Thesis Title Influence of Methacrylic Acid Copolymer Film Thickness on Properties of Enteric Coated Diclofenac Sodium Tablets.

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ABSTRACT

Three types of methacrylic acid copolymer (Eudragit® L 100, Eudragit® S 100 and Eudragit® L 100-55) which was widely used were evaluated on diclofenac sodium tablets both 25 mg and 50 mg contents. The enteric coatings were prepared in a perforated pan coater (ThaiCoater®15"). The coating condition was adjusted to suit each type of polymers. The influence of various film thicknesses on properties of enteric coated tablets were studied, such as tablet weight, thickness, diameter, hardness, friability, gastric fluid resistance and drug release in pH 6.8 medium. Furthermore, the stability at 45°C in tight containers and at 45°C/75% RH were also studied.

It was found that Eudragit® L 100-55 and Eudragit® L 100 exhibited excellent enteric properties at their film thicknesses not less than 5 mg/cm^2. Eudragit® S 100 was not suitable for enteric based on the USP requirement for enteric tablets. Eudragit® L 100-55 coating offered the advantages of aqueous dispersion system whereas the others employed organic solvent. The increase in film thickness had less effects on the tablets coated with Eudragit® L 100-55 than with the others regarding the disintegration and dissolution. Moreover, the drug releases of tablets coated with Eudragit® L 100-55 were faster than those coated with the others. The stability test

indicated that the enteric coated tablets should be protected from moisture and stored in tight containers.