CHAPTER IV

CONCLUSIONS

The increase in the dissolution of IMC might be achieved by forming BCD or SLS solid dispersion. Although the evidence obtained in this study were not sufficient to conclude whether IMC and BCD inclusion complexes prepared by spray drying methods were formed, NMR study of the other reserachers reported the formation of inclusion complexes between IMC and BCD (Backensfeld, 1990). An increase in the proportion of SLS or BCD did not significantly improve dissolution rate.

The results of the dissolution study showed that IMC/BCD solid dispersion and IMC/SLS solid dispersion prepared by spray drying method had a faster dissolution rate than IMC itself or spray dried IMC or its physical mixtures. However, the dissolution rates of physical mixtures and spray dried IMC were faster than IMC due to the surfactant-like properties of beta BCD and salt formation of IMC, respectively.

In contrast to SLS, it seemed that the chemical interaction occurred between IMC and BCD and salt formation during the spray drying process. It was confirmed by the phase solubility diagrams, solubility studies and dissolution rate studies and the data obtained by physical determination (SEM, FTIR, DSC and PXRD). Furthermore an increased solubility of IMC was due to the small particle size and the metastable amorphous state formation of spray dried products.

The dissolution rate of spray dried IMC/SLS was faster than IMC, spray dried IMC and its physical mixtures. The reasons for this result were the micellar effects of SLS and the salt formation during spray drying process. Moreover, the low crystallinity and smaller particle size resulted in an increased in the dissolution rate of IMC.

The results of the effects of spray drying conditions such as inlet air temperature and feed rates showed that there were no significant differences in the physicochemical properties of spray-dried particles, confirmed by FTIR, DSC, PXRD, particle size determination, flowability of spray dried products, solubility study and

dissolution study. On the other hand, the amounts of BCD or SLS affected the solubility of spray dried products. The higher amount of BCD, the lower solubility of IMC. However, there are no significant different in the solubility of IMC due to the various amount of SLS.

Furthermore, HPLC study indicated that the chemical interaction between IMC and BCD in the spray drying process retarded the degradation rate of IMC. But the degradation of IMC was accelerated when IMC was spray dried alone or with SLS. Therefore, the spray drying method of incorporating BCD or SLS as an excipient in formulations to enhance the stability of chemically drugs should be further investigated.

Finally, it could be concluded that an enhancement of dissolution rate of IMC with BCD and SLS was affected by spray drying process. The spray drying conditions or the amount of BCD or SLS did not affect the dissolution rate of IMC. From this study the spray drying method is another method for the improvement of the dissolution rate of poorly soluble drugs especially when used with solubilizers (BCD or SLS). However limitation of using BCD or SLS as solubilizers and the stability of spray dried products should be studied further.