



***NIPcaps***<sup>TM</sup>  
*Non-animal Polymer Capsules*



**CAPSUGEL®**  
Quality  
People and Products Working Together™

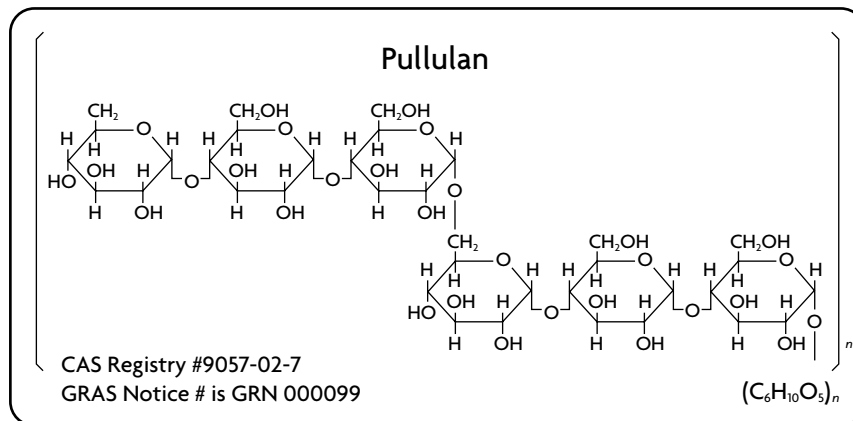
# When you require a non-animal capsule, nothing performs like NPcaps™ capsules

To support non-animal formulation initiatives, as well as address patients' dietary and cultural requirements, Capsugel is proud to introduce NPcaps™. Made from pullulan, NPcaps offer similar stability, dissolution and disintegration, machinability, appearance and dimensions as our Coni-Snap® gelatin capsules.



## Pullulan properties enable gelatin-like performance

Pullulan is a water-soluble polysaccharide that is very stable and well characterized, and has been used as a food additive for decades. Produced from corn through a fermentation process, it is non-cross-linking and has wide regulatory acceptance and a proven safety record. It is also suitable for diabetic patients as well as those on restricted diets, as it is minimally digested in the upper GI tract before breaking down in the large intestine.



### ▶ NPcaps™ meet the requirements and preferences of your entire development team for all new and existing formulations

#### ▶ FORMULATORS

Non-cross-linking • well characterized • compatible with current excipients and assays • gelatin-like dissolution

#### ▶ MARKETING

Elegant gelatin-like luster • non-animal product • meets dietary and cultural needs of patients

#### ▶ MANUFACTURING

Gelatin-like performance • runs on existing filling equipment

#### ▶ REGULATORY

Proven safety record • wide regulatory acceptance

#### ▶ CLINICIANS

Patient compliance assured



# NPcaps offer numerous performance advantages with no cross-linking issues

## Chemical Stability

- Non-cross-linking
- Compatible with all major excipients, including: lactose, maize starch, sorbitol, magnesium stearate, pre-gelatinized starch, microcrystalline cellulose and carboxymethylcellulose

## Mechanical Stability

- Similar to gelatin, moisture control assures flexibility of the capsule shell
  - Studies show 0% broken capsules at standard manufacturing conditions (50% RH)

## Dissolution

- *In vivo* studies confirm that disintegration occurs quickly in the stomach, similar to gelatin
- *In vitro* studies with acetaminophen closely match the dissolution profile of gelatin across the entire pH range

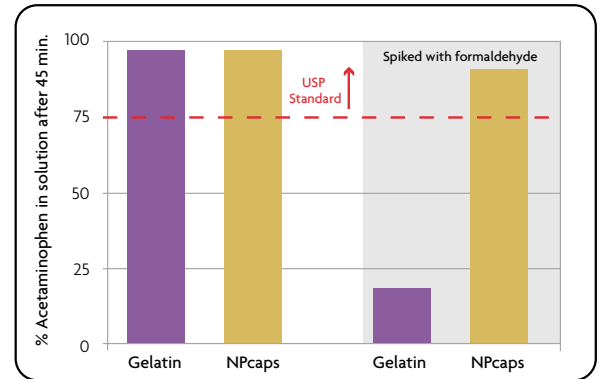
## Machinability

- NPcaps capsule dimensions are identical to gelatin
- Machinability tests have been successfully conducted with major CFM manufacturers

## Appearance

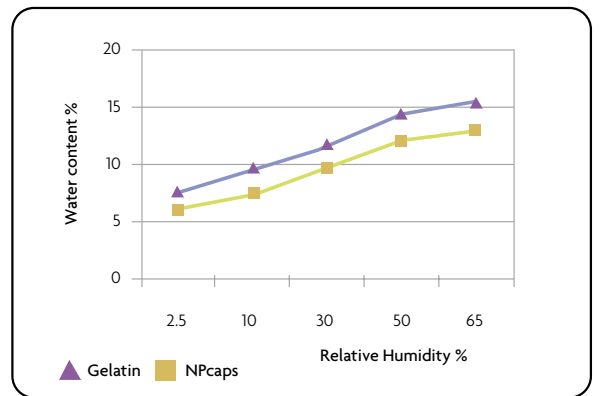
- Side by side, gelatin and NPcaps are virtually identical and utilize similar colorants
- To assure patient compliance, NPcaps capsules match the look and feel of gelatin, with the same lustrous sheen and smooth capsule surface

