

INTISARI

Fast disintegrating tablet (FDT) Promethazine-HCl merupakan bentuk sediaan yang dapat melepaskan obat dengan cepat. Kecepatan pelepasan obat dipengaruhi oleh kecepatan sediaan untuk hancur. Kombinasi Ac-Di-Sol[®] dan *crospovidone* akan mempercepat hancurnya tablet dengan mekanisme yang bekerja secara sinergis. Penelitian ini bertujuan untuk memperoleh nilai optimum kombinasi keduanya agar didapatkan FDT dengan sifat fisik optimum sesuai persyaratan.

Dalam penelitian ini dibuat 8 *run* FDT dengan variasi kadar *superdisintegrant* Ac-Di-Sol[®] dan *crospovidone* menggunakan metode kempa langsung. Evaluasi sifat fisik tablet dilakukan pada tiap *run* meliputi uji keseragaman bobot, uji keseragaman kadar, uji kekerasan, uji kerapuhan, uji waktu pembasahan, uji waktu disintegrasi tablet, uji rasio absorpsi air, dan uji disolusi. Data yang didapatkan kemudian dianalisis menggunakan metode *simpex lattice design* dengan aplikasi Design Expert[®] version 9.0.6 (*trial*) sehingga diperoleh formula FDT optimum. Formula optimum hasil prediksi diverifikasi dengan analisis *one sample t-test* taraf kepercayaan 95%.

Berdasar hasil penelitian diperoleh kombinasi Ac-Di-Sol[®] : *crospovidone* sebesar 2% : 6% mampu memberikan tablet dengan sifat fisik yang optimum dan sesuai persyaratan yang ditentukan. Analisis *one sample t-test* menunjukkan bahwa tidak terdapat perbedaan yang signifikan antara formula hasil prediksi dengan hasil penelitian.

Kata Kunci: *Fast Disintegrating Tablet*, Promethazine-HCl, Ac-Di-Sol[®], *crospovidone*, *taste masking*, β -siklodelstrin.

ABSTRACT

Fast Disintegrating Tablet (FDT) Promethazin-HCl is an alternative dosage form for motion sickness, which is able to release the drug faster. The rate of the drug release is influenced by the disintegrating time. Superdisintegrant is used to accelerate the disintegration time of a tablet. Combination of Ac-Di-Sol[®] and crospovidone will accelerate the disintegration time of the tablet with synergic mechanism. This study aims to gain the optimum combination of Ac-Di-Sol[®] and crospovidone to obtain FDT with optimum physical properties.

Eight runs of FDT with variation proportion of Ac-Di-Sol[®] and *crospovidone* were made by direct compression method. The FDTs were evaluated for its physical properties such as weight uniformity, content uniformity, hardness, friability, disintegration time, wetting time, water absorption ratio, and dissolution. The results were analyzed using simplex lattice design method with Design Expert[®] version 9.0.6 (trial) software to obtain the optimum formula. Verification between actual result and prediction of the software was analyzed by one sample t-test with 95% confidence level.

The study showed that the combination of 2% Ac-Di-Sol[®] and 6% *crospovidone* was able to give tablets with optimum physical properties and met the requirements. One sample t-test analysis showed no significant difference between the prediction formula and the actual result.

Key Words: *Fast Disintegrating Tablet*, Promethazine-HCl, Ac-Di-Sol[®], *crospovidone*, *taste masking*, β -cyclodextrine.