

Aplikasi protein kedelai tersuksinilasi sebagai eksipien dalam sediaan film cepat hancur yang mengandung ekstrak meniran (*phyllanthus niruri* linn) = Application of succinylated soybean protein as excipient in fast disintegrating film containing (*phyllanthus niruri*) extract

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Abstrak

[ABSTRAK

Film cepat hancur merupakan bentuk sediaan lapis tipis yang dapat segera hancur dalam mulut tanpa memerlukan air. Penelitian ini bertujuan untuk memformulasi dan mengevaluasi film cepat hancur ekstrak meniran, dengan protein kedelai tersuksinilasi (PKS) sebagai eksipien. Protein kedelai (PK) disuksinilasi dengan anhidrida suksinat sebanyak 100% b/b PK (PKS1) dan 250% b/b PK (PKS2), dalam suasana basa dengan medium berair. Film cepat hancur dibuat dengan metode solvent casting dan dievaluasi. Berdasarkan pengujian dengan FTIR, PKS memiliki intensitas yang lebih tinggi pada bilangan gelombang 1697,41 cm⁻¹ yang menunjukkan gugus karboksilat, dan pada bilangan gelombang 1653,05 cm⁻¹ yang menunjukkan gugus karboksil amida yang terbentuk pada ikatan antara gugus amin dari asam amino lisin dengan gugus karboksil dari suksinat, serta tidak ditemukannya spektrum untuk PKS2 pada 2359,02 cm⁻¹ yang menunjukkan bahwa gugus amin primer pada PKS2 seluruhnya telah digantikan oleh suksinat. PKS1 memiliki derajat suksinilasi 35,741 ± 0,380%, dengan daya larut 0,3437 ± 0,0081 gr/100ml pada pH 6,8. Sementara PKS2 memiliki derajat suksinilasi 100,380 ± 0,380%, dengan daya larut yang lebih tinggi pada pH 6,8 yaitu 0,4390 ± 0,0111 gr/100ml. Evaluasi film cepat hancur menunjukkan bahwa F3 memiliki kriteria yang terbaik sebagai film cepat hancur, dengan waktu hancur in vitro 11,27 ± 1,050 detik. Hasil uji kesukaan menunjukkan 80% responden menyukai penampilan dan rasanya. Rata-rata waktu hancur di rongga mulut responden adalah 10,6 ± 2,513 detik. Berdasarkan hasil penelitian, dapat disimpulkan bahwa protein kedelai tersuksinilasi dapat digunakan sebagai eksipien untuk film cepat hancur.

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ABSTRACT

Fast disintegrating film (FDF) is a thin layer dosage form which is rapidly disintegrated without water in oral cavity. The aim of this study was to formulate and evaluate FDF containing *Phyllanthus niruri* extract, using succinylated soybean protein (SSP) as excipient. Soybean protein (SP) was succinylated using succinic anhydride 100% w/w SP (SSP1) and 250% w/w SP (SSP2), in basic condition of aqueous medium. FDF was formulated using solvent casting method and evaluated. FTIR results of SSP showed higher intensity at 1697.41 cm⁻¹ which attribute to carboxylic group, and 1653.05 cm⁻¹ which attribute to amide carbonyl group which is formed on bound between amine group from lysine, and carboxyl group from succinic, there was also no spectrum found for SSP2 at 2359.02 cm⁻¹ which showed that all of primary amine from lysine has substituted by succinic. SSP1 has 35.741 ± 0.380% as its substitution degree, with 0.3437 ± 0.0081 g/100ml as its solubility at pH 6.8. SSP2 has 100.380 ± 0.380% as its substitution degree, with higher solubility with 0.4390 ± 0.0111 g/100ml as its solubility at pH 6.8. Evaluation of FDF showed that F3 had the best characteristics as FDF, with 11.27 ± 1.050 seconds disintegration time. The hedonic test

results showed that 80% responders like FDF's appearance and taste. The average of FDF's disintegration time in responders' oral cavity was 10.6 ± 2.513 seconds. Based on the research results, it can be concluded that succinylated soybean protein can be used as excipient for FDF., Fast disintegrating film (FDF) is a thin layer dosage form which is rapidly disintegrated without water in oral cavity. The aim of this study was to formulate and evaluate FDF containing Phyllanthus niruri extract, using succinylated soybean protein (SSP) as excipient. Soybean protein (SP) was succinylated using succinic anhydride 100% w/w SP (SSP1) and 250% w/w SP (SSP2), in basic condition of aqueous medium. FDF was formulated using solvent casting method and evaluated. FTIR results of SSP showed higher intensity at 1697.41 cm^{-1} which attribute to carboxylic group, and 1653.05 cm^{-1} which attribute to amide carbonyl group which is formed on bound between amine group from lysine, and carboxyl group from succinic, there was also no spectrum found for SSP2 at 2359.02 cm^{-1} which showed that all of primary amine from lysine has substituted by succinic. SSP1 has $35.741 \pm 0.380\%$ as its substitution degree, with $0.3437 \pm 0.0081 \text{ g/100ml}$ as its solubility at pH 6.8. SSP2 has $100.380 \pm 0.380\%$ as its substitution degree, with higher solubility with $0.4390 \pm 0.0111 \text{ g/100ml}$ as its solubility at pH 6.8. Evaluation of FDF showed that F3 had the best characteristics as FDF, with 11.27 ± 1.050 seconds disintegration time. The hedonic test results showed that 80% responders like FDF's appearance and taste. The average of FDF's disintegration time in responders' oral cavity was 10.6 ± 2.513 seconds. Based on the research results, it can be concluded that succinylated soybean protein can be used as excipient for FDF.]