

## Application note

### Probiotic stability

## DRcaps™ capsules, the new vegetarian capsule for the food supplements market with acid-resistant features

### Purpose

Probiotics play an important role in the immunological, digestive and respiratory system of humans and animals. However, there are some challenges to delivering probiotics, such as:

- Some strains have a sensitivity to moisture that requires extra protection
- Premature activation causes a loss of viability prior to ingestion
- Optimal effectiveness over time requires a long shelf-life

Some strains of probiotics are also especially sensitive to the low pH conditions in the stomach and must survive through gastric and bile acids to reach the gastrointestinal tract to be most effective.

To address these challenges, Capsugel created DRcaps™ capsules, an innovative dosage form composed of hypromellose.

Capsugel's DRcaps™ capsules also have a low moisture content, making it an ideal oral dosage container for moisture sensitive or hygroscopic food supplement ingredients.

The main objective of the In Vitro gastric model measurement below is to confirm that probiotics powder filled in DRcaps™ capsules will survive gastric conditions and are released in the intestinal fluid.

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### Conclusions

- The In Vitro gastric model measurement confirmed that DRcaps™ capsules protect probiotics from acidic conditions and would permit their survival and delivery to the intestine.



## Methodology

Probiotics stability	
Dosage forms	DRcaps™ capsules
Fill	Capsules are filled with a (Bifido bacterium) probiotic strain
Analysis performed	<p>Capsules are immersed for one hour in pH 1.2 buffer followed by three hours at pH 6.8 buffer.</p> <p>The dissolution media are described hereafter:</p> <ul style="list-style-type: none"> <li>The stomach medium consisted of 2 g/L NaCl, 3,2 g/L Pepsin and 7mL/L HCl (37%), resulting in a final pH of 1.2</li> <li>The small intestinal medium consisted of 3 g/L bile salts (oxgall), 0.9 g/L Pancreatin and a sufficient quantity of NaOH to achieve a final pH of 6.88.</li> </ul>
Period	T=0, 30 min, 60 min (at Ph 1,2), 120 min, 180 min and 240 min (at Ph 6,8)

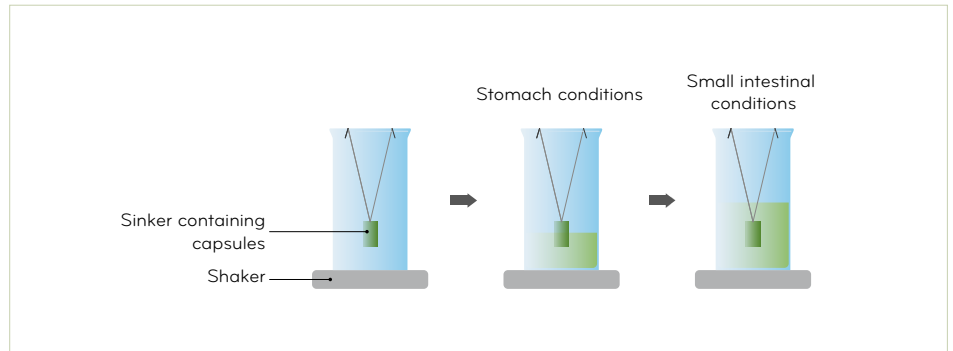


Figure 1: General concept of the screening assay to study the intestinal fate of probiotic capsules

## Results

### DRcaps™ capsules Probiotics Stability Profile

Probiotics filled in DRcaps™ capsules passed the gastric fluid and probiotics were delivered to the intestinal fluid.

\*No probiotic presence measured in media for 1 h

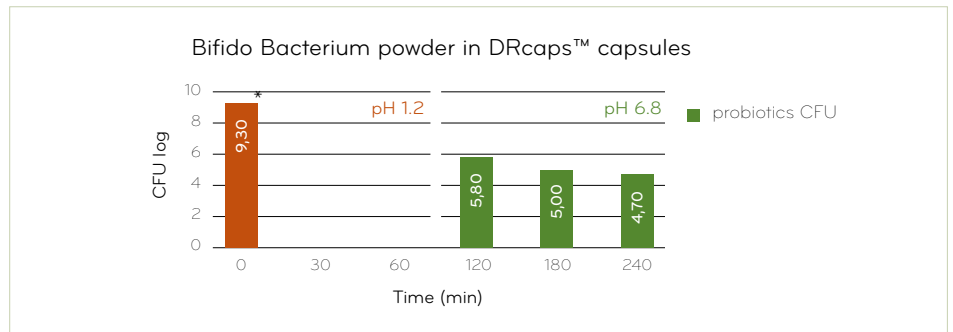


Figure 2: DRcaps™ capsules Probiotics stability profile

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#### Disclaimer

The information in this leaflet is not intended to be used as a claim. It is the responsibility of the customers to check with the current regulations in their respective countries.

#### More information?

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