Stability by Microencapsulation – A novel formulation for long term preservation of Probiotics

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INTRODUCTION

Probiotic ingredients are nowadays used for a wide range of health benefits, many of those can be shown in studies to have good health effects on the end user. It is possible to buy probiotic food and nutraceuticals, as well as pharmaceuticals in pharmacies and supermarkets all over Europe. However, the health benefit of those available products is very much depending on the time of use, as those contain free and untreated probiotics, that tend to degrade over time of transport and storage. Pharmaceutical products containing probiotics have often to be stored at last refrigerated, in some cases even deep frozen. That adds a lot of costs to transport and storage and renders a product inconvenient for the user. To overcome those drawbacks, new ways of delivering probiotics have to be found.

In the past years, microencapsulation was used to produce stabilized particles with probiotics. However, those formulations had a low yield in the encapsulation performance – meaning the finally entrapped probiotics in comparison to the probiotics used for producing the particles –, the transport and storage stability was not increased much over the natural form and the release in the intestine, where the probiotics are finally active, was not clearly controllable. The transport and storage stability is – besides the inconvenience for the customer – just a miner issue in highly developed countries as western Europe. However, in countries as Africa or India, and also in China or South-East Asia, where temperatures often reach 40°C and more, temperature stability is an issue. As long as not even the stability of the production between purchase and home use can be guaranteed or if the truck transport is uneconomically expensive when using cooling trucks, those countries cannot be targeted.

This shows clearly the need for new formulations that solve those issues and provide a high encapsulation rate, easy transport and storage as well as controlled release properties.

The first step to achieve this formulation, jointly developed by Vesale Pharma and Brace, was the use of the BRACE Microencapsulation processes. Those are extrusion processes that produce Microspheres or Microcapsules, i.e. matrix- or core-shell-encapsulated formulations, with a very narrow size distribution. As a very wide range of shell materials can be used, those processes are extremely flexible and can be used to generate particles in a diameter range of ca. 20 – 10000µm. Henceforth, the active material that will be encapsulated can be supplied as a formulation optimized to the application. As additional advantage, these processes are cost efficient and easy to use, can therefore be deployed in many different labs and production facilities all over the world.

MATERIALS AND METHODS

In this comparative study a commercial available *Bifidobacterium lactis 300B* was encapsulated with to show a strongly prolonged high temperature stability as well as a high encapsulation efficiency. The encapsulation was performed by using BRACE vibrational nozzle processes at the BRACE laboratory.

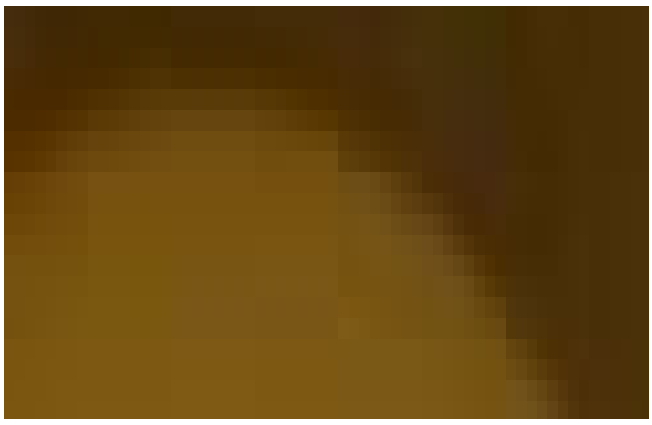
The materials that have been used for encapsulation were a commercially available alginate BR-GM, two experimental starches BR-07 and BR-08 (BRACE), Dextrin (Sigma), CMC (Dow Chemical), HPMC (Harke Pharma), Microcrystalline Cellulose (Rettenmayer) and Polymaltotriose BR-P (BRACE). The alginate was always the base (1.5 wt%) and the other materials were used as filler materials.

Table 1 : Samples prepared

1.5 % BR-GM	Filler 1.5%
Sample A	HPMC
Sample B	CMC
Sample C	Microcrystalline Cellulose
Sample D	Starch BR-07
Sample E	Starch BR-08
Sample F	Dextrin
Sample G	Polymaltotriose BR-P

RESULTS AND DISCUSSION

The preparation of the particles was performed with a Spherisator M and Spherisator L device. With the recipes it was possible to produce uniform Microspheres with a very tight size distribution (figure 1).



It could be shown that it was possible to encapsulate with all filler materials at high encapsulation efficiency the bacterias.

The produced Microspheres were freeze dried and the cell count was measured. Here it could be shown that the highest survival rate was achieved with BR-P as filler.

After the encapsulation the samples were stored at 4°C and 22°C. The survival rate was regulary. Only the two best samples A and G were investigated.

It was found that the sample G with BR-P as a filler had the highest survival rate during the controlled period at room temperature (figure 2). At elevated temperature (40°C) the survival rate stayed almost identical (data not shown, [3]).

Figure 2: Survival at 22°C

CONCLUSION

This development shows that the newly developed formulation is far advanced and more relyable as currently commercially available probiotic formulations. Especially the temperature and high temperature stability is given and significantly increased.

This new formulation is already introduced into the market and commercialised [Pat 2011, Pat 2012], however, the development continues to optimize temperature stability further, reduce loss during processing and drying as well as the adaptation for new and different strains of probiotics.

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REFERENCES

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