

## INTISARI

*Promethazine HCl* adalah obat yang digunakan dalam mengatasi *motion sickness* terutama untuk anak-anak. Obat *promethazine HCl* memiliki sifat mudah larut sehingga cocok diformulasi dalam bentuk sediaan *fast disintegrating tablet* (FDT) karena akan memberikan absorpsi obat yang lebih cepat. Rasa pahit obat *promethazine HCl* dapat diatasi dengan membentuk campuran menggunakan  $\beta$ -siklodekstrin. Tujuan penelitian ini adalah mengetahui proporsi *crospovidone* dan Ludipress® yang menghasilkan sifat fisik FDT PM-HCl optimum dan mengetahui karakteristik sifat fisik tablet hasil percobaan.

Formula FDT *promethazine HCl* dibuat menggunakan kombinasi *superdisintegrant crospovidone* dan *filler binder Ludipress®* dengan metode *Simplex Lattice Design* (SLD). Analisis SLD menggunakan *Software Design Expert® version 9.0.5.1* menghasilkan delapan *run*. Hasil komposisi *run* dibuat tablet kemudian dilakukan uji sifat fisik sediaan yang meliputi uji keseragaman kadar, uji kekerasan, uji kerapuhan, uji waktu disintegrasi, uji disolusi obat, rasio absorpsi air, dan uji waktu pembasahan.. Kombinasi kadar Ludipress® dan *crospovidone* dianalisis *statistic* menggunakan *Software Design Expert® version 9.0.5.1* untuk mendapatkan komposisi formula optimum.

Hasil penelitian menunjukkan bahwa peningkatan proporsi *crospovidone* dapat meningkatkan kerapuhan, rasio absorpsi air, dan disolusi sedangkan peningkatan proporsi Ludipress® dapat meningkatkan kekerasan, waktu disintegrasi, dan waktu pembasahan. Formula optimum FDT *promethazine HCl* diperoleh pada proporsi *crospovidone* sebesar 5,35% dan Ludipress® sebesar 24,65% terhadap bobot tablet.

Kata Kunci : *Fast Disintegrating Tablet, Promethazine HCl, Crospovidone, Ludipress®*,  $\beta$ -siklodekstrin.

## ABSTRACT

Promethazine HCl is a drug used to cure motion sickness, especially for children. Promethazine HCl's properties is easily soluble making the drug suitable formulated in dosage form of fast disintegrating tablet (FDT) because it can increase drug's absorbtion. The bitter taste of promethazine HCl can be solved by forming mixture with beta cyclodextrin. The purpose of this study was to determine the proportion of crospovidone and Ludipress<sup>®</sup> that produce optimum physical properties of FDT PM-HCl and to know the physical properties's characteristic of the experimental tablet.

FDT promethazine HCl's formula is made using combination of superdisintegrant crospovidone and filler binder Ludipress<sup>®</sup> with Simplex Lattice Design (SLD) method. SLD analysis using Software Design Expert<sup>®</sup> version 9.0.5.1 produced eight runs. Tablet is made by the run and then the physical properties are tested which includes content uniformity test, hardness test, test friability, disintegration time test, drug dissolution test, water absorption ratio, and wetting time test. The combination of crospovidone and Ludipress<sup>®</sup> were analyzed statistically using Software Design Expert<sup>®</sup> version 9.0.5.1 to obtain optimum composition of the formula.

The results showed that increasing proportion of crospovidone increase the fragility, the ratio of water absorption and dissolution while increasing proportion of Ludipress<sup>®</sup> can increase hardness, disintegration time and wetting time. Optimum formula of FDT promethazine HCl obtained in proportion of 5.35% crospovidone and 24.65% of Ludipress<sup>®</sup>.

**Keywords:** Fast Disintegrating Tablets, Promethazine HCl, Crospovidone, Ludipress<sup>®</sup>,  $\beta$ -cyclodextrin.