

CHAPTER IV

CONCLUSIONS

The mixture film properties between ethylcellulose and ammonio methacrylate copolymer type B in both organic system and aqueous dispersion system using different types and amounts of plasticizers were investigated. Type and amount of the plasticizer in the film coating had strong effects on the permeation of propranolol hydrochloride through plasticized films, mechanical properties of films and surface characteristics. If the good characteristics of films were considered, the film coating with ethylcellulose and higher portion of ethylcellulose should be plasticized with dibutyl phthalate whereas the film coating with Eudragit[®]RS100 and higher portion of Eudragit[®]RS100 should be plasticized with triethyl citrate. Because of leaching-out problem of water soluble plasticizer, an enhanced drug release could be observed in the films prepared from Eudragit[®]RS100 or the mixed polymers containing triethyl citrate.

Aqueous dispersions of Surelease[®], Eudragit[®]RS30D and their blended films should be plasticized with triethyl citrate rather than triacetin because the resulting films showed good film characteristics and the sustained-release properties. Incorporation of higher amount of plasticizers affected the release characteristics by causing both increases and decreases in drug release depending on the properties of film and plasticizer. The higher level of plasticizers could develop better mechanical properties as well as the surface characteristics. However, the properties of films, e.g. coating surface characteristics and mechanical properties, from organic system with higher amount of triethyl citrate were better than those with higher amount of dibutyl phthalate. But the higher quantity of dibutyl phthalate could retard drug release when compared to coated pellets with lower quantity of dibutyl phthalate.

An increase in proportion of Eudragit[®]RS100 in ethylcellulose led to an improvement in film appearances whereas the incorporation of Eudragit[®]RS30D in Surelease[®] could not modify the appearances of polymer blends. The higher the proportion of Eudragit[®]RS type, the faster drug release was attained. Additionally, to achieve the desired release profiles, it is not only dependent on the proportion of Eudragit[®]RS type but also the amount and type of plasticizers. However, the increasing proportion of Eudragit[®]RS100 in the mixture films of less than 50% could not increase drug release while only 30% increase in Eudragit[®]RS30D in the mixed films could augment drug release. Consequently, the property of Eudragit[®]RS type that could augment drug release characteristic was markedly influenced when films were prepared from aqueous dispersion system. The mechanical properties from the blended films could not be equivalent to the good mechanical properties of single film. The data generated from mechanical testing could be correlated with scanning electron microscopic evaluation. Nevertheless, some data on mechanical testing with dry casting method could be useful to relate the drug release characteristics. Because the leaching out of water soluble plasticizer occurred. The films prepared from dry casting method could not be associated with the film properties of the coated pellets in dissolution medium.

From the transmission infrared spectra, the interaction between two polymers from aqueous dispersion system (Surelease[®] and Eudragit[®]RS30D) was observed because of the new additional band at 805.52 cm^{-1} while the X-ray diffractogram and DSC studies could not detect this interaction between Surelease[®] and Eudragit[®]RS30D. Nevertheless, the blended polymer with the ratios of 5:5 and 7:3 from this system could be accomplished and produced moderate appearances.