Chapter 4

Conclusions

The propranolol hydrochloride pellets were prepared by oscillating granulator and spheronizer. Avicel PH101 was used as binder, corn starch and lactose were used as diluent. Sustained release formulation could be prepared by coating propranolol hydrochloride pellets with a polymer membrane. A mixture of ammonio methacrylate copolymer and ethylcellulose in various ratios were implemented to form a film controlling the release of the drug. Two types of ammonio methacrylate copolymer were employed in combination with ethylcellulose polymer, Eudragit® RL100 (high permeability, ammonio methacrylate copolymer type A), and Eudragit® RS100 (low permeability, ammonio methacrylate copolymer type B). The pellets was coated with polymers using Wurster type fluidized bed coater. In fluidized bed coating, simultaneous drying and particle enlargement were carried out by spraying the coating polymer onto surface of pellets. Particle growth occurred by solidification of polymeric solution from the feed liquid onto the surface of pellets. The physical properties of propranolol hydrochloride core pellets and coated pellets were evaluated. Also, the release of the coated pellets were tested in acid buffer pH 1.2 and phosphate buffer pH 6.8 to observe the effect of the dissolution medium.

The effect of varying coating levels and ratios of the mixture polymers for the release rate were studied. The higher coating level resulted in retarding the release of the drug from the pellets. This was corresponding with the result from scanning electron microscope (SEM) that relatively thicker film layer was obtained by increasing percent of film coating.

The coating of various ratios of polymer represented that ethylcellulose possesed very low permeability which showed slow drug diffusion through the

coated film. Eudragit®RL100 possesed high permeability and gave high drug diffusion but Eudragit®RS100 exhibited medium permeability that resulted in a moderate drug diffusion through its film. These characteristics could be used to modify ethylcellulose film properties in order to increase propranolol hydrochloride release rate.

After completion of the release studied, the release profile of each coating formulations were observed. The three coating formulations were selected and combined to adjust the drug release to comply with the USP XXIII for 24 hours propranolol hydrochloride extended release capsule in term of the release testing. Moreover, the release characteristics of the sustained release propranolol hydrochloride capsules was comparable to the release behavior of Inderal®LA160.