Effect of HPMC K4M on *Lactobacillus acidophilus* 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 generally 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 acidophilus* microparticle using HPMC K4M 5% (F1) and HPMC K4M 10% (F2) prepared by spray drying method. The microparticle was compressed to tabletting 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 matrix which probiotic is still living.

Keywords: probiotic, viability, tablet, HPMC K4M

INTRODUCTION

The development of suitable dry dosage form enable higher bacterial survival and consequently is the main aim of the present study. The viability was an important factor because the probiotic will exert health beneficial effect if the minimum account 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 acidophilus* as a model)
HPMC K4 M (Lawzin zecha), Avicel pH 102 (Dow), Mg Sterate (Dow), MRS media (Dipa)
Agar Plate

Methods:
1. Preparation of Spray Dried Milk-Probiotic –HPMC K4M (5% and 10%) and Tablet:
The cell (*Lactobacillus acidophilus*, as a model) were suspended in 10% skimmed milk solution. The cultures were then 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%

<table>
<thead>
<tr>
<th>Composition</th>
<th>F1</th>
<th>F2</th>
</tr>
</thead>
<tbody>
<tr>
<td>SD Milk-Probiotic-HPMC 5%</td>
<td>100 mg</td>
<td>-</td>
</tr>
<tr>
<td>SD Milk-Probiotic-HPMC 10%</td>
<td>-</td>
<td>100 mg</td>
</tr>
<tr>
<td>Avicel pH 102</td>
<td>100 mg</td>
<td>100 mg</td>
</tr>
<tr>
<td>Mg Stearic</td>
<td>0,1%</td>
<td>0,1%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>REPLI</th>
<th>KASI</th>
<th>MLK</th>
<th>SPRAY DRIED MILK-PROBIOTIC-HPMC K4M (5%)</th>
<th>SPRAY DRIED MILK-PROBIOTIC-HPMC K4M (10%)</th>
<th>TABLET F1</th>
<th>TABLET F2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TN TC*</td>
<td>TNTC</td>
<td>TNTC</td>
<td>127, 0</td>
<td>134, 0</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>TN TC</td>
<td>TNTC</td>
<td>TNTC</td>
<td>176, 0</td>
<td>160, 0</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>TN TC</td>
<td>TNTC</td>
<td>TNTC</td>
<td>101, 0</td>
<td>120, 0</td>
<td></td>
</tr>
<tr>
<td>X</td>
<td>TN TC</td>
<td>TNTC</td>
<td>TNTC</td>
<td>134, 0</td>
<td>138, 0</td>
<td></td>
</tr>
</tbody>
</table>

*TNTC = TOO NUMEROUS TOO COUNT

2. Viability test of probiotic in the tablet
Each tablet was broken and suspense in water for injection. A serial dilution \(10^{-1}, 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5}, 10^{-6}, 10^{-7}, 10^{-8}, 10^{-9}\) 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 \(10^{-1}, 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5}, 10^{-6}, 10^{-7}, 10^{-8}, 10^{-9}\) 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 probiotic decrease, and it cause by compression process and the addition of Avicel pH 102.
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