# Pengaruh Penambahan Plasticizer Trietil Sitrat dan Triasetin Terhadap Karakteristik Fisik Berupa Cracking pada Tablet Salut Enterik Natrium Diklofenak = The Effect of Addition Triethyl Citrate and Triacetin as Plasticizers on Physical Characteristics of Cracking in Diclofenac Sodium Enteric Coated Tablets

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Abstrak

Natrium diklofenak termasuk anti-inflamasi non-steroid (OAINS) dengan efek samping iritatif terhadap lambung sehingga perlu dibuat sistem pelepasan zat aktif ditunda. Tablet lepas tunda memerlukan polimer bersifat pH dependent, seperti hidroksipropil metil selulosa ftalat (HPMCP). Masalah yang dapat terjadi pada tablet salut, yaitu retakan di lapisan penyalut akibat ketidakelastisan polimer akan pemuaian akibat pemanasan. Diperlukan penambahan plasticizer yang kompatibel terhadap polimer untuk menambah keelastisannya, seperti triasetin dan trietil sitrat. Penelitian ini berfokus dalam mengevaluasi pengaruh penambahan trietil sitrat ataupun triasetin terhadap adanya cracking serta efeknya terhadap pelepasan obat pada variasi weight gain tertentu. Dilakukan metode penyalutan, yaitu formula HPMCP atau HP (F1) ; HPMCP-Triasetin atau HP-TRI (F2) ; HPMCP-Trietil Sitrat atau HP-TEC (F3) ; dan HPMCP-Triasetin-Trietil Sitrat atau HP-TRI-TEC (F4) yang akan dibuat dalam variasi weight gain 8%, 10%, dan 12%. Morfologi cracking dievaluasi dengan scanning electron microscopy (SEM). Hasil evaluasi SEM tidak ditemukan cracking dan kekasaran lapisan penyalut tablet, yaitu F1 > F3 > F4 > F2. Semua formula dan variasi weight gain-nya memenuhi syarat pelepasan obat di medium asam maupun basa. Jadi, penggunaan polimer HPMCP saja sudah mampu menahan pelepasan obat di kondisi asam dan penambahan plasticizer triasetin dan trietil sitrat mampu memperhalus morfologi lapisan penyalut tablet salut enterik.
.....Sodium diclofenac is a non-steroidal anti-inflammatory drug (NSAID) with gastric irritative, necessitating the development of a delayed-release drug delivery system. This system require a pH-dependent polymer, such as hydroxypropyl methylcellulose phthalate (HPMCP). A problem that can occur is cracking in the coating layer due to the polymer's lack of elasticity during expansion caused by heating. To enhance its elasticity, the addition of a compatible plasticizer is needed, such as triacetin and triethyl citrate. This study focuses on evaluating the influence of adding triethyl citrate or triacetin on the occurrence of cracking and its effects on drug release at specific weight gain variations. The coating methods used include HPMCP or HP (F1), HPMCP-Triacetin or HP-TRI (F2), HPMCP-Triethyl Citrate or HP-TEC (F3), and HPMCP-Triacetin-Triethyl Citrate or HP-TRI-TEC (F4). These formulations will be made with variations of weight gain at 8%, 10%, and 12%. Cracking morphology will be evaluated using scanning electron microscopy (SEM). The SEM evaluation results showed no cracking and the surface roughness are F1 > F3 > F4 > F2. All formulations and their weight gain met the requirements for drug release in both acidic and basic media. Therefore, the use of HPMCP polymer alone is already capable of controlling drug release in acidic conditions, and the addition of triacetin and triethyl citrate plasticizers can further smoothen the morphology.