Effect of HPMC K4M on *Lactobacillus acidophillus* Viability in Tablet Dosage Form

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ABSTRACTS

Objective : There are a lot of clinical data supporting the role of probiotics in human health. A probiotic is generaly defined as a live microbial food supplement which beneficially affect the host by improving the intestinal microbial balance. The probiotic products available nowadays, most of them are liquid or semisolid formulations which show low cell viability after oral administration. The purpose of the research was to study the effect of HPMC K4M on bacterial viability in the tablet dosage form using avicel as a filler. The bacterial viability was an important factor according to the prerequisite minimum viability 10^6 Cfu.

Methods : *Lactobacillus acidophillus* microparticle using HPMC K4M 5% (F1) and HPMC K4M 10% (F2) prepared by spray drying method. The microparticle was compressed to tableting using avicel as a filler by direct compression method.

Result :The result shows that it is possible to prepare tablet using HPMC K4M as a matrices which probiotic is still living

Keywords: probiotic, viability, tablet, HPMC K4M

INTRODUCTION

The development of suitable dry dosage enable higher bacterial survival and consequently is the main aim of the present study. The viability was an impotant factor because the probiotic will exert health beneficial effect if the minimum accouunt was 10^6 Cfu. An anticipated advantage is that due to the low water content will preserve their viability. Dehydration is commonly used as means to stabilize probiotic.

Methods of production of dried probiotic powder is spray drying methods with 50^0 C of temperatur. After spray drying process, the powder were compressed to be a tablet.

To obtained a dosage form with higher bacterial survival, the temperatur of spray dryer is kept on 50^0 C and the formulas have been added with a protectant. In this research, HPMC K4M is used as a protectant, with 5% and 10% concentration. The microparticel was compressed to tablet using Avicel pH 102 and Mg Stearic used as a matrices and lubricant tablets , respectively

MATERIALS AND METHODS

Materials:

Probiotic (Lactobacillus acidophillus as a model)

HPMC K4 M (Lawzin zecha), Avicel pH 102 (Dow), Mg Stearat (Dow), MRS media (Dipa)

Agar Plate

Methods :

1. Preparation of Spray Dried Milk-Probiotic –HPMC K4M (5% and 10%) and Tablet :

The cell (Lactobacillus acidophillus, as a model) were suspended in 10% skimmed milk solution. The cultures were than frozen at -20^0 C for about 12 hours, and subsequently mix suspension of HPMC K4M 5% and 10% , and then dried by a spray drying method using spray dryer model. The spray dried probiotic containing milk and HPMC 5% and 10% were carefully ground into the powders. Avicel ph 102 were added, and mixed for 5 minute. Finally add and mix Mg Stearate.

This mixture was compressed into tablet by a flat face punch of 8 mm diameter. The compression process of 1 ton for 3 sec (hydraulic press Grace by Specac).

Table 1. Composition of Tablet Probiotic with HPMC K4M 5% and 10%

Composition	**F1**	**F2**
SD Milk-Probiotic-HPMC 5%	100 mg	-
SD Milk-Probiotic-HPMC 10%	-	100 mg
Avicel pH 102	100 mg	100 mg
Mg Stearic	0,1%	0,1%

2. Viability test of probioitc in the tablet

Each tablet was broken and suspense in water for injection. A serial dilution (10^{-1}, 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5}, 10^{-6}, 10^{-7}, 10^{-8}, 10^{-9} and 10^{-10}) of this suspension was made and then spread on the media (agar).The survival probiotic reported after 8 hours

Spray dried milk-probiotic-HPMC K4M 5% and 10% suspenses in water for injection. A serial dilution (10^{-1}, 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5}, 10^{-6}, 10^{-7}, 10^{-8}, 10^{-9} and 10^{-10}) of this suspension was made and then spread on the media (agar). The survival probiotic reported after 8 hours

Milk suspense in water for injection. A serial dilution (10^{-1}, 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5}, 10^{-6}, 10^{-7}, 10^{-8}, 10^{-9} and 10^{-10}) of this suspension was made and then spread on the media (agar). The survival probiotic reported after 8 hours.

