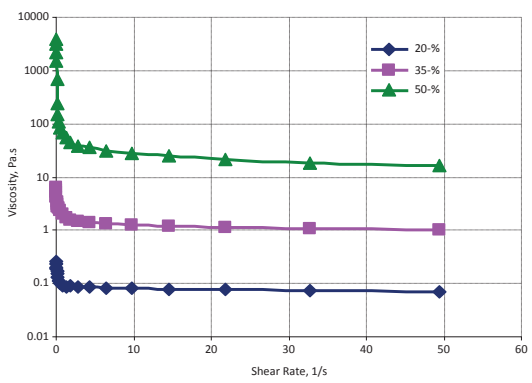
Corn Starch: Viscosity vs. Shear Rate at 60°C.



Potato Starch: Viscosity vs. Temperature.



Potato Starch: Viscosity vs. Shear Rate at 60°C.



Viscosity Comparison.

Starch	Viscosity (Pa.s)		
	20%	35%	50%
Pea	0.073	0.544	30.4
Potato	0.093	1.68	54.72
Corn	0.136	8.748	72.63

Film Strength and Elasticity Comparison.

Starch	Strenght (Newton)	Elasticity (mm)
Pea	24.1	30.6
Corn	21.5	42.7
Potato	26.3	48.7

Capsule Burst Strength and Elasticity Comparison.

Starch	Burst Strenght (Newton)	Elasticity (mm)
Pea	288.8	4.9
Corn	167.6	4
Potato	178.6	3.2

Capsule Dissolution Studies.

Starch	Dissolution Media	Rupture Time (min)
Corn	0.1N HCl	20.0
	DI Water	8.7
Pea	0.1N HCl	36.7
	DI Water	23.7

Pea Starch Soft Capsules.

Capsule Burst Strength and Elasticity as a Function of Sealing Temperature.

Starch	Temperature (°F)	Burst Strenght (Newton)	Elasticity (mm)
Pea	245	289.1	4.5
	250	241.1	4.9
Corn	190	131.7	3.4
	200	156.6	3.6
	210	158.3	3.8
	220	173.4	4
	225	174.4	3.9
	230	167.7	4

- Pea and potato HP starches produced clear and shiny films and capsule with good mechanical strength and elasticity.
- Pea starches compared to corn starch produced films with improved clarity, mechanical strength and elasticity, which resulted in softgel capsules with excellent clarity and superior physical integrity.
- Starch solutions viscosities increased dramatically with starch concentration increase.
- Starches viscosities decreased almost linearly as a function of temperature increase.
- Pea starch had the lowest viscosity at all concentrations allowing to increase the dry substance without affecting the viscosity values.
- Pea starch capsules required higher sealing temperature due to its high amylose content.
- Pea starch capsules dissolving time is longer than corn starch capsules due to high sealing temperature.

CONCLUSION

- All three starches can produce acceptable soft capsules.
- Capsules made with pea starch had higher burst strength and elasticity.
- Starches as film former materials can provide alternatives to gelatin for softgel capsules industry.