INTISARI

Penggalian potensi amilum singkong sebagai eksipien telah dilakukan dengan modifikasi polimer pada amilum singkong (*Manihot esculenta* Crantz). Penelitian ini bertujuan untuk mengembangkan eksipien baru untuk menghasilkan sediaan tablet *non effervescent floating systems* melalui modifikasi secara fisika (*fully gelatinized*) amilum singkong.

Kondisi proses modifikasi terdiri atas suhu *fully gelatinized cassava starch* (FGCS), lama pemanasan, suhu oven dan lama oven. Analisis karakteristik sifat fisik meliputi morfologi granula amilum dengan mikroskop polarisasi cahaya dan *Scanning Microscope Electron* (SEM), profil *Native Cassava Starch* (NCS) dan *Fully Gelatinized Cassava Starch* (FGCS) dengan menggunakan *Rapid Visco Analysis* (RVA), analisis sifat kristanilitas *cassava starch* menggunakan *X-ray Diffraction* (XRD), makroskopik-mikroskopik, analisis perubahan daerah kristalin dan *amorf* menggunakan spektroskopi *Fourier Transform Infrared* (FTIR), Viskositas, *Texture Profile Analyzer* (TPA) dan analisis derajat retrogradasi menggunakan *Differential Scanning Calorimetry* (DSC). Metode formulasi tablet *Non Effervescent Floating Tablets* (NEFT) ranitidin HCl menggunakan metode granulasi. Metode granulasi dipilih karena semua bahan yang ada dalam formula berupa serbuk halus, sehingga tidak dapat langsung dikempa. Analisis data disolusi berbasis kompartemen dihitung dengan menggunakan *software* WinSAAM dan penetapan kadar ranitidin HCl untuk uji *in vivo* dilakukan dengan HPLC.

Hasil modifikasi fisika (*fully gelatinized*) amilum singkong menunjukkan SEM FGCS Permukaan tampak seperti sponge dengan lubang yang lebih banyak dan memiliki diameter rata – rata lebih besar dari NCS (11,8-29,25 µm), peningkatan daerah *amorf* pada FGCS (1,010) lebih tinggi dibandingkan dengan NCS (0,991) pada pengamatan dengan spektroskopi FTIR. Hasil analisis sifat termal polimer dengan DSC didapatkan hasil FGCS memiliki *onset temperature* (To) 102,09^{o}C; entalpi transisi (ΔH) 4,32; derajat retrogradasi 143,4; dan *glass transition* (tg) FGCS tidak terlihat yang menunjukkan amilum sudah mengalami *fully gelatinized* secara total, pengamatan XRD menunjukkan proses *fully gelatinized* menyebabkan hilangnya puncak pada 2 teta 15^{o} dan 23^{o}C dan yang tersisa pada 2 teta 17^{o} sehingga hasil modifikasi dengan FG mengubah kristalin tipe A menjadi tipe B. RVA yang menggambarkan sifat amilograf FGCS memiliki profil gelatinisasi amilum tipe A. Analisis tekstur dengan TPA didapatkan hasil FGCS memiliki nilai *hardness*, *fracturability* yang rendah dan *springiness* yang tinggi ini mengindikasikan semakin tingginya jumlah amilopektin pada FGCS. NEFT memiliki *floating lag time* rata-rata 15-30 menit. Dengan *software* WinSAAM, diperoleh hasil pelepasan ranitidin HCL dari sediaan NEFT mengikuti model tiga kompartemen.

Dari penelitian ini, disimpulkan bahwa ranitidin HCl dapat diformulasikan menjadi sediaan *gastroretentive* dengan sistem *non effervescent floating tablets* menggunakan matrik FGCS.

Kata Kunci: *fully gelatinized*, amilum, *non effervescent*, tablet, *floating*, WinSAAM

ABSTRACT

Potential exploration of cassava starch as an excipient has been carried out by modifying the polymer in cassava starch (Manihot esculenta Crantz). This research aims to develop new excipients to produce non-effervescent floating systems tablets through physical modification (fully gelatinized) cassava starch.

Modification process conditions consist of fully gelatinized cassava starch (FGCS) temperature, heating time, oven temperature and oven duration. Analysis of physical characteristics including morphology of starch granules was carried out using a light polarization microscope and Scanning Microscope Electron (SEM), Native Cassava Starch (NCS) and Fully Gelatinized Cassava Starch (FGCS) profiles using Rapid Visco Analysis (RVA), analysis of cassava starch crystallinity using X- ray Diffraction (XRD), macroscopic-microscopy, analysis of changes in crystalline and amorphous regions using Fourier Transform Infrared (FTIR), Viscosity, Texture Profile Analyzer (TPA) and analysis of degree of retrogradeation using Differential Scanning Calorimetry (DSC). The Non Effervescent Floating Tablets (NEFT) ranitidine HCl tablet formulation method uses granulation method. The granulation method was chosen because all the ingredients in the formula are in the form of fine powder, so they cannot be directly compressed. Compartment-based dissolution data analysis was calculated using the WinSAAM software and HPLC system for determination of ranitidine HCl levels for in vivo testing.

The result of physics modification (fully gelatinized) of cassava starch showed SEM FGCS The surface looks like a sponge with more holes and has an average diameter greater than NCS (11,8-29,25 µm), Increased amorphous region in FGCS (1,010) higher than NCS (0,991) based on FTIR observation. The results of the analysis of the thermal properties of the polymer with DSC showed that the FGCS had an onset temperature (To) 102,09^{o}C transition / ΔH 4,32; degree of retrogradation 143,4; and glass transition (tg) FGCS is not visible which indicates that starch has fully gelatinized, XRD observations show fully gelatinized process causing loss of peak at 2 tides 15^{o} and 23^{o}C and remaining at 2 tides 17^{o} so that the results of the modification with FG convert crystalline type A to type B. RVA illustrates the nature of the amylograph FGCS has a type A profile of starch gelatinization. Texture analysis with TPA shows that FGCS has a value of hardness, low fracturability and high springiness, indicating the higher amount of amylopectin in FGCS. NEFT has an average floating lag time of 15-30 minutes. Using WinSAAM software, the results of releasing ranitidine HCL from NEFT preparations follow the three compartment model.

This study can be concluded that ranitidine HCl can be formulated into a gastroretentive preparation with a non-effervescent floating tablets system using the FGCS matrix.

Keywords: fully gelatinized, starch, non effervescent, tablet, floating, WinSAAM