

SABINSA NEWS RELEASE

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SABINSA'S SHELF STABLE PROBIOTIC LACTOSPORE® FOUND TO REVERSE DEPRESSION SYMPTOMS IN PATIENTS SUFFERING FROM IBS ACCORDING TO PUBLISHED STUDY

East Windsor, NJ (July 30, 2018) – A clinical study conducted in India and published in the peer reviewed journal *Food & Nutrition Research* reported that adults with irritable bowel syndrome (IBS) showed improvement from co-existing depression when they took a probiotic strain *Bacillus coagulans* MTCC 5856 (2 billion spores per day); subjects of the study given a placebo did not report the same improvement.

This study, *Bacillus coagulans* MTCC 5856 for the management of major depression with irritable bowel syndrome: a randomised, double blind, placebo controlled, multi-centre, pilot clinical study, published in *Food & Nutrition Research*, provides evidence of clinical



efficacy of *B. coagulans* MTCC 5856 in patients experiencing major depression symptoms with IBS and supports the hypothesis that the modification of microbial ecology in human gut by supplementing probiotics may be an alternative strategy to ameliorate or prevent depression. The study demonstrates that consumption of probiotic *B. coagulans* MTCC 5856 may improve gut symptoms and psychological issues i.e. major depression, sleeplessness, and dementia in IBS. This provides new opportunity not only to help patients suffering from gastrointestinal related disorders but also the patients suffering from extra-intestinal disorders such as major depression, quality of sleep and dementia.

IBS is characterized by the alterations in bowel function or discomfort, abdominal pain or bloating and diarrhea or constipation, with the prevalence estimated between 9% and 23% in the population across the world. IBS patients are also frequently affected by chronic anxiety, mood disorders and major depression.

This 90 day randomized, double blind, placebo controlled trial involved 40 adults with IBS co-existing with major depressive disorder. Twenty participants took a daily dose of the probiotic *B. coagulans* MTCC 5856 (2 billion spores per day) and other 20 subjects were on placebo. At 90 days, subjects receiving *B. coagulans* MTCC 5856 (2×10^9 spores/day) reported a significant change/decrease in their depression clinical symptoms along with decrease in IBS as compared to subjects receiving placebo. It was also noticed that the subjects in the *B. coagulans* MTCC 5856 group reported improvement in sleeplessness and to a lesser extent for dementia.

The study reported no clinically significant changes in vital signs, no abnormal lab values (biochemistry and hematology), and also no Serious Adverse Events or Significant Adverse Events associated with the consumption of probiotic *B. coagulans* MTCC 5856, suggesting its excellent clinical safety in patients suffering from major depression with IBS.

These clinical findings indicate that *B. coagulans* MTCC 5856 may be an important new treatment option for major depressive disorder in IBS patients and opens a new avenue for the probiotic use in gut and psychological conditions.

Sabinsa undertook this study after Shaheen Majeed, President-worldwide, noticed depression to be commonly reported among subjects suffering from IBS at the time of screening for the first clinical trial conducted on LactoSpore® for the treatment of IBS predominant diarrhea and those patients were excluded in the study (Majeed et al. 2016. Nutrition Journal 15:21. <https://doi.org/10.1186/s12937-016-0140-6>).

Original Research: Full open access research for “*Bacillus coagulans* MTCC 5856 for the management of major depression with irritable bowel syndrome: a randomised, double blind, placebo controlled, multi-centre, pilot clinical study” by Muhammed Majeed, Kalyanam Nagabhushanam, Sivakumar Arumugam, Shaheen Majeed and Furqan Ali in Food & Nutrition Research. Published online July 04 2018. DOI: <https://doi.org/10.29219/fnr.v62.1218>

LactoSpore® is Sabinsa’s clinically validated and commercial probiotic preparation containing L(+) lactic acid producing microbial preparation from *Bacillus coagulans*, MTCC 5856 (earlier known as *Lactobacillus sporogenes*). For more information, visit www.lactospore.com.



About Sabinsa Corporation:

Sabinsa's mission is to provide alternative and complementary natural products for human nutrition and well-being. Over the past 30years, Sabinsa has brought to market more than 100 standardized botanical extracts, and privately funded clinical studies in conjunction with prestigious institutions in support of these products. With more than 100 full-time scientists conducting ongoing research in India and the United States, Sabinsa and parent company Sami Labs Ltd. continue to develop, patent and manufacture phytonutrients for the world market, with ingredients that are both Halal and Kosher. For more information, visit www.sabinsa.com.

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