LactoCran: A fruitful synbiotic with functional advantages

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INTRODUCTION

The word probiotic has been relatively newer from its original use, which dates back to ancient civilization where people first discovered the health benefits of sour milk. Since then probiotics have been recognized for supporting healthy digestive systems and treating intestinal illnesses such as traveler diarrhea, constipation, etc. Human history, if closely followed, will reveal that research focus oscillated between probiotics and antibiotics.

Much emphasis was put on the research of antibiotics in the late 19th century as antibiotics were deemed as a savior from diseases like the plague. By 20th century an exponential increase in antibiotic research was observed, especially during World War II (1). Overuse of antibiotics and subsequent resistance it builds in pathogens was realized and we naturally went into battle mode creating more powerful antibiotics that could overcome resistant strains. While this approach killed most resistant bacteria, it did not spare the beneficial ones either. Plenty of research occurred in the early part of the 20th century through efforts of Élie Metchnikoff who undertook the work of exploring the use of probiotics at therapeutic levels, i.e. treating diseases. His observation that replacing the putrefactive bacteria in the gut with lactic acid bacteria could normalize the bowel movement and health, forms the basis of probiotic therapy today (2).

With time, the probiotic industry has grown into one of the top five segments in dietary supplement industry and with a CAGR of 6.2, it is expected to reach US$ 36 billion by 2018, as per market research report from BCC Research group.

By definition, the term probiotics should be used only for live micro-organisms which have documented health benefits when administered (3).

Cranberry
Lacto-CRANdOr™
Probiotic

There are many reasons or factors for this healthy growth. Clinical research into use of probiotics in managing health issues related to the gut and other external factors, brought focus to the benefits previously unknown to man. Today we are looking at exploring the gut-brain axis and gut-brain-muscle axis. Still further, research is being focused on identifying specific strains of bacteria and their applications, along with innovation in delivery systems, which together has helped satisfy the consumers need for quick and easy solutions to good gut health.

While probiotics entered the consumer market, concerns were raised on their shelf life since a major drawback for most of the bacteria was the requirement for storage at low temperatures. This all time high interest in probiotics for health benefits and the hunger for new innovation in delivery systems, shifted the focus to a very special category of probiotics – spore forming lactic acid producing probiotics. Spore forming bacteria such as *Bacillus coagulans*, not only bring probiotic benefits recognized in ancient civilizations but bring the flexibility in choosing the delivery systems and storage at room temperature.

LACTOSPORE: PROBIOTIC OF CHOICE

One such probiotic is the branded and patent pending LactoSpore®, containing *Bacillus coagulans* MTCC 5856 which belongs to the group of spore forming lactic acid bacteria (SFLAB) (4). This probiotic strain (MTCC 5856) is manufactured at

Sabinsa's in-house Biotechnology facility in Bangalore, India. This cGMP audited facility, which also has a National Accreditation Board for Testing and Calibration (NABL) certified testing lab, handles exclusively the single strain of bacteria (MTCC 5856) and maintains purity of the strain with strict manufacturing and quality control. LactoSpore has several advantages over the non-spore forming bacteria including its ability to withstand harsh manufacturing conditions with minimum overages. These bacteria with their naturally coated or spore form are able to survive the low pH conditions existing in the stomach while transiting to the small intestine.

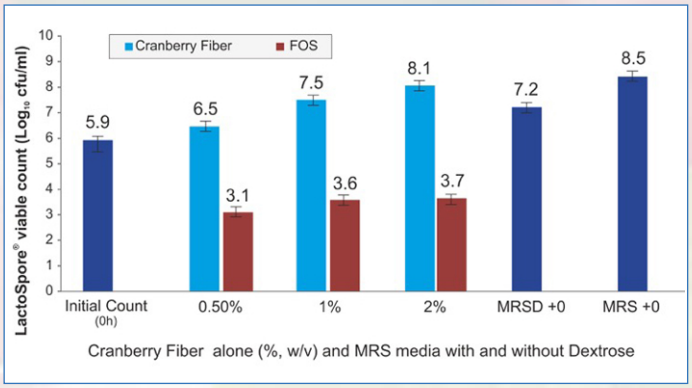

Figure 1 – Effect of Cranberry fiber alone and in MRS media with and without dextrose (MRSD) on the LactoSpore® viability.

GENESIS OF LACTOCRAN

While Sabinsa focused on its single strain of *B. coagulans* MTCC 5856 for its health benefits and has been engaged in several clinical trials, a team of scientists went to explore a new concept – creating unique tailor-made combinations of LactoSpore with a prebiotic providing nutritional requirements specifically for spore forming *B. coagulans* MTCC 5856.

It is a well established concept of prebiotics providing nutrition to gut bacteria and food with high fiber content since prebiotics have been consumed since ancient times, however the choice of the prebiotic can actually be very important for the overall probiotic growth and its functionality (5).

