Chapter IV
Conclusions

In this study , glutinous rice starch was modified by substitution reaction and three different degrees of substitution were obtained. On the basis of the above results it could be concluded that the obtained modified starches possessed the properties as the aid for manufacture of pellets by extrusion and spheronization process. The amount of microcrystalline cellulose which commonly used as an extrusion aid in the pellet formulation could be decreased in comparison with the formulations of the previous studies. Degree of substitution of modified starch had an influence on the pellet properties. The following conclusions can be drawn from the study ;

1. Utilization of modified glutinous rice starch in the sucrose formulations did not produce a suitable sphere , only rod shaped particles were generated.

2. For lactose pellet formulations , using the modified starch affected some physical properties of pellets. The results clearly showed that the average particle size (D_{50}) , bulk and tapped densities , hardness and sphericity of modified starch containing pellets were greater but size distribution was narrower than those of blank pellets. In addition , the less agglomeration , less friability and smoother surface of pellets were observed from MGS containing pellets. Using different degrees of substitution (DS) of MGS had negligibly effect on size distribution , D_{50} , sphericity and surface morphology of spheres. The highest hardness was obviously observed from pellets prepared with MGS at DS 0.26 whereas with MGS at DS 0.16 produced the lowest. The amount of added water in granulated mass played a critical role in extrusion-spheronization process. The greater the added water level employed, the higher the average size , hardness and surface roughness were found. The sphericity of pellets was slightly affected by the different quantities of added water. Generally , friability value is an indication of pellet hardness , however , in this experiment no

correlation of these properties was found. Moreover , cross-section of lactose pellets showed an internal cavity which could be used to describe the formation of spheres.

3. For dicalcium phosphate formulations , MGS containing pellets mostly showed the higher average size (D_{50}) , hardness and sphericity in comparison with blank pellets. The less degree of agglomeration and smoother surface of pellets could be obtained from MGS containing pellets. The bulk and tapped densities of pellets prepared by modified starches , when compared with blank pellets , exhibited inconsistent results , that was lower densities were found in 65% model but the higher densities was observed in 80% model. Non-significant effects of using various DS of MGS were found on size distribution , D_{50} and sphericity of pellets. The highest hardness of 65% pellet formulations was obtained by using MGS at DS 0.16 whereas that of 80% formulations was produced by using DS 0.32. In addition , the surface of pellets using MGS with DS 0.16 was rougher than using MGS with other DS. At different amounts of added water , the average particle size was considerably increased and the hardness , sphericity and surface roughness was mostly increased with increasing the amount of water. Changes of hardness and sphericity were also depended upon pellet size fraction. In contrast with lactose pellets , the bulk and tapped densities tended to be decreased upon increasing the water level.

4. Formulation $6L_{22}$ employing MGS at DS 0.26 and 37% of water and $8D_{35}$ using MGS at DS 0.32 and 44% of water were chosen as the basic formulas for lactose and dicalcium phosphate pellets to evaluate the effect of various amounts of modified starch on pellet properties. The results showed that

- As the amount of MGS increased , the average particle size of pellets tended to be increased. It was obviously seen in 0.8% MGS containing pellets.
- The influence of various amounts of MGS on bulk and tapped densities including size distribution was not clearly observed.

- The pellet hardness mostly increased with increasing MGS quantity , however , it was relied on the size of pellets. This was obviously seen in dicalcium phosphate pellets.

- Various amounts of MGS did not affect the sphericity of pellets.

5. Formulations $6L_{22}$ and $8D_{35}$ were used to study the pellet porosity in comparison to blank pellets. The results displayed that modified starch did not affect the porosity of lactose pellet whereas the porosity of dicalcium phosphate pellet containing modified starch was greater than that of blank pellet. The porosity of dicalcium phosphate pellets was greater than lactose pellets.

Under observation in this study , the use of modified starch in drug containing pellet is very interesting. However , in manufacture of drug containing pellet employing sodium carboxymethyl starch , the formulations and processing parameters must be adjusted relying on the physical properties of drug substance.