RESULTS AND DISCUSSIONS

The experimental was undertaken to observe the influence of HPMC K4M 5% and 10% on the viability of probiotic.

The table, shows that probiotic viability does not influenced by HPMC K4M, from data give by milk and spray dried milk. But from tablets data, it is showed that the viability of probotic decrease, and it cause by compression process and the addition of Avicel pH 102.

Tabel 2 : Viability of probiotic after 8 hours incubation (10^{10} cfu/ml)

REPLIKASI	MILK	SPRAY DRIED MILK-PROBIOTIC-HPMC K4M (5%)	SPRAY DRIED MILK-PROBIOTIC-HPMC K4M (10%)	TABLET F1	TABLET F2
1	TNTC[+)]	TNTC	TNTC	127,0	134,0
2	TNTC	TNTC	TNTC	176,0	160,0
3	TNTC	TNTC	TNTC	101,0	120,0
X	TNTC	TNTC	TNTC	134,0	138,0

[+)] TNTC =TOO NUMEROUS TOO COUNT

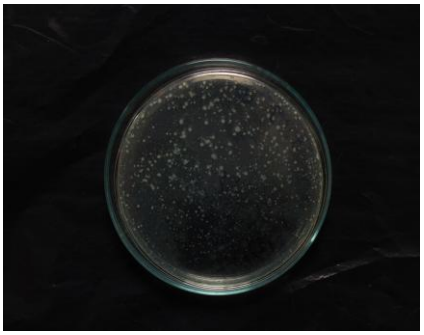

Fig . 1 . Viability of probiotic in milk after HPMC 8 hours of incubation

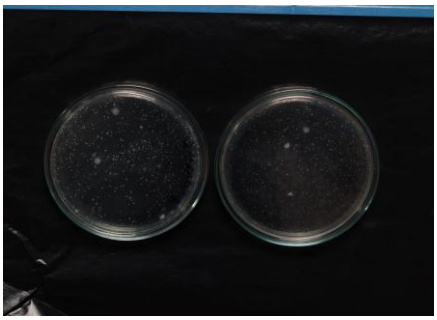

Fig 2Viability of dried milk-probiotic-K4M 5% and 10% after 8 hours of incubation

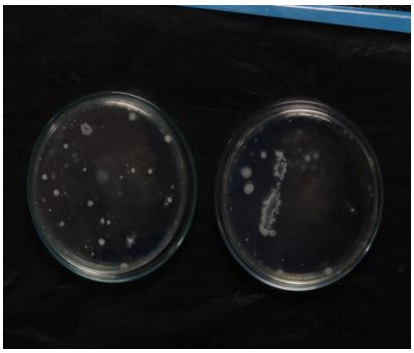

Fig 3. Viability of probiotic in tablet F1 and F2 after 8 hours of incubation

CONCLUSION

1. HPMC K4M 5% and 10% did not influence the viability of probiotic
2. Tablet preparation (compaction force and the formulation) decrease the viability of probiotic

REFERENCES

1. Corcoran BM, Stanton C, Filtered CGF, Ross RP., Survival of lactobacillus in acidic environments is enhanced in the presence of metabolizable sugars.Applied and Enverinmentasl Microbiology, 2005. 71. 300-3067
2. Heller KJ.,(2001) Probiotic bacteria in fermented foods : product characteristic and starter organism. Am. J Clin Nutr
3. Klayraung ,S., Viernstein ,H., and Oknogi S., (2009) Development of tablet containing probiotic: Effects of formulation and processing parameters on bactial viablity., International Journal of Pharmaceutics 370
4. Hart AL., (2009) Mechanisme of action of Probiotic : Recent Advances Inflammation Bowel Disease
5. Lachman, L., Lieberman, A.H., Kanig J.L.,(1986) The Theory and Practice of Industrial Pharmacy , Philadelphia: Lea & Febiger.