POSTER SECTION

Novelty in the Field of Spore-Forming Probiotics: Safety and Efficacy of the New Strain *Bacillus coagulans* GBI-30

B. Pacchetti[a], M. Elli[b], Michael Bush[c], L. Morelli[d]

[a]Sochim International SpA, Milan (Italy), [b]AAT Srl, Via Martiri della Resistenza-Galleria San Giuseppe, 1 29100 Piacenza (Italy), [c]Ganeden Biotech Inc., Mayfield Hts.-OH (USA), [d] Ist. Microbiologia, Univ. Cattolica del Sacro Cuore, 29100 Piacenza (Italy)

Introduction

Probiotics need to comply with the indications of international guidelines related to safety aspects and clinical efficacy issues (EFSA, QPS) (Fig.1). *Bacillus coagulans* is a spore-forming, lactic acid-producing, Gram-positive rod that is widely used as food supplement for humans, even if a lesser degree of scientific substantiation has been noticed. Some criticisms have recently focused on *B. coagulans* basically due to misleading classification and the scientific substantiation of its probiotic properties (De Vecchi, 2006; Drago, 2009, Sanders, 2003), claimed to be poor with special reference to *in vivo* trials on humans.

B.coagulans GBI-30 6086 (PTA-6086) is a new, patented, probiotic strain, with a strong scientifically-driven background, introducing innovative options in prospective applications and usage of spore-forming probiotics.

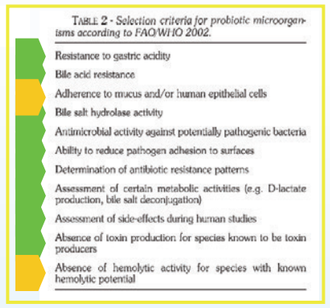


Fig.1 Assessment of probiotic strains following international guidelines (FAO/WHO 2022). Green arrows indicate criteria met for *B.coagulans* GBI-30, orange arrows refer to criteria under investigation.

Materials and Methods

Validation of *B.coagulans* GBI-30 as a probiotic was performed in accordance with three main aspects: safety, efficacy and technological properties.

In vitro tests were performed to check its broad sugar spectrum, its survival to gastric acidity and its production of L+ -lactic acid. *In vivo* trials on murine model and on humans allowed for the evaluation of *B.coagulans* GBI-30 immune-stimulatory activity, competitive exclusion of pathogens, such as bacteria and virus, and its efficacy on dismicrobism-related gut disturbances. Antibiotic-sensitivity pattern was also measured in accordance to EFSA's reference, as well as resistance to physical stresses and its potential in various food applications.

Results

Taxonomy

16S rRNA coding gene analysis of GBI-30 was performed, confirming the identification with 99% identity level (Fig. 2). GBI-30 was indeed confirmed to be a pure strain of *B.coagulans*.

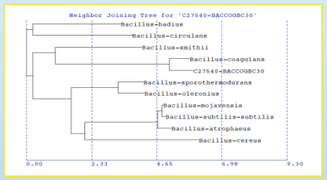


Fig. 2
Neighbour joining tree for GBI-30

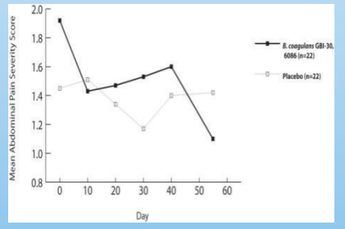


Fig. 5
Reduction of severity of IBS symptoms associated to GBI-30 assumption.

Safety assessment

The self affirmed GRAS (Generally Recognized As Safe) status was attributed to GBI-30 based on bacterial reverse mutation (Ames) assay, acute oral toxicity studies on murine model, subchronic 13-week oral toxicity studies in rats, acute eye irritation test in rabbits and the absence of serious adverse reactions in humans during clinical trials for the assessment of probiotic efficacy. Furthermore, antibiotic sensitivity pattern was measured by plate inhibition assays. Pathogen exclusion was evaluated with reference to enterococci (Donskey, 2001).

Efficacy in humans

Randomised, double-blind placebo-controlled clinical trials were performed in order to evaluate GBI-30 efficacy in the treatment of several human diseases.

- ***Irritable bowel syndrome (IBS)*** – A statistically significant improvement in pain and bloating symptoms was demonstrated in a study involving 44 IBS subjects (Hun, 2009).
- ***Chrohn's Disease (CD)*** – A positive trend in the liquid, loose stools and in the number of subjects that go off of their anti-diarrheal medications was observed. Twenty subjects were involved. (Fig. 4)
- ***Osteoarthritis and Rheumatoid Arthritis*** – A total number of 77 subjects were concerned. Statistically significant improvements were detected in pain, global assessment and self-assessed disability.
- ***Viral respiratory tract infections*** - The use of GBI-30 significantly increased T-cell production of TNF-α in response to adenovirus exposure and influenza A (H3N2 Texas strain) exposure, but it did not have a significant effect on the response to other strains of influenza. Ten humans participated in the study (Baron, 2009).

