CHAPTER I

INTRODUCTION

The application of organic polymer solutions has been historically used for film coating. Toxicity and environmental concerns associated with the use of organic solvents have pushed the pharmaceutical industry to explore alternative procedures. Many polymers have been formulated into aqueous colloidal polymer dispersions or aqueous micronized polymer dispersion. (Fukumori, Y. 1994) However, aqueous coatings are at times unsuitable. A fair high energy of evaporation of water requires a higher coating temperature and/or long processing times, which may cause thermal degradation of heat-sensitive materials (Lehmann, K. 1994). Moisture-sensitive cores may also be deteriorated during the coating process on contact with water. In addition, drug migration into the coating could occur during aqueous-based coating, depending on the drug molecule. To overcome these limitations of liquid-based coating, a novel alternative coating technology based on polymer powder has been introduced.

Dry powder coating, which directly attaches micronized polymer particles (guest or fine) onto the surface of relatively larger particles (host or core) without any solvents, binder, or even water, is a promising alternative approach. In Pharmaceutical science, few studies on this technique have been done and, hence, very little information has been published in this regard. Based on our literature searches, little or no work has specifically addressed the same principle of dry powder coating as in this work.

Some researchers (Obara et al., 1999 and Pearnchob et al., 2003a, b and c) have been developed and revealed that a coating technique in a fluidized bed; however, the process was not completely dry due to the use of liquid binder and curing with humidity (100 % RH) during the process. The polymer particles and an emulsion of liquid material (plasticizers plus 10 %w/w HPMC solution) were fed/sprayed separately onto pellets.

However, knowledge of thermal transitions in polymers was used an important basic of this experiment. The solid-to-liquid transition occurs very gradually through an intermediate "rubbery" state without a phase transformation. The transition from the hard and brittle glass into a softer, rubbery state occurs over a narrow temperature

range referred as the glass transition temperature (Tg). The tackiness of polymer increased with higher temperature above Tg due to the softening of the polymer. This point was applied to use in this technique. The polymer powder had to adhere to the heated surface (due to polymer powder was transformed glassy to rubbery state) and then a thermal after treatment (curing) at elevated temperatures was necessary for the coalescence of polymer particles and good film formation.

This study is used propranolol hydrochloride pellets as a model core material due to spherical shape is suitable for coating. And suitable polymer powder should have low glass transition temperature and high adhesion property.

Objectives of the study

The main objective is to develop dry powder coating technique by

1. Evaluating the optimum conditions in coating core pellets with dry polymer powder using conventional coating pan.
2. Investigating the parameters that affect polymer adhesion and film formation by evaluating the physical and solid state properties of free film, core and coated pellets.