

Eksipien koproses xanthan gum-amilosa tersambung silang sebagai matriks dalam formulasi sediaan tablet lepas lambat natrium diklofenak = Coprocessed excipient xanthan gum crosslinked amylose as matrix for sustained release tablet formulation of sodium diclofenac / Lusiana Ariani

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Abstrak

ABSTRAK

Tablet lepas lambat merupakan tablet yang di desain untuk melepaskan obat secara perlahan – lahan di dalam saluran cerna, dengan menggunakan matriks sebagai salah satu komponen utama. Penelitian ini bertujuan untuk memperoleh eksipien koproses xanthan gum – amilosa tersambungsilang (Ko-CLA6-XG dan Ko-CLA12-XG); (CL6-Ko-A-XG dan CL12-Ko-A-XG) sebagai matriks tablet lepas lambat natrium diklofenak. Eksipien Ko-CLA6-XG dan Ko-CLA12-XG merupakan hasil koproses xanthan gum dengan CLA6 dan xanthan gum dengan CLA12. Eksipien CL6-Ko-A-XG dan CL12-Ko-A-XG dihasilkan dengan cara sambungsilang dari hasil koproses xanthan gum dan amilosa menggunakan natrium trimetafosfat dengan perbandingan masing – masing eksipien yaitu 1:1, 1:2 dan 2:1. Ko-CLA6-XG, Ko-CLA12-XG, CL6-Ko-A-XG dan CL12-Ko-A-XG yang dihasilkan dikarakterisasi sifat fisik, kimia dan fungsional. Ko-CLA6-XG dan Ko-CLA12-XG mempunyai derajat substitusi 0,070 dan 0,110. Eksipien CL6-Ko-A-XG 1:1, 1:2 dan 2:1 berturut – turut 0,077; 0,081 dan 0,083 serta CL12-Ko-A-XG 1:1, 1:2 dan 2:1 berturut – turut 0,113; 0,119 dan 0,122. Eksipien tersebut mempunyai kemampuan mengembang yang baik, viskositas yang cukup besar dan kekuatan gel yang baik. Tablet dengan matriks Ko-CLA6-XG, Ko-CLA12-XG, CL6-Ko-A-XG dan CL12-Ko-A-XG diformulasikan dengan metode cetak langsung dan seluruhnya memenuhi persyaratan evaluasi tablet. Profil pelepasan natrium diklofenak dari tablet yang mengandung matriks Ko-CLA6-XG (F1 – F3), Ko-CLA12-XG (F4 – F6), CL6-Ko-A-XG (F7 – F9) dan CL12-Ko-A-XG (F10 – F12) dalam medium dapar fosfat selama 8 jam, menunjukkan profil pelepasan obat diperlambat dengan kinetika pelepasan orde nol (F1 – F6, F9, F11) dan Korsmeyer-Peppas (F7, F8, F10, F12). Oleh karena itu, F1 – F6 dapat digunakan untuk sediaan lepas lambat selama 16 jam sedangkan F7 – F12 dapat digunakan untuk sediaan lepas lambat selama 32 jam.

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ABSTRACT

Sustained release tablet was solid dosage form which was designed to release drugs slowly in gastrointestinal tract. This present research was intended to produce coprocessed excipient of xanthan gum-crosslinked amylose (Co-CLA6-

XG and Co-CLA12-XG); (CL6-Co-A-XG and CL12-Co-A-XG) as matrix for sustained release tablet of sodium diclofenac. Co-CLA6-XG and Co-CLA12-XG were produced by coprocessing xanthan gum with CLA6 and xanthan gum with CLA12. CL6-Co-A-XG and CL12-Co-A-XG were produced from the coprocessed xanthan gum and amylose then were crosslinked with sodium trimetaphosphate. All excipient had a ratio 1:1, 1:2 and 2:1. The obtained Co-CLA6-XG, Co-CLA12-XG, CL6-Co-A-XG and CL12-Co-A-XG were characterized physically, chemically and functionally. The degree of substitution (DS) of Co-CLA6-XG and Co-CLA12-XG were 0,070 and 0,110. Then the DS of CL6-Co-A-XG 1:1, 1:2 and 2:1 were respectively 0,077; 0,081 and 0,083. The DS of CL12-Co-A-XG 1:1, 1:2 and 2:1 were respectively 0,113; 0,119 and 0,122. All excipients had good swelling index, high viscosity and good gel strength. Tablets with Co-CLA6-XG, Co-CLA12-XG, CL6-Co-A-XG and CL12-Co-A-XG matrix were formulated by direct compression method and passed tablet evaluation tests. The release profile of sodium diclofenac which contained matrix from Co-CLA6-XG (F1 – F3), Co-CLA12-XG (F4 – F6), CL6-Co-A-XG (F7 – F9) and CL12-Co-A-XG (F10 – F12) in phosphate buffer medium for 8 hours, showed that the sustained release profile followed zero order kinetics (F1 – F6, F9, F11) and Korsmeyer-Peppas (F7, F8, F10, F12). Thus, F1 – F6 tablet formulations could be applied as sustained release tablet formulas and could retard drug release up to 16 hours. Then F7 – F12 could be applied as sustained release tablet formula and could retard drug release up to 32 hours.