CHAPTER V

CONCLUSION

This research was conducted to develop of dry powder coating on pellets. Propranolol hydrochloride core pellets were prepared by extrusion-spheronization technique. Eudragit[®] E was used as a coating material due to low glass transition temperature and good adhesion property. The core pellets were coated with pure Eudragit[®] E using conventional coating pan and then were oven-cured at 90 °C for 8hr. From the propranolol hydrochloride pellets, the following observation could be summarized:

- 1. The effect of various coating levels were studied. The higher coating level resulted in smoother and more uniform film, however, increasing the polymer quantity within the range studies resulted in the same film thickness.
- 2. The coating of various ratios of pellet and polymer size represented that smaller polymer particle size gave better adhesion, better heat dissipation and more uniform film distribution than larger particles. However, large pellet size would give higher film thickness than smaller pellet size.
- The coating of various surfaces of core pellets showed that the rougher surface pellets resulted in higher polymer adhesion. This was due to the increase effective contact area.
- 4. The coating of various moisture contents of core pellets represented that higher moisture content on surface of core pellets might result in better polymer adhesion, however, these results were still indistinctive.
- 5. The secondary layer coating gave higher film thickness than primary layer coating and no interference between both layers. However, the process induced undesirable pellet aggregation due to thermosoftening of the primary coating material.
- 6. The drug release profiles from coated pellets are not significantly different than release profile of core pellets (Similarity factor "f2" test).

 No interaction and incompatibility between the drug and polymer or other excipients in the formulation was observed.

Consequently, This process is temperature dependent and it has been demonstrated that below minimum softening temperature, polymer particles would only slightly adhere on pellets and below suitable curing temperature and time, polymer particles would not form continuous film. The thermal after-treatment (curing) was necessary for the coalescence of the polymer particles and good film formation to occur. The size of polymer particles considerably affected the polymer adhesion, better results were found by using smaller particles (Eudragit® E PO) in the coating. The physical properties of the substrate could significantly influence polymer adhesion. Higher effective contact areas were more readily adhered by the polymer particle and provided greater adhesion contact between the film and surface (such as rough surface). Therefore, this dry powder coating technique may be considered as an alternative method for coating core material without the use of toxic solvents being involved and should be later adjusted in the future experiment.

The future work for this dry powder coating could be summarized as follows:

- 1. The fluidized-bed coater should be further selected to use in this technique due to the close-system might reduce the floating-out the dry polymer powder during coating process. In curing process, curing temperature and time might be reduced when using this equipment because the impact force might enhance the film formation. However, the surface of chamber should be modified by using non-sticky substance (teflon) to reduce the heated polymer adhesion on the chamber.
- In this curing process, the high temperature and duration were used. Therefore, the degradation might occur. HPLC analysis should be used to detect this degradation.
- 3. The measured film thickness in this experiment were not exactly data, however, they could be the tendency of film thickness of coated pellets. Because, the film thickness might be reduced by pressing force during crossed section of coated pellets (before measuring by SEM). And when image analysis was used to determine the size of pellets, the position of light source is particularly crucial in providing an accurate particle size value. Top light is

recommended, as here it gave a mean pellet size similar to the true pellet size. But in this experiment, the use of light table might produce significantly larger pellet size values. Therefore, the measurement of film thickness of coated pellets should be optimized in the future experiments.

- 4. The conditions in liquid-based coating should be further optimized. Because the surface morphology of coated pellets still showed non-glossy and very rugged. But this phenomenon might cause from the properties of Eudragit® E, hence, it should be studied in the future experiment.
- 5. Plasticizers should be used to reduce the glass transition temperature and to improve the properties the selected polymers. The spray dryer might be selected to produce this plasticized polymer (micronized polymer powder).