Formulation and Evaluation of Dosage Forms of Starter Cultures and Probiotics for use as Inocula/ Food Ingredient/Dietary Supplement in the Household and Industrial Level

Sreeja V. and J. B. Prajapati

Department of Dairy Microbiology, SMC College of Dairy Science, AAU, Anand-388110.
Email: sreeja_p70@rediffmail.com

Objective

Ease of handling and addition to food, precise dosage and functionality for specific application and long term preservation are some of the important aspects the consumers want in food dosage forms. The present work was carried out to formulate and evaluate different dosage forms of starter cultures and probiotics such as sachets, capsules and fast disintegrating tablets for use as inocula/ food ingredient/ dietary supplement in the household and industrial level.

Methodology

Freeze dried cultures of *Streptococcus thermophilus* MTCC 5460, *Lactobacillus helveticus* MTCC 5463, *Lactobacillus rhamnosus* MTCC 5462 and *Lactobacillus delbrueckii* subsp. *bulgaricus* NCIM 2358 were used for preparation of dosage forms *viz*., sachets, capsules and tablets. Active ingredients (AIs) for the dosageforms were initially prepared using mixtures of freeze dried cultures, reducing agent L-ascorbic acid and two bulking agents, maltodextrin and spray dried lactose. AIs were evaluated for viability, activity and micromeritic properties. The optimized AIs were then mixed with selected excipients to prepare the formulations. The excipients were optimized on the basis of viability and activity of the formulations in each stage. Viability was estimated using selective agar plating technique for each strain. Ability to form curd was taken as a measurement of activity and the curd characteristics were also studied. To understand the interaction effect between active ingredient and excipients, Fourier Transform Infrared (FTIR) Spectroscopy was used. The concentration of super disintegrant in the final formulation for fast disintegrating tablets was derived using Response surface Methodology(RSM). The optimized formulations were filled in sachets (superdisintegrants and lubricants were excluded from the formulation meant for sachets) and capsules and for making tablets the formulations were subjected to direct compression method. Each dosageforms were subjected to storage study at room (30±2°C) and refrigerated (5±2°C) conditions and were evaluated for viability and activity at one month interval for six months. For tablets, additional characteristics such as disintegration time, hardness, friability and weight variation were measured to understand the technological stability. The dahi made using dosage forms were analyzed for sensory, microbiological, chemical and textural properties.

Result and Discussion

Viability, activity and micromeritic properties of the AIs revealed superiority of spray dried lactose as bulking agent over maltodextrin. Among the various formulations comprising different kinds and levels of excipients tried for tablet making by direct compression method, the formulation containing crospovidone, super starch 200, PVP K-30, magnesium stearate and talc was found to be superior in terms of viability and disintegration time of tablets. Excipient-culture compatibility using FTIR Spectroscopy showed no chemical interaction between probiotics and excipients used, hence further proved their compatibility and suitability for preparation of dosage forms. Further optimization of formulations for level of superdisintegrant (crospovidone) and lubricant (magnesium stearate) using response surface methodology revealed that crospovidone had a major effect on wetting time and disintegration time of tablets. The dosage forms at refrigerated temperature exhibited good viability, activity and physical characteristics till the end of storage period of six months. The viable counts in all dosage forms decreased with increased storage period for

ABSTRACT

both storage temperatures. But the rate of decrease was more in case of room temperature (30±2°C) stored dosage forms within one month (~2 log reduction) compared to refrigerated (5±2°C) stored ones (~1log reduction) within 6 months. Percent survival for individual strains in each dosage forms varied between 93 to 95% in case of sachets and capsules, whereas for tablets it varied between 83 to 85% at the end of 6 months of refrigerated storage. Storage period of one month at room temperature and six months at refrigeration temperature did not have a significant effect on disintegration time, hardness, friability and weight variation of tablets. The dahi prepared using dosage forms exhibited good sensory, chemical and textural characteristics. Culture count in dahi samples varied between 9.94 to 9.98 log cfu/g and the average viscosity varied between 1809.55 to 1822.67 cp.

Conclusion

The current study resulted in the development of dosage forms such as sachets, capsules and tablets containing starter cultures and probiotics for use as inocula for preparation of fermented milks or probiotic products. The same dosage forms can be used as functional ingredients or dietary supplement also. For making dahi at household level, one unit of dosage form, i.e., 1 sachet/1 capsule/1 tablet of 300 mg as inocula per 100 ml of milk and incubation at 37°C for overnight (12 to 14 h) is recommended.