

**OPTIMASI FORMULA FAST DISINTEGRATING TABLET
PROMETHAZINE-HCl TERINKLUSI β -SIKLODEKSTRIN
MENGUNAKAN KOMBINASI SUPERDISINTEGRANT SODIUM
STARCH GLYCOLATE DAN CROSPVIDONE**

INTISARI

Promethazine-HCl merupakan antihistamin golongan *Phenothiazine* yang efektif digunakan untuk mengatasi mual muntah akibat mabuk perjalanan (*motion sickness*). *Promethazine-HCl* umumnya tersedia dalam bentuk tablet konvensional yang memiliki kelemahan yaitu aksi obat lambat, bioavailabilitas rendah, serta tidak nyaman digunakan untuk pasien *pediatric*. *FDT Promethazine-HCl* merupakan pilihan tepat bagi pasien *pediatric* dengan onset cepat dan rasa yang menyenangkan. Rasa pahit dari *Promethazine-HCl* ditutupi menggunakan agen penginklusi β -siklodekstrin. Penelitian ini bertujuan untuk mendapatkan formula *FDT Promethazine-HCl* yang memiliki sifat fisik optimum dengan kombinasi *superdisintegrant Sodium Starch Glycolate (SSG)* dan *Crospovidone*.

Delapan *run FDT Promethazine-HCl* dibuat menggunakan metode kempa langsung menggunakan kombinasi *superdisintegrant SSG* dan *Crospovidone* dalam berbagai konsentrasi. Evaluasi sifat fisik *FDT* dilakukan dengan menguji beberapa parameter antara lain kekerasan, kerapuhan, waktu disintegrasi, waktu pembasahan, rasio absorpsi air, dan disolusi. Optimasi formula *FDT Promethazine-HCl* dilakukan dengan metode *Simplex Latice Design* menggunakan *software Design Expert[®] version 10.0.0 (trial)*.

Hasil penelitian menunjukkan bahwa kombinasi *SSG* dan *Crospovidone* berpengaruh terhadap sifat fisik *FDT Promethazine-HCl*. Peningkatan proporsi *SSG* dapat meningkatkan kekerasan, memperlama waktu disintegrasi dan waktu pembasahan. Sedangkan, peningkatan proporsi *Crospovidone* dapat meningkatkan kerapuhan dan rasio absorpsi air. Proporsi *SSG* 2% dan *Crospovidone* 6% terhadap bobot tablet memberikan sifat fisik optimum pada *FDT Promethazine-HCl*.

Kata kunci: *Fast Disintegrating Tablet, Promethazine-HCl, Sodium Starch*

Glycolate, Crospovidone, β -siklodekstrin.

ABSTRACT

Promethazine-HCl is an antihistamine drug, which is classified into Phenothiazine group, used to treat motion sickness effectively. Promethazine-HCl generally available in tablet dosage form which has the disadvantages such as slow action, low bioavailability, and inconvenience for pediatric patients. FDT Promethazine-HCl is the right choice for pediatric patients with rapid onset and a pleasant taste. The bitter taste of Promethazine-HCl was covered using β -siklodekstrin by forming inclusion complex. This study aims to determine the formula of FDT Promethazine-HCl which is giving the optimum physical properties with combination of *superdisintegrant Sodium Starch Glycolate* (SSG) dan *Crospovidone*.

Eight runs of FDT Promethazine-HCl were made using direct compression method, with the combination of SSG and *Crospovidone* in various concentration. Evaluation of the physical properties including hardness, friability, disintegration time, wetting time, water absorption ratio, and drug dissolution. Optimization of FDT Promethazine-HCl formula were analyzed using Simplex Lattice Design method with Design Expert[®] software version 10.0.0 (trial).

The results shows that the combination of *Sodium Starch Glycolate* and *Crospovidone* is effecting the physical properties of FDT Promethazine-HCl. Increasing proportion of SSG may increase hardness, prolong the disintegrating time and the wetting time. Whereas, increasing the proportion of *Crospovidone* may increase the friability and water absorption ratio. The proportion of 2 % SSG and 6 % *Crospovidone* against the weight of the tablet provides optimum physical properties of FDT Promethazine-HCl.

Keywords: Fast Disintegrating Tablet, Promethazine-HCl, *Sodium Starch*

Glycolate, *Crospovidone*, β -siklodekstrin.