CHAPTER V

CONCLUSIONS

Starch has been selected as a partial substitute for hard gelatin capsule shells by dipping method.

Eight starches, Glutinous starch, Elastigel 1000J®, Elastigel 2000C®, Elastigel 3000M®, Alpha starch®, Eragel®, Rice starch and Tapioca starch were selected to represent three kinds of starches which are native, pregelatinized and modified starches. This study is to find out suitable substituted starches, maximum amount of substituted starches, the amount of appropriate plasticizer, the percentage of SLS by using dipping method. The appropriate starch-gelatin films and capsules were selected by using the appearance, the physical properties such as the maximum stress and extension at break, the viscosity, weight, thickness and moisture content.

After adding starch in gelatin, the appearance of all starch-gelatin solutions and films were homogenous and slightly different from gelatin films such as higher viscosity, more brittle and slightly cloudy. The maximum amount for homogenous and appropriate Elastigel 2000C®-gelatin, Eragel®-gelatin and Elastigel 3000M®-gelatin were 35%, 25% and 20% respectively. This amount of substitution can reduce the cost of hard gelatin capsule production vastly. However, the properties of starch-gelatin films were necessary to improve. Plasticizers such as sorbitol and glycerin were chosen for starch-gelatin films improvement.

From the experiment, 35% Elastigel 2000C® with no plasticizer, 25% Eragel® with 0-4% sorbitol or 0-2% glycerin and 20% Elastigel 3000M® with 0-4% sorbitol and 0-2% glycerin produced films which have properties nearly similar to gelatin properties.

SLS is a process aid which has been added to wet the moulds, reduce surface tension, to enhance the gross of films and to produce thickness consistency of films. 0.1% SLS was suggested to be added in Elastigel 2000C® and Eragel® formulations while it caused severe bubbles for Elastigel 3000M® formulation. Thus, SLS should not be added in Elastigel 3000M® formulation. Finally, three best formulations were 35% w/w

Elastigel 2000C® with 0.1% w/w SLS, 25% w/w Eragel® with 0.1% w/w SLS and 1% w/w glycerin, and 20% w/w Elastigel 3000M® with 2% w/w glycerin.

In order to prove the ability of starch-gelatin capsules as compared to gelatin capsules, starch-gelatin capsule were tested for disintegration and dissolution. All of capsules could be disintegrated within 10 minutes. Also, all capsules containing Dicloxacillin were dissolved completely in 10 minutes which met USP XXV requirement.

After stability test, the storage condition was recommended to be less than 30°C, 75% RH inside LDPE bag. This experiment showed promising results, which confirmed that three starches could be used to homogenously blend with gelatin and produced hard starch-gelatin capsules.

However, further works are required to improve the properties of starch-gelatin capsules such as the clarity, the stability etc. As widely known, colouring agents, opaque agent for example; TiO_2 or preservative were necessary ingredients for hard capsules production. Thus, the effects of these ingredients are interesting for the future study. If starch can be used to replace gelatin in hard capsule production by dipping method, this means our dream comes true.