Protection of probiotics filled in non coated DRcaps™ acid resistant Hypromellose capsules

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Purpose

The aim of the study was to document the protection of probiotics filled in gelatin hard capsules and DRcaps™ acid resistant Hypromellose hard capsules without coating.

Methods

The different types of capsules were filled with a probiotic strain and incubated under standardized simulated stomach and small intestine conditions by ProDigest.

Samples collected at different time points were evaluated for their concentration of viable bacteria. Additionally, the remaining integrity of the capsules was visually checked at each sampling time.

All experiments were performed in triplicate in a temperature controlled continuously mixed reactor.

In the reactor, a sequential simulation of the stomach and small intestine conditions was performed by using appropriate medium composition and pH.

The setup used in this experiment applied extreme intestinal conditions, occurring under fasted conditions.

The stomach medium consisted of 2g/l NaCl, 3.2g/l Pepsin and 7ml/l HCl (37%) resulting in pH 1.2.

The small intestinal medium consisted of 3g/l bile salt (oxgall), 0.9g/l Pancreatin and sufficient quantity of NaOH to achieve pH6.8.

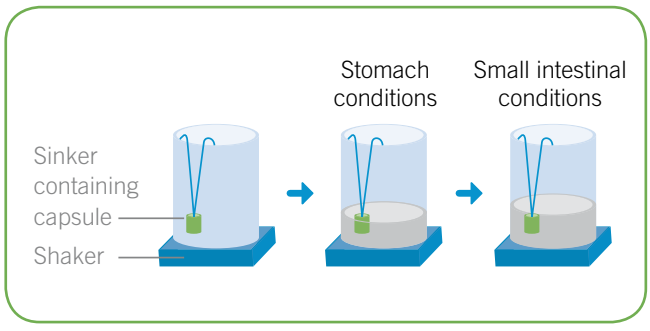

Fig. 1: General concept of the screening assay to study the intestinal fate of probiotic capsules

Evaluation of the survival of the probiotics strain upon release from the capsules was performed by sampling in the media using plate counting in combination with an appropriate growth medium.

To perform the study Bifidobatcterium longum was used as model probiotic.

Sampling plan

MEDIA	SAMPLING POINTS (MIN)					
	0	30	60	120	180	240
pH 1.2	✓	✓	✓			
pH 6.8				✓	✓	✓

Table1: overview of the experimental design

The remaining integrity of the capsules was visually checked at each sampling time and scored from 1 to 4, with 1 being completely intact and 4 being completely destroyed.

Results

The results are expressed as total amount of viable counts in the sampled medium from the experiments.

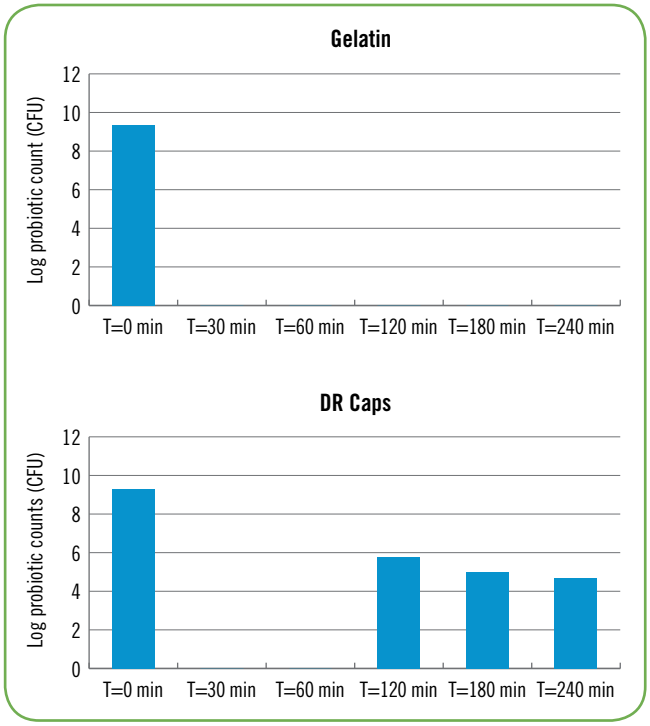

Fig. 2: Quantification (Colony Forming Units) of the viable counts of probiotics strains at the start of the experiment and at specific sampling points

CAPSULES	VISUAL SCORES OF THE CAPSULES TIME IN MINUTES				
	30	60	120	180	240
Gelatin	4	4	4	4	4
DRcaps ™	1	2	3	3	3

Table 2: visual inspection of the integrity of the capsules at the different sampling times.

Conclusions

In this experiment, we compared the use of gelatin and DRcaps™ acid resistant Hypromellose hard capsules for the intestinal delivery of probiotics.

Whereas classical gelatin capsules disintegrated under the simulated stomach conditions, DRcaps™ capsules with their gastric acid resistance allowed to overcome the stomach conditions.

Avoiding exposure to stomach conditions with the DRcaps™ capsules led to the detection of higher counts of viable probiotics in the simulated small intestinal conditions.

We therefore confirmed the protection of probiotics when filled in DRcaps™ acid resistant Hypromellose hard capsules without coating.

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