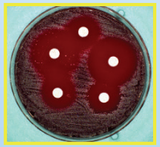


Fig. 3
Inhibition of GBI-30 growth on plate by antibiotics

Mean Changes of liquid or very soft stools

	Mean	Change From Baseline	% Change From Baseline
Base Line - Active	23.7	N/A	N/A
Day 30 - Active	13.7	-10.0	-42.19
Day 60 - Active	14.5	-9.2	-38.82
Base Line - Placebo	39.9	N/A	N/A
Day 30 - Placebo	25.4	-14.5	-36.34
Day 60 - Placebo	27.9	-12.0	-30.08

Fig. 4
Efficacy of GBI-30 on Chrohn's Disease

Conclusions

B.coagulans GBI-30 has been shown to be a new probiotic strain able to overcome clinical and technological limits of other beneficial microbes and the lack of scientific background of the majority of commercial *B. coagulans* strains. *B.coagulans* GBI-30 meets the preliminary requirements on probiotic strain set by international guidelines and the safety profile, including genotypic taxonomic identification. Clinically proven benefits and safety aspects of *B.coagulans* GBI-30 were extensively investigated in the course of several studies on animals and humans. High levels of survival through high heat, high pressure processes, freezing conditions and the shelf-stability for two years at room temperature were also investigated. Stable preparations of *B.coagulans* GBI-30 were suitable for the application to supplements and to functional food as bakery, dairy, confectionary, beverages as well as topical applications.

Literature

Baron M. (2009) Postgrad Med 121(2), 114-118.
De Vecchi E., Drago L. (2006) Int J Prob Preb 1(1), 3-10.
Drago L., De Vecchi E (2009) J Chemotherapy 21(4), 371-377.
Hun L. (2009) Postgrad Med 121(2), 119-124
La Rosa M., Bottaro G., Gulino N. et al. (2003) Minerva Ped 55, 447-452.
Sanders M.E., Morelli L., Tompkins T.A. (2003) Comprehen Rev Food Sci Food Safety 2, 101-110.
Select Ganeden Patents: US 6,461,607, EP 1107772, US 6,849,256, US 7,232,571, EP 1067945

IL MICROBIOTA

Sui circa 300 metri quadrati del nostro tratto gastro-intestinale opera un'elevata popolazione microbica che svolge funzioni vitali basilari. L'insieme di questi microrganismi costituisce un vero e proprio organo endocrino: il microbiota. Organo troppe volte dimenticato ma ora giustamente rivalutato.

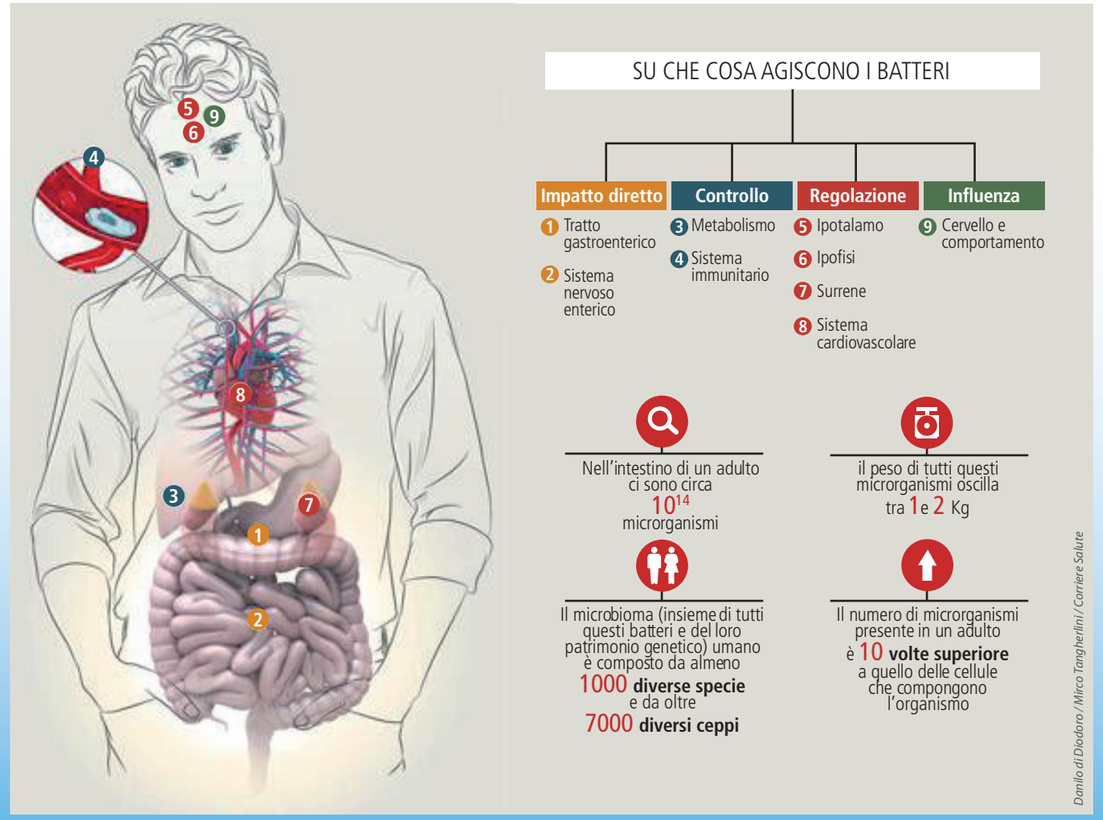
Il nostro apparato digerente contiene circa 1.000 specie microbiche, che operano nel tratto gastro-intestinale, costituendo un vero e proprio ecosistema intimamente collegato con le cellule umane.