In order to create the specific prebiotic–probiotic combination using LactoSpore as the probiotic, scientists at Sabinsa screened several fruits and plant based fibers. The present research article is related to the use of cranberry seed powder as an effective prebiotic for the growth of LactoSpore.

THE STUDY

In this study, the cranberry seed powder from FruitD'Or was selected for its unique nutritional profile. FruitD'Or Nutraceuticals is one of the largest organic cranberry producers in Quebec area in Canada. The Cranberry seed powder obtained from organically grown cranberry contained 40-45% fiber content, 20-25% protein content along with 1-3% proanthocyanidins which are well known antioxidants and one of the important phytochemicals in Cranberry fruits. The *B. coagulans* MTCC 5856 culture was inoculated in cranberry seed powder as well as with Fructo-oligosaccharide (FOS) for comparison of their prebiotic strength. Inoculation was carried out on MRS media with and without dextrose.

The results of the study showed that the combination of LactoSpore and Cranberry seed powder was an excellent synbiotic combination, which showed healthy bacterial growth as seen in Figure 1 as compared to Fructo-oligosaccharides.

The combination LactoCran showed superior growth of the bacteria. While cranberry seems to be well known for its benefits in urinary health, the application of the cranberry seed powder as a prebiotic for *B. coagulans* is deemed to be novel and opens some new avenues for the use of synbiotic combinations containing *B. coagulans* MTCC 5856 and cranberry seed powder from FruitD'Or.

SYNBIOTIC COMPOSITION

This patent pending combination of the Cranberry seed powder and LactoSpore provides a first of its kind tailor-made synbiotic formulation. With longer shelf life stability at room temperature of both cranberry seed powder and LactoSpore, this product has a shelf life of 3 years at room temperature. LactoSpore is stable against low pH, heat and other manufacturing stresses making it a distinctive probiotic, which can be used in variety of formulations with room temperature stability. Keeping in mind the various formulation possibilities using this combination, LactoCran is available in powder form in two different strengths based on the dosage of the prebiotic and probiotic:

- LactoCran for Capsules / Tablets – LactoCran contains LactoSpore 2 billion spores and 750 mg of Cranberry seed powder. This combination can be formulated in both capsules and tablets for dosage ranging from 1-2 capsules twice per day.
- LactoCran for Milk Shake / Whey protein – LactoCran contains LactoSpore 2 billion spores and Cranberry seed powder 5 g per serving to be taken once or twice per day.

REGULATORY STATUS

LactoSpore, the probiotic organism in LactoCran, is a GRAS ingredient and can be formulated in variety of food based products in USA. LactoSpore is marketed as a probiotic dietary ingredient for nutraceuticals and functional foods in the European Union, Japan, USA, Korea, Australia, South Africa and Asian regions. Recently LactoSpore also received approval in Canada to be marketed as a Natural Health Product and also has obtained the NPN number there for the 2 billion dosage in tablet form.

FORMULATIONS

As a special synbiotic combination, LactoCran was added in a granola bar (Figure 2) for its potential health benefits. Granola is a breakfast food that consists of rolled out nuts, oats and honey. Value addition of probiotics to this nutritious breakfast meal with the addition of LactoCran helps to provide the probiotic benefits. Since LactoCran can be formulated in a variety of supplements as well, use of LactoCran in bulk protein powder providing the probiotic benefits as well as fiber to the gut will be of great interest. In recent times the role of probiotics in gut-brain-muscle axis has been much in focus as probiotic supplementation has produced benefits such as reduced frequency or duration of

Figure 2 – Granola bar with LactoCran.

GI tract and respiratory illnesses. LactoCran can play an important role in immune support products as probiotics have been well established to play an important role in immunity since mucosal membrane of the GI tract acts a first line of defense against pathogens (6).

SAFETY

Bacillus coagulans has been used since ages and in recent times has been part of several clinical trials in adults and in children, which have shown its probiotic benefits in several gut related conditions (7-9). Recently, Sabinsa Corporation completed two trials on safety and efficacy of their probiotic strength MTCC 5856. LactoSpore, a dairy free probiotic was studied for its safety as a dietary supplement / natural health product in Canada in a randomized double blind placebo controlled parallel phase I trial conducted by KGK Synergize, Canada. In this clinical trial 40 healthy subjects were randomized in two groups. The LactoSpore group was administered 2 billion spores per day in a single tablet once daily for 30 days and matching placebo to the other group. The consumption of LactoSpore was found to be safe without any harmful or adverse effect on supplementation (10).

CONCLUSION

As a synbiotic formulation, LactoCran provides flexibility to formulators in formulations and dosage designing. As a room temperature shelf stable synbiotic combination, containing GRAS affirmed probiotic strain *B. coagulans* MTCC 5856, LactoCran can be added in variety of formulations and functional foods. Its unique taste profile due to Cranberry seed powder does not require any taste masking excipients in food formulations. LactoCran as a synbiotic opens new avenues for probiotic delivery systems.

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