Probiotic Lactobacillus Lactospore®

Shelf-Stable Probiotic Lactospore®
Easy to use probiotic providing 15 billion *Lactobacillus sporogenes* spores (also called *coagulans*), stable. Activities are multiple, interacting for the whole body, including digestion, cholesterol management and health of the intestinal tract.

LactoSpore® is a lactic acid producing Bacillus preparation providing 15 billions of spores per gram.

After ingestion (medium for awakening), the spores revive and produce acid L (+) Lactic, with the positive action on other micro-organisms. Lacstospore is used in dietary supplements, in dairy products, bakery products, in tablets or vaginal ovules and in veterinary products.

Bacillus coagulans as a probiotic

Clinical studies have revealed that L. sporogenes can be successfully implanted in the intestine : it satisfies the essential requirements of an efficient probiotic. Preparations of L. sporogenes in pharmaceutical dosage forms such as tablets, capsules, dried granules or powder have the following characteristics:

Contain a large number of viable lactobacilli that retain viability during preparation in pharmaceutical dosage forms and during storage before consumption. The spores are thermostable as against viable L. acidophilus cells which may not withstand spray drying.

Survive in gastric secretions and bile of the upper digestive tract and reach the intestine safely.

Settle in the digestive tract and produce enough lactic acid and other antagonistic substances to inhibit the growth of pathogenic bacteria.

Being sporulated, they germinate under favorable conditions and produce sufficient viable cells which proliferate and perform vital healthful functions as described earlier. In addition, L. sporogenes spores are semi-resident and are slowly excreted out of the body (7 days after discontinuation of administration).

Clinical Studies

Different studies are available, and detailed on the website. We just mention few of them.

Gastro-intestinal and associated effects : administration of L. sporogenes markedly improved the general clinical condition of the subjects and provided relief from intestinal disorders and allergic skin conditions. Studies performed on patients suffering of gastro-intestinal disorders proved the efficacy on :

- Acute and chronic intestinal catarrh
- Diarrhea
- Constipation
- Abnormal intestinal fermentation
- Dyspepsia infantum
- Allergic skin diseases
- Etc...

Hypocholesterolemic effects : Total serum cholesterol, LDL-cholesterol and total cholesterol to HDL-cholesterol and LDL-cholesterol to HDL-cholesterol ratios ($p < 0.001$) was reduced significantly over a period of three months.

Non-specific vaginitis : increase the vaginal acidity by the action of the lactic acid (produced by Lactobacillus)

Veterinary probiotic (weight gain, feces)

Recommended dosage Stability

The daily recommended dose is 100 to 200 Million organisms per dose - 3 times daily, in tablets, capsules, chewable tablets, vaginal tablets or ovules, etc... Recommended dosage in feed and veterinary products are upon request.

Sabinsa has studied the heat stability at 90°C and 140°C (stability on viable count of Lactospore with high temperature) and the viable counts remain over 90% even after 150 sec at 90% or 30 sec at 140°C. **Virtually 100% of spores are revived**, one reason for the choice of Bacillus coagulans (sporogenes), and specific drying method. Spores will not grow during their action, and disappear by natural ways after working, hence the need for regular intake.

New Safety, Stability And Efficacy Studies Published

LactoSpore: Anti-diarrheal & Gastrointestinal motility study (International Journal of Pharma and Biosciences. 7 (1): 311-16. 2016)

The effect of Bacillus coagulans MTCC 5856 (LactoSpore) on castor oil induced diarrhoea and gastrointestinal (GI) motility using well established in vivo studies found LactoSpore exerted dose dependent anti- diarrhea activity and reduced the faecal output (33%). It also inhibited the gastrointestinal motility. The results suggested that LactoSpore possess significant anti-diarrheal activity and therefore could be a potential agent in the management of diarrhea.

LactoSpore in treatment of diarrhea predominant IBS study (Nutrition Journal.15:21. 2016)

A double blind placebo controlled multicentered trial was conducted to evaluate the safety and efficacy of LactoSpore in diarrhea predominant Irritable Bowl Syndrome (IBS) patients. Thirty-six newly diagnosed diarrhea predominant IBS patients were enrolled in three clinical centers. Along with standard care of treatment, 18 patients in group one received placebo while in group two, 18 patients received LactoSpore for 90 days.

The study concluded that LactoSpore along with standard care of treatment was found to be safe and effective in diarrhea predominant IBS patients for 90 days of supplementation. Hence, LactoSpore could be a potential agent in the management of diarrhea predominant IBS patients.

LactoSpore: Genetic and Phenotypic Consistency Findings (World Journal of Microbiology and Biotechnology 32:60. 2016)

That *B. coagulans* strain is stable over multiple years of commercial production was clearly demonstrated through this study designed to evaluate probiotic potential, in-vitro safety, product stability, genetic and phenotypic consistency of the probiotic strain used for production of LactoSpore. Phenotypic and genotypic studies proved that the commercial preparations of LactoSpore contained the same strain of B. coagulans MTCC 5856 over multiple years of commercial production. B. coagulans MTCC 5856 strain showed probiotic potential and found to be non-mutagenic, non-cytotoxic, negative for enterotoxin genes and stable at ambient temperature (25 ± 2°C) for 36 months. Findings of this study provide confidence to use B. coagulans MTCC 5856 as a probiotic ingredient in various dietary and functional foods and health products.

LactoSpore Safety Study (Journal of Clinical Toxicology 6: 283. 2016)

A Double-Blind, Placebo-Controlled, Parallel clinical trial was conducted to evaluate the Safety and tolerability of B. coagulans MTCC 5856 at a dose of 2 billion spores per day in healthy adults. Safety and tolerability of B. coagulans MTCC 5856 was assessed over 30 days by safety laboratory parameters (blood hematology and clinical chemistry parameters), anthropometric measures (weight, BMI, blood pressure and heart rate), adverse events, Bristol stool score, tolerability questionnaire and bowel habit diary.

LactoSpore has recently obtained the approval as Natural Health Product (NHP) that allows formulators and marketing companies to market LactoSpore in Canada as NHP. This approval renders Canadian market readily accessible by US and Canadian marketing companies. Pre-approved NHP ingredients can reduce the review period of Product license application in Canada, where a pre-market approval system precedes actual marketing. LactoSpore's approval in natural health products in Canada is also supported by Sabinsa's Utah facility, a registered foreign site for manufacturing the NHP for the Canadian market.

FOCUS HINTS