La flora intestinale, essenziale per un equilibrato funzionamento dell'intestino e per rafforzare le naturali difese dell'organismo, se alterata, spesso lascia spazio ai microrganismi nocivi, nemici della nostra vita.

Nell'apparato gastro-enterico risiede circa il 75% del sistema immunitario.

PROTEGGI L'INTESTINO

Rilevo, educazione alimentare, conosce ciò che fa bene all'organismo. Sa quindi come difendere e migliorare le funzioni del tratto gastro-intestinale. Nei casi di modificazioni sostanziali del microbiota, indotte da un alimentazione non corretta, Rilevo ha realizzato, solo con ingredienti naturali, un alimento in cui è attiva una carica probiotica di 1 miliardo di cellule di *Bacillus coagulans* BC30.



1 Miliardo di Fermenti

Fermenti

I fermenti sono batteri lattici che rispondono a delle caratteristiche particolari e per questo vengono considerati probiotici.

Probiotici

Etimologia: a favore della vita

Microrganismi vivi in grado di esercitare, se ingeriti in adeguata quantità, effetti benefici per la salute dell'organismo ospite.

Bacillus coagulans BC30

BC30 si caratterizza per la capacità specifica di resistere e sopravvivere indenne all'interno dell'alimento.
È pertanto in grado di superare lo stress fisico durante la preparazione dell'alimento stesso.
Una volta superata la barriera acida dello stomaco e quella basica dei sali biliari, il probiotico BC30 germina, prolifera a livello intestinale ed esercita gli effetti benefici desiderati. La natura sporigena del probiotico BC30 ha inoltre capacità di sopravvivenza superiore ad altri ceppi probiotici non sporigeni.
Circa il 78% delle cellule del probiotico BC30 sopravvivono per colonizzare l'intestino.

TABELLA NUTRIZIONALE	per 100g	per 25g	
Energia	510 kcal	127,5 kcal	
	2119 kJ	529,8 kJ	
Grassi	34 g	8,50 g	
di cui: ac.grassi saturi	5 g	1,25 g	
Carboidrati	32 g	8 g	
di cui zuccheri	20 g	5 g	
Fibre alimentari	12 g	3 g	
Proteine	13 g	3,25 g	
Sale	0,068 g	0,017 g	
Fosforo	545 mg	136,25 mg	20% VNR
Magnesio	249 mg	62,25 mg	17% VNR
Rame	1,1 mg	0,275 mg	27% VNR
Zinco	7 mg	1,75 mg	18% VNR

VNR = valore nutrizionale di riferimento

GLI INGREDIENTI
Semi di **sesamo** 63%, miele italiano, sciroppo di riso e malto d'**orzo**, miglio soffiato 9%, **nocciole** 6%, *Bacillus coagulans* GBI-30,6086. Contiene glutine. Può contenere tracce di **latte**, **soia**, altra **frutta a guscio** e **arachidi**.

NON CONTIENE
Additivi, conservanti, grassi idrogenati, dolcificanti di sintesi e coloranti

Carico glicemico per barretta: 4,48
Unità AW: 0,156

1 Miliardo di Fermenti

926979206

Prezzo al pubblico 3,20 €

segreteria@rilevo.com
www.rilevo.com

Rilevo
EDUCAZIONE ALIMENTARE

Ke Integratore Srl
Via Londonio 23
20154 Milano
Tel. 3429253735