CHAPTER I
GENERAL INTRODUCTION

Introduction

It is generally accepted that a drug must be in dissolved state before being absorbed into blood circulation. The first important step in the sequence of the solid dosage form to be in solution state is the break-down of tablet into granules, smaller particles and finally dispersed into a primary drug particles. This process is known as disintegration. The disintegration of tablet is necessary to achieve rapid availability of active ingredients. To accomplish this, a certain substance is added to the tablet formulation which accelerates the disintegration of tablet into primary particles and such substances are called disintegrant (List and Muazzam,1989).

Starch is a substance commonly used as the tablet disintegrant. It is readily available, inexpensive and inert. Starches are obtained from various sources. Commercially starch powders from different native sources may not have identical properties. In the western countries, the potato starch is widely used as the tablet disintegrant (Sheth, et al., 1980). In the tropical countries such as Thailand the potato is not commonly cultivated. In these countries the use of potato starch in tablet manufacturing implies importing potato starch from Europe or America. However, there are many other plants that serve as a source of starch such as maize, rice, glutinous rice, wheat, arrow root and tapioca (Boss, et al.,1987).

In addition, the plain starch was modified by chemical approaches to improve the efficiency of disintegrant properties. The first successful attempt to

improve on a native starch was the development of carboxymethyl starch from potato starch and available under the trade name of Explotab^{R} and Primojel^{R}. Since the starches are obtained from various sources and the potato is not widely cultivated in tropical countries, the development of the other starches to be a new powerful disintegrant is of interest.

From the preliminary study, there is a breakthrough to improve the disintegrating property of tapioca starch by carboxymethylation of native tapioca starch. Basic informations suggest that the properties of tapioca starch are not significantly different from the properties of potato starch as follows:

1. Morphology

Particle shapes of both tapioca starch and potato starch are rather round but the particle sizes of tapioca starch (4-35 μ) are smaller than the sizes of potato starch (5-100 μ)

2. Chemical compositions

The chemical compositions of tapioca starch and potato starch are similar as shown in table 1 and table 2 (Product Information written by Swinkels).

Table 1 Chemical Composition of Starch Granules.

Starches	Moisture at 20 ^{0}C (%)	Lipid (%)	Protein % (X6.25)	Phosphorous odor substances (%)
Potato	19	0.1	0.10	0.08
Maize	13	0.8	0.35	0.02
Wheat	13	0.9	0.40	0.06
Tapioca	13	0.1	0.10	0.01

Table 2 Amount of Amylose and Amylopectin and Degree of Their Polymerization (DP) in Starches.

Starches	Amylose	Amylopectin	Average DP of Amylose	Average DP of Amylopectin
Potato	21	79	3000	2,000,000
Maize	28	72	800	2,000,000
Wheat	28	72	800	2,000,000
Tapioca	17	83	3000	2,000,000

From the reasons above the objective of this study is to develop a tapioca starch derivative which produces a high efficiency of disintegrating properties.

The significance of this study

1. There is no report on the modification of the tapioca starch for the purpose to be used as a tablet super disintegrant.

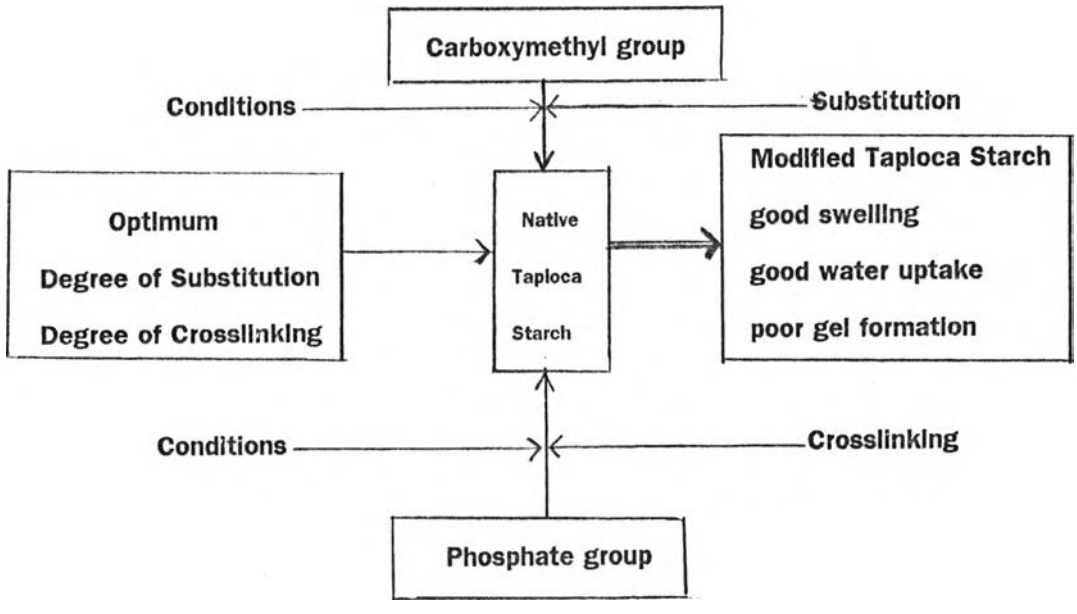
2. This modified tapioca starch might be considered to be a new starch derivative product to be used as a super disintegrant.

3. From the preliminary study, the new product is likely to be more effective than starch products available in the market.

4. The modified tapioca starch has a high potential to be developed for commercial purpose at a lower price in the market.

Principle of the modification

The principle of the modification of tapioca starch in this study was shown in the following scheme



Purpose of the study

The scope of this research is to develop a new super disintegrant from native tapioca starches via chemical reactions: substitution and crosslinking. To improve physico-chemical properties of the developed starch as a new tablet disintegrant, the effect of variations of degree of substitutions and crosslinkings have been studied and also the physico-chemical properties of a new modified starches were examined to compare with other super disintegrants. Finally, the factors affecting the efficiency of the new modified starch were evaluated.