CHAPTER I

INTRODUCTION

Many nutritive, pharmaceutical and chemical materials are usually not compressible in their pure form. Additive are included to increases their compressibility and flow, allowing for a more elegant and reproducible product.

Solid stages, especially tablet formulations are a majority of all prescriptions dispensed in the world today cause of their portability and convenience.

There are number of methods for making tablets, but the wet granulation is still frequency used in the production of these dosage forms, which is commonly employed to make powder mixtures more free flowing, compressible and homogenous. In order for this process to be successful certain pharmacologically inert compounds are includes into these tablet formulations to administer active ingredients effectively.

A most important excipient in the wet granulation process is the pharmaceutical filler/binder, which are used to increase particle size and flow, enhance granule quality, and aids in bonding during compression. The choice of filler/binder, as well as method of addition, have been shown to have a profound effect on the biopharmaceutical, chemical and physical properties of the final tablet. Without the inclusion of pharmaceutical filler/binder to meet tablet formulation, unsuccessful deformation would take place resting in tablets with poor mechanical strength, tablets which are prone to lamination or capping or in extreme case, no tablet would be form under the normal range of compact pressure used in pharmaceutical production setting.

There are many kinds of filler/binder. Some fill all the requirements for making a hard, non-friable tablet, but fail when the tablet is to be used. The carrier material in some cases does not aid in the disintegration of the tablet, and may actually prevent it.

In pharmaceutical system, starch is, at first, used directly in native form without modification as a filler/binder and disintegrant. It is normally used in the form of starch pasted producing tablets, which are generally soft and brittle.

Since Thailand is an agricultural country, producing tremendous amount of starches annually and as a reason that the characteristic of starch can be altered by chemical and/or physical means to improve its intrinsic properties or to impart a new one, so attempts have been made to modifies starches by various means in order to make their properties more appropriate and effective for pharmaceutical used.

Pregelatinized starch is starch that has been chemically and/or mechanically processed to rupture all or part of the granules in the presence of water and subsequently dried. Some types of pregelatinized starch may be modified to render them compressible and flowable character.

Numerous studies dealing with pregelatinized starches have been reported so far. However, the process can not be regarded as one that is well understood. It is clear for the literature that there are many processes and formulation variables involved in the process which govern granule formulation and granule properties.

The fully pregelatinized starch, which is considered 100% cold water soluble, behaves in decreasing the disintegration and dissolution of the tablets. Because the outer surface made from fully pregelatinized starch "gels" rapidly on contact with water. The tablets become "gummy" and never dissolves completely. The completely cold water soluble, gelatinized portion tends to gel as indicated above, and it interferes with the disintegration of the remaining portion of tablet. (Short and Verbanac, 1978)

Those such events were also occurred in the recent study by Daranee Phenjareon (1999). The research explored the different types of pregelatinized starch by drum drying from two kinds of native starch (tapioca and corn starch) used as filler/binder with dry incorporation in wet granulation method. Dry binder addition would be the preferred method as it eliminates one step of an already lengthly process.

The investigator found a good disintegration and dissolution of acetaminophen tablet when pregelatinized of corn starch by drum drying were used as binders were dry mixed prior to wet granulation. And found that the pregelatinized tapioca starches tended to produce tablets with greater binding strength, less friable but extremely longer disintegration and dissolution time compared with the pregelatinized corn starches and other commercial pregelatinized starches.

This present work is a continuation of the mentioned research project on the development of pregelatinized starch as fillers/binders to improve the tablet disintegration and dissolution properties of pregelatinized corn, glutinous rice and tapioca starches by acid modification prior to pregelatinization by drum drying.

The acid modification was performed in order to decrease the viscosity of starch when making in pregelatinized form that may not induce to high viscous gels when contact with water. The process used is drum drying because of its common technique.

In this study, all pregelatinized starches obtained were investigated in comparison to native starches and three of commercial pregelatinized starches (Era-Gel, National 1551, Starch 1500) regarding their potential use as a filler/binder in the conventional wet granulation process.

OBJECTIVES OF THE STUDY

a. To study the method of preparation of pregelatinized starches by drum drying from hydrochloric acid treated corn, glutinous rice and tapioca starch.

b. To characterize powder chemical and physical properties of pregelatinized starches prepared compare with native starches and commercial pregelatinized starches.

c. To apply pregelatinized starches prepared in manufacture of acetaminophen tablet as filler/binder by dry incorporation in wet granulation method and investigate tabletting properties of of pregelatinized obtained.