

INTISARI

Amlodipin besilat merupakan obat antihipertensi dan antiangina pectoris yang tersedia dalam bentuk tablet konvensional. Kelemahan tablet konvensional diantaranya pelepasan obat yang lama dan ketidaknyamanan penggunaan terutama pasien geriatri. Pembuatan *fast disintegrating tablets* (FDT) diharapkan mampu mengatasi masalah tersebut. Penggunaan kombinasi *superdisintegrant* berupa *crospovidone* dan *sodium starch glycolate* (SSG) dilakukan karena kedua bahan tersebut memiliki mekanisme disintegrasi utama yang berbeda. Penelitian ini bertujuan untuk mendapatkan formula optimum kombinasi *superdisintegrant* pada FDT amlodipin besilat.

Tablet dibuat dengan metode kempa langsung dan terdapat 8 formula dengan perbandingan kadar *crospovidone*:SSG yaitu FI (1%:6%), FII (1%:6%), FIII (2%:5%), FIV (3%:4%), FV (3%:4%), FVI (4%:3%), FVII (5%:2%), dan FVIII (5%:2%). Uji sifat alir serbuk yang digunakan adalah kecepatan alir dan sudut diam. Evaluasi tablet yang digunakan adalah uji keseragaman bobot, kekerasan, kerapuhan, waktu disintegrasi, waktu pembasahan, rasio absorpsi air, dan disolusi. Untuk mengetahui kombinasi kadar *superdisintegrant* pada formula optimum untuk tiap parameter, dilakukan analisis dengan model *Simplex Lattice Design* menggunakan program *Design Expert version 9.0.4.1*.

Hasil penelitian menunjukkan bahwa kombinasi kadar *crospovidone* dan SSG berpengaruh terhadap sifat alir dan sifat fisik FDT amlodipin besilat. Peningkatan proporsi *crospovidone* mampu meningkatkan kecepatan alir, kekerasan, disolusi, serta menurunkan waktu disintegrasi dan waktu pembasahan, sedangkan peningkatan SSG mampu meningkatkan sudut diam dan rasio absorpsi air. Formula optimum diperoleh dengan kombinasi *crospovidone*:SSG 5%:2%.

Kata kunci : FDT, amlodipin besilat, *crospovidone*, SSG

ABSTRACT

Amlodipine besylate is a drug which is used to treat chronic stable angina and hypertension that available in conventional tablets dossage form. Several weaknesses of conventional tablets is the release of drugs that requires a long time and often times people experience inconvenience especially geriatric patiens. Fast disintegrating tablets or known as FDT is expected to solve these problems. The use of crospovidone and sodium starch glycolate (SSG) as superdisintegrants is because of difference in main disintegration meccanism. The objective of this study was to obtain the optimum formula of amlodipine besylate FDT with combination of crospovidone and SSG as superdisintegrants.

FDT were manufactured using direct compression method in eight formulas combination of crospovidone and SSG namely FI (1%:6%), FII (1%:6%), FIII (2%:5%), FIV (3%:4%), FV (3%:4%), FVI (4%:3%), FVII (5%:2%), and FVIII (5%:2%). Methods for testing powder flow were angle of repose and flow rate. FDT were evaluated by the uniformity of weight, hardness, friability, disintegration time, wetting time, absorption ratio, and dissolution. To obtain the combination of superdisintegrant in the optimum formula, data were analyzed using simplex lattice design method by software Design Expert 9.0.4.1.

Results of the study showed that the combination of crospovidone and SSG affect powder flow and the physical properties of amlodipine besylate FDT. Increasing the proportion of crospovidone can increase the flow rate, hardness, dissolution, and decrease disintegration time and wetting time, while increasing the proportion of SSG can increase the angle of repose and absorption ratio. Optimum formula of FDT were obtained with the composition of crospovidone 5% and SSG 2% of the tablet weight.

Keywords : *FDT, amlodipine besylate, crospoovidone, SSG.*