# INTISARI

*Promethazine-HCl* merupakan antihistamin yang efektif digunakan untuk mengatasi mual muntah. *Promethazine-HCl* dalam sediaan tablet konvensional memiliki kelemahan yaitu membutuhkan waktu yang lama untuk diabsorpsi dan penggunaan yang tidak nyaman untuk anak-anak. *Fast Disintegrating Tablet* (*FDT*) *promethazine-HCl* merupakan salah satu sediaan alternatif dengan onset cepat dan rasa yang menyenangkan. Penelitian ini bertujuan untuk mengetahui pengaruh penggunaan *crospovidone* dan Pearlitol® 400DC terhadap sifat fisik *FDT promethazine-HCl.*

Pembentukan kompleks inklusi *promethazine-HCl* dan β-siklodekstrin dilakukan dengan menggunakan metode *kneading*. Delapan formula *FDT* promethazine-HCl dibuat dengan metode kempa langsung dalam berbagai konsentrasi *superdisintegrant crospovidone dan filler binder* Pearlitol® 400DC. Evaluasi sifat fisik *FDT* yang dilakukan dengan menguji kekerasan, kerapuhan, waktu disintegrasi, waktu pembasahan, rasio absorpsi air, dan disolusi obat. Data sifat fisik yang diperoleh diolah menggunakan metode *simplex lattice design* dengan program *Design Expert® version 10.0.0.3* untuk memperoleh formula optimum.

Hasil penelitian menunjukkan bahwa peningkatan proporsi *crospovidone* dapat meningkatkan kerapuhan dan rasio absorpsi air, sedangkan peningkatan proporsi Pearlitol® 400DC dapat meningkatkan kekerasan, waktu disintegrasi, dan waktu pembasahan. Formula optimum *FDT promethazine-HCl* diperoleh pada proporsi *crospovidone* sebesar 6% dan Pearlitol® 400DC sebesar 24% terhadap bobot tablet.

**Kata Kunci**: Optimasi, *Fast disintegrating tablet* (*FDT*), *promethazine-HCl*, *Crospovidone*, Pearlitol® 400DC

# ABSTRACT

Promethazine-HCl is an effective antihistamine used to treat nausea and vomiting. The conventional tablet dosage form of Promethazine-HCl has several issues, such as, being slow to absorb and not easy to consume by children who cannot swallow tablet. Another solid dosage form of antiemetic is Fast Disintegrating Tablet (FDT) promethazine-HCl, which provides fast dissolution rate, so that the expected therapeutic effect can be gained quickly. The objective of this research is to investigate the impact of *crospovidone* and Pearlitol® 400DC on the physical properties FDT promethazine-HCl.

The development of inclusion complex was performed using *kneading* method. Subsequently, we prepared eight FDT promethazine-HCl formulas using direct compression method in several different concentrations. To evaluate the physical properties of FDT, we conducted several tests, including hardness test, friability test, disintegration time, wetting time, water absorption ratio, and drug dissolution. We analyzed the obtained data of physical properties using simplex lattice design method, where the Design Expert® version 10.0.0.3 was used to obtain the optimum formula.

The experimental results showed that the increase of *crospovidone* proportion may increase the friability and water aborsption ration. On the other hand, the increase in of Pearlitol® 400DC proportion may lead to the increase of hardness, disintegration time, and wetting time. The optimum formula of FDT promethazine-HCl was obtained when we *crospovidone* and Pearlitol® 400DC with proportion 6% and 24% relative to the tablet weight, respectively.

**Keywords:** Optimization, Fast Disintegrating Tablet (FDT), promethazine-HCl, *crospovidone*, Pearlitol® 400DC