## CHEMICAL STABILITY

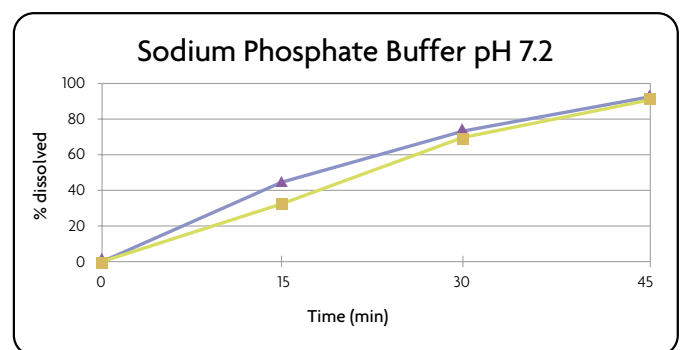
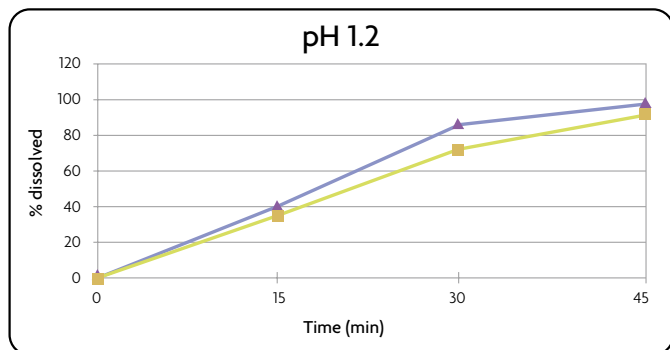
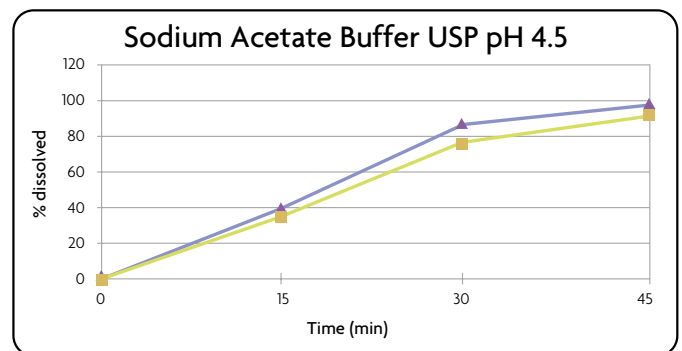
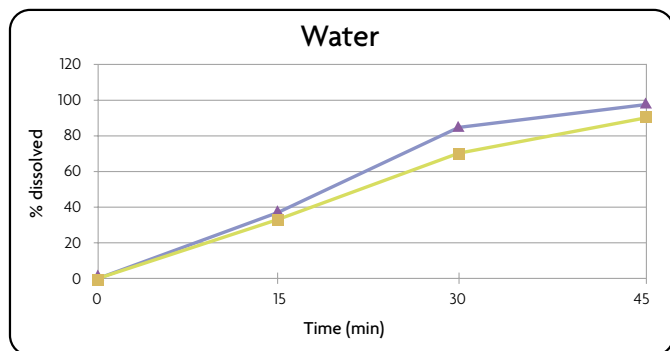


Dissolution of NPcaps is unaffected by inclusion of a known cross-linking agent (formaldehyde). *Test protocol: capsules filled with lactose and stored in closed bottles for 3 months at room temperature. USP Apparatus II; water medium. (n=6)*

## MOISTURE CONTENT



## DISSOLUTION PROFILES



Dissolution of NPcaps is similar to gelatin at various pH levels. *Test protocol: capsules filled with unformulated acetaminophen. USP Apparatus II, 50 rpm, 900 ml fluid @ 37°C with buffers as indicated.*

▲ Gelatin ■ NPcaps

## NPcaps Composition

NPcaps utilize carrageenan as a gelling agent and potassium chloride as a gelling promoter.

## NPcaps Dimensional Specifications\* (other sizes available upon request)

SIZE	00	0	1	2	3	4
<b>Weight</b>						
Mg	118	96	76	63	50	40
<b>Capacity</b>						
Capsule volume ml	0.91	0.68	0.50	0.37	0.30	0.21
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Powder density	Capsule capacity mg					
0.6 g/ml	546	408	300	222	180	126
0.8 g/ml	728	544	400	296	240	168
1 g/ml	910	680	500	370	300	210
1.2 g/ml	1092	816	600	444	360	252
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<b>Length of the capsule parts (body and cap)</b>						
Body inches	0.796	0.726	0.654	0.601	0.535	0.480
Body mm	20.22	18.44	16.61	15.27	13.59	12.19
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Cap inches	0.462	0.422	0.385	0.352	0.318	0.284
Cap mm	11.74	10.72	9.78	8.94	8.08	7.21
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<b>External diameter</b>						
Body inches	0.322	0.289	0.261	0.239	0.219	0.199
Body mm	8.18	7.34	6.63	6.07	5.57	5.05
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Cap inches	0.336	0.300	0.272	0.250	0.229	0.209
Cap mm	8.53	7.64	6.91	6.35	5.82	5.32
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<b>Overall closed length</b>						
Inches	0.917	0.854	0.765	0.709	0.626	0.563
mm	23.3	21.7	19.4	18.0	15.9	14.3

\* As specifications are under continuous review, be sure to contact Capsugel for the most up-to-date technical information.

**A proven track record of commercial viability assures you that NPcaps are ready for full-scale production runs. For further information, contact your sales representative.**  
[www.capsugel.com](http://www.capsugel.com)

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