

INTISARI

Fast disintegrating tablets (FDT) merupakan tablet yang diletakkan di mulut, hancur atau melarut kurang dari 3 menit oleh cairan saliva dan kemudian ditelan tanpa membutuhkan air dan memberikan aksi yang cepat. FDT amlodipin besilat diharapkan mampu mengatasi kekurangan yang ada pada tablet konvensional untuk menghasilkan onset cepat dalam pengobatan angina pektoris. Penelitian ini bertujuan untuk mengetahui kadar optimum penggunaan *superdisintegrant* Kollidon[®]CL yang dikombinasikan dengan *filler binder* Avicel[®] PH 102 yang akan memberikan formula tablet optimum pada FDT amlodipin besilat.

Pada penelitian ini delapan *run* kombinasi Kollidon[®]CL dan Avicel[®] PH 102, yaitu *run* I (2%:60%), II (3,5%:58,5), III (5%:57%), IV (6,5%:55,5%), V (8%:54%), VI (8%:54%), VII (5%:57%), VIII (2%:60%) dibuat dengan menggunakan metode kempa langsung. Evaluasi sifat fisik FDT dilakukan dengan menguji beberapa parameter diantaranya uji kekerasan, uji kerapuhan, uji waktu pembasahan, uji waktu disintegrasi, uji rasio absorpsi air, dan uji disolusi secara *in vitro*. Data selanjutnya diolah untuk memprediksi formula optimum dengan metode *simplex lattice design* menggunakan *Design Expert[®] version 9.0.4.1 (trial)*.

Hasil yang diperoleh menunjukkan bahwa kombinasi Kollidon[®]CL dan Avicel[®] PH 102 memberikan pengaruh terhadap sifat fisik FDT amlodipin besilat. Peningkatan kadar Kollidon[®]CL dalam tablet mempercepat waktu pembasahan, waktu disintegrasi, meningkatkan respon kerapuhan, serta rasio absorpsi air FDT dan kombinasi keduanya meningkatkan respon waktu disintegrasi dan disolusi. Formula optimum FDT amlodipin besilat diperoleh pada perbandingan komposisi Kollidon[®]CL 6,07% dan Avicel[®] PH 102 sebesar 55,93% terhadap bobot tablet.

Kata Kunci: FDT, Amlodipin Besilat, Kollidon[®]CL, Avicel[®] PH 102

ABSTRACT

Fast Disintegrating Tablet (FDT) is a tablet which is put in your mouth, crumbled or dissolved in less than three minutes by saliva and then swallowed without any water. In other words, FDT gives immediate onset. FDT amlodipine besylate is expected to supplement the conventional tablets to give immediate onset in the angina pectoris treatment. This research is aimed to know the maximum rate of the use of the superdisintegrant Kollidon[®] CL combined with the filler binder Avicel[®] PH 102 to establish the optimum tablets formula of FDT amlodipine besylate.

In this research, eight combination runs of Kollidon[®] CL and Avicel[®] PH 102; run I (2%:60%), II (3,5%:58,5%), III (5%:57%), IV (6,5%:55,5%), V (8%:54%), VI (8%:54%), VII (5%:57%), VIII (2%:60%) were made using direct compression method. The physical properties of FDT was evaluated by examining some parameters as follows: hardness test, friability test, wetting time, disintegration test, water absorption ratio, and in vitro dissolution test. The data was then analyzed to predict the calculation of optimum formula with the simplex lattice design method using Design Expert version 9.0.4.1 (trial).

The result shows that the combination of Kollidon[®] CL and Avicel[®] PH 102 gives impact on the physical properties of FDT amlodipine besylate. The increasing rate of Kollidon[®] CL accelerates the wetting time, the disintegration time, and improves the friability respond also the ratio of water absorption. The combination of those two develops the respond of disintegration and dissolution time. The optimum formula of FDT amlodipine besylate was established by the composition ratio of Kollidon[®] CL 6,07% and Avicel[®] PH 102 55,93% of the tablet weight.

Key words: *FDT, Amlodipine Besylate, Kollidon[®] CL, Avicel[®] PH 102*