CHAPTER V

CONCLUSIONS

The main objective of this study aimed to investigate fillers/binders properties of three types of native starches, corn, glutinous rice and tapioca starches when acid treated prior to pregelatinization by drum drying. The pregelatinized starches obtained could be incorporated in dry form in wet granulation method. This would be the preferred method as it eliminates one step of an already lenghtly process.

From the preliminary study of the acid modified starches. It was found that the processing temperature, time and acid concentration were the important factors influencing the viscosity of the treated starches obtained, the higher in these factors, the lower viscosity would be. The acid treated starches obtained in this study produced in the condition of 0.5% HCl acid, 35°C in 0.5 hr, possessed properties suitable high level viscosity, while those were produced in the condition of 2% HCl acid, 50°C in 0.5 hr, possessed properties suitable low level viscosity. However, when they were prepared to pregelatinized starches, no clearly difference of viscosity was observed.

To study the properties of starch powder obtained comparing with three types of commercial pregelatinized starches, Era-Gel (fully pregelatinized rice starch), National 1551 (fully pregelatinized corn starch) and Starch 1500 (partially pregelatinized corn starches). It was found that each starch is unique in terms of granule organization and structure, which could be identified by SEM, polarizing microscope, X-ray diffractometer, DSC and FTIR. The morphology of acid treated starches at both levels of viscosity appeared virtually unchanged from their native starches while the pregelatinized starch exhibited the entirely different morphology. The X- ray patterns exhibited that all of the pregelatinized starches obtained were completely gelatinized due to their complete loss of crystallinity. The result was confirmed by DSC data since there were no endothermic peak of all fully pregelatinized starches. The infrared spectrums indicated that there were no occurrence of chemical function groups in all starches during their processing neither acid modification nor pregelatinization.

In comparison of swelling capacity and amount of soluble substance among all types of starches obtained, it was found that the pregelatinized tapioca starches and pregelatinized glutinous rice starches exhibited higher in swelling capacity than that of corn starches whereas the native and acid treated of all starches showed the lowest values due to the amylopectin enclosed in the disrupted starch grains was not able to come into action. The amount of soluble of pregelatinized starches were higher than that of native starches and acid treated starches but it was lower than that of pregelatinized of both levels of acid treated starches.

All types of pregelatinized starches had larger particle size and also exhibited higher flowability than that of native and acid treated starches.

Acetaminophen formulation containing 11.17% pregelatinized starches as filler/binder were prepared under the same processing conditions. All granulation were found to posed similar traits when evaluate base upon geometric mean diameter, particle size distribution, flowability and compressibility. The main difference in granule properties was seen in granule friability. It was found that the pregelatinized of acid treated starches gave granules with higher friability than that of pregelatinized of untreated starches.

When monitoring compression force to produce tablets of the same degree of hardness (6-8 kp), the formulation of pregelatinized of acid treated starches were found to use higher force than pregelatinized of unmodified starch formulations.

Tablets prepared from these granulations were shown to be similar when testing for degree of friability, weight variation, hardness, thickness. There were some pregelatinized starch formulations disintegrated within 5 min except the formulas containing TD, GD, GE and GF, which had the disintegration time more than 60 min. The formulations, which were conformed the USP specification for disintegration time, produced similar dissolution performance. The ranks of the $T_{80\%}$ was CF < E < S ≅ CE < TF < N < TE < CD. Anyway no significant differences of $T_{80\%}$ were observed

in tablets containing CE and CF, while the significant differences ($p < 0.05$) were illustrated in those of TE and TF.

Regarding, the recent study (Daranee Phencharoen, 1999), it was found that the pregelatinized tapioca starches tended to produce tablets with extremely longer disintegration and dissolution time. The present study was succeeded in improving those properties by treating the native starch with HCl acid in the proper condition prior to pregelatinization by drum dryer, so the pregelatinized starch obtained was decreased in viscosity leading to produce tablets with less disintegration and dissolution time. But this elimination could not be use in the case of glutinous rice starch.

Furthermore, it has also been noted during the study that, in the case of tablet formulation containing all types of pregelatinized glutinous rice starch and pregelatinized of native tapioca starches, in the presence of water, the thin film is converted into a mucilagenous, viscous barrier between granules and water, retarding the disintegration time and dissolution time of the tablets. Such special properties could be recommended for further study in the field of sustained released dosage forms.