



LYCAGEL™

UNLOCKING NATURE'S POTENTIAL

Introducing LYCAGEL™

A Vegetarian Softgel Solution for Nutraceutical Supplements and Pharmaceutical Drug Products

INTRODUCTION

Gelatin-based softgels have long-standing acceptance for nutraceutical supplements and pharmaceutical drug products. Gelatin has excellent properties for softgels, including requiring few ingredients needed to form a strong capsule film.

However, gelatin is animal-derived and exhibits crosslinking and incompatibility issues with fill ingredients that can shorten softgel shelf life. At the same time, consumers for a variety of reasons, including vegetarians and vegans, are demanding companies use non-animal derived ingredients. That presents a challenge for supplement and drug product companies to replace gelatin-based softgel formulations and their manufacturing processes.

To meet this challenge, Roquette, a leader in plant-based nutritional and functional ingredients, has developed a veggie-based softgel formulation and process that has the following potential benefits, aside from being appealing to health and diet conscious consumers:

- ✓ **Adaptable to existing rotary die gelatin softgel manufacturing processes with minor modifications**
- ✓ **Pharma excipient grade availability for drug product (OTC, Rx) softgel applications**
- ✓ **Strong and durable capsules with seal integrity to avoid leaker defects**
- ✓ **Reproducible and capable of fills in different capsule sizes and shapes**

ROQUETTE'S VEGGIE SOFTGEL SOLUTION

Roquette has developed a formulated system for aqueous veggie softgel manufacturing that contains the following functional ingredients:

- 1. Modified pea starch (film-forming agent)**
- 2. Carrageenan (setting agent)**
- 3. Plasticizers (nutra use approved)**
- 4. Other minor ingredients (e.g., gelling aids and buffer)**

Roquette's solution leverages patented technology for manufacturing a modified pea starch composition that is high in amylose content. This enables the desired film-forming performance of Roquette's veggie softgel solution.

Roquette can provide system components or a convenient premix for proof-of-concept R&D work. In addition, Roquette provides formulation, gel mass preparation and process (e.g., equipment, temperature, pressure control) know-how as part of a technical service package offering to support customer trials and adoption.

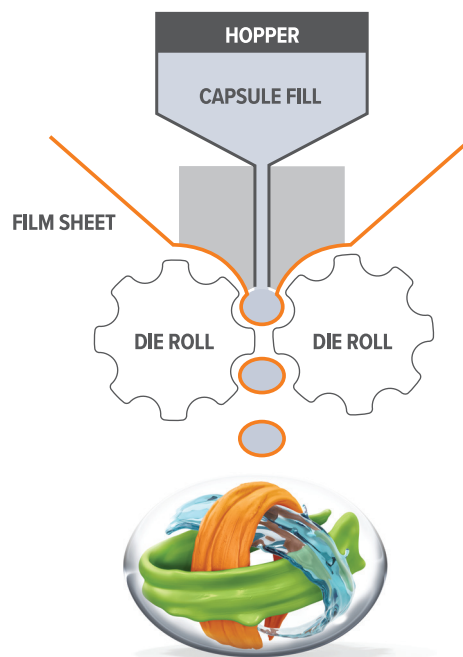
Performance data

Capsules were prepared using a pilot scale rotary die softgel encapsulation machine. The machine and feed equipment were modified to accommodate the Roquette starch-based formulation.

Process Parameters:

Film thickness	400-800 µm
Rotary die (1)	#10 oval production
Capsule fill (2), (3)	300 mg paraffin oil

- (1) Also demonstrated with #6 & #12 oval and oblong
- (2) Fills are 60-70% compared to gelatin capsules, typical of starch-based soft capsules
- (3) Also successfully encapsulated with stability testing in progress: omega-3 and in combination with vitamin D3



Results after drying capsules show acceptable initial structural integrity and disintegration as well as performance stability upon aging:

Properties	Test method	Results at time zero	Results at 6 months, 25%/60% RH (blisters)	Results at 6 months, 40%/75% RH (blisters)
Appearance	Visual inspection	<ul style="list-style-type: none"> • Clear and transparent • Absence of leakage • No sticking together 	No change	No change
Hardness test	Texture analyzer	30.9 N	19.1 N	4.1 N
Perforation test	Texture analyzer	4.9 N	2.3 N	1.7 N
Disintegration time	Disintegration apparatus	3 min	5 min	8 min
Water content	Moisture analyzer	6.3 %	5.8 %	18.8 %

FOR INFORMATION, CONTACT

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