

Degradasi enzimatis matriks eksipien sambung silang koproses xanthan gum amilosa dan profil disolusi tablet natrium diklofenak = Enzymatic degradation of matrix cross linked of coprocessed xanthan gum amylose excipient and dissolution profile of diclofenac sodium tablet

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Abstrak

Berdasarkan penelitian sebelumnya, eksipien sambung silang koproses xanthan gum-amilosa (CL-Ko-A-XG) berpotensi sebagai matriks dalam formulasi tablet lepas lambat. Penelitian ini bertujuan untuk mengetahui jumlah eksipien yang terdegradasi oleh -amilase dan pengaruh -amilase terhadap profil disolusi dari tablet lepas lambat yang menggunakan matriks CL-Ko-A-XG. Eksipien disambungsilang dengan dua konsentrasi natrium trimetafosfat, yaitu 6% (CL6-Ko-A-XG) dan 12% (CL12-Ko-A-XG). Tiap eksipien dibuat dengan tiga perbandingan amilosa-xanthan gum, antara lain 1:1, 1:2 dan 2:1. Uji degradasi enzimatis dilakukan terhadap serbuk eksipien selama 60 menit. Selain itu, eksipien digunakan sebagai matriks tablet lepas lambat dan diformulasi dengan metode kempa langsung. Kemudian, dilakukan uji disolusi dalam medium dapar fosfat pH 7,4 dengan dan tanpa -amylase selama 8 jam. Hasil penelitian ini menunjukkan bahwa eksipien CL6-Ko-A-XG dan CL12-Ko-A-XG terdegradasi sebesar 20% berturut-turut selama 10 dan 30 menit. Selain itu, tablet F1-F6 menunjukkan profil pelepasan obat diperlambat yang mengikuti kinetika pelepasan orde nol dan Korsmeyer-Peppas, dan tidak terpengaruh dengan adanya -amylase. Dari penelitian ini, dapat disimpulkan bahwa eksipien CL-Ko-A-XG lebih tahan terhadap degradasi enzimatis dibandingkan amilosa. Oleh karena itu, eksipien ini berpotensi sebagai matriks tunggal tablet lepas lambat.

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Based on previous studies, cross-linked of coprocessed xanthan gum-amylose excipient (CL-Co-A-XG) has potential as a matrix in a sustained release tablet formulation. This study aims to determine amount of excipient that is degraded by -amylase and influence of -amylase to the dissolution profile of sustained release tablet that used matrix CL-Co-A-XG. Excipient is cross-linked with two concentration of sodium trimetaphosphate, which is 6% (CL6-Co-A-XG) and 12% (CL12-Co-A-XG). Each excipient was made with ratio 1:1, 1:2 and 2:1 amylose-xanthan gum. Enzymatic degradation test has been performed on excipient powder for 60 minutes. Beside that, sustained release tablet with CL-Co-A-XG excipient as matrix was formulated by direct compression method. Then, performed drug dissolution test in phosphate buffer pH 7.4 using and without -amylase as medium for 8 hours. The results of this study showed that CL6-Co-A-XG and CL12-Co-A-XG were degraded 20% for 10 and 30 minutes. In addition, the release profile of F1-F6 tablets showed the sustained release profile which follow zero-order and Korsmeyer-Peppas kinetic, and not affected by presence of -amylase. From this study, it can be concluded that the CL-Ko-A-XG excipients is more resistant from enzymatic degradation than amylose. Therefore, this excipient potential as a single matrix sustained release tablets.