ABSTRAK

Judul : Uji Disolusi Terbanding Tablet Karbamazepin Generik Berlogo Dan Bermerek
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Program Studi : Farmasi

Karbamazepin merupakan obat antiepilepsi yang tersedia dalam produk generik berlogo maupun generik bermerek. Penelitian ini bertujuan untuk membandingkan kualitas tablet karbamazepin generik berlogo dan bermerek terhadap inovator berdasarkan sifat fisik tablet serta untuk mengetahui profil disolusi terbanding secara *in-vitro* dalam media disolusi dengan metode spektrofotometri UV-Vis. Penelitian ini menggunakan 3 macam produk tablet karbamazepin yang terdiri dari produk inovator (A) sebagai pembanding, produk generik berlogo (B), dan produk generik bermerek (C). Tablet karbamazepin kemudian dilakukan uji sifat fisiknya terhadap parameter visual (organoleptis), keseragaman bobot, keseragaman ukuran, kekerasan, friabilitas, dan waktu hancur. Validasi metode analisis karbamazepin secara spekrofotometer UV-Vis dilakukan mengacu pada *International Conference on Harmonization* (ICH) dengan berbagai parameter yang digunakan memberikan hasil yang baik dan memenuhi persyaratan yaitu linearitas, akurasi, presisi, batas deteksi, batas kuantisasi, dan kekuatan (*Robustness*). Uji disolusi terbanding tablet karbamazepin inovator (A), generik berlogo (B), dan generik bermerek (C) menggunakan alat *dissolution tester* tipe 2 (dayung), kecepatan rotasi 75 rpm dalam 900 mL media disolusi dapar HCl pH 1,2, dapar asetat pH 4,5, dan dapar fosfat pH 6,8 pada suhu 37º ± 2ºC. Pengujian fisik tablet karbamazepin inovator (A), generik berlogo (B), dan generik bermerek (C) memenuhi persyaratan uji visual (organoleptis), uji keseragaman bobot, uji keseragaman ukuran, uji friabilitas, dan uji waktu hancur, sementara hanya uji kekerasan tablet yang tidak memenuhi persyaratan fisik tablet. Uji faktor kemiripan (f2) dengan menggunakan *software DD Solver* menunjukkan bahwa antara produk tablet karbamazepin generik berlogo (B) ekivalen dengan produk inovator (A) dalam media disolusi dapar HCl pH 1,2, dapar asetat pH 4,5, dan dapar fosfat pH 6,8, sedangkan antara produk tablet karbamazepin generik bermerek (C) tidak ekivalen dengan produk inovatornya (A) dalam media disolusi dapar fosfat pH 6,8.

Kata kunci: Disolusi Terbanding, Tablet Karbamazepin, Faktor Kemiripan (f2), *DD Solver*.

ABSTRACT

Title : Comparative Dissolution Test Of Generic And Branded Tablet Carbamazepine Tablets
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Carbamazepine is an antiepileptic drug available in various generic and brand names. This study aims to compare the quality of generic and branded carbamazepine tablets against innovators based on the physical properties of the tablets and to determine the similar dissolution profile *in-vitro* in dissolution media using spectrophotometry UV-Vis. This study used three kinds of carbamazepine tablet products, consisting of an innovator product (A) as a comparison, a generic product (B) and a branded product (C). The carbamazepine tablets were tested for their physical properties on the visual (organoleptic) test, weight uniformity, size uniformity, hardness, friability, and disintegration time. In addition, the validation of the carbamazepine analysis method by spectrophotometer UV-Vis was carried out referring to the *International Conference on Harmonization* (ICH) with various parameters used, giving good results and meeting the requirements of linearity, accuracy, precision, the LOD, the LOQ, and robustness. Comparative dissolution test of innovator carbamazepine tablets (A), generic products (B), and branded products (C) using a type 2 dissolution tester, the rotational speed of 75 rpm in 900 mL of dissolution medium HCl buffer pH 1.2, acetate buffer pH 4.5, and phosphate buffer pH 6.8 at 37º ± 2ºC. Physical testing of the innovator carbamazepine tablets (A), generic products (B), and branded products (C) met the requirements of the visual (organoleptic) test, weight uniformity test, size uniformity test, friability test, and disintegration test. In contrast, only the tablet hardness test that was carried out did not meet the physical requirements of the tablet. The similarity factor test (f2) using DD Solver software showed that the generic carbamazepine tablet product (B) was equivalent to the innovator product (A) in the dissolution medium of HCl buffer pH 1.2, acetate buffer pH 4.5, and phosphate buffer pH 6.8, while the branded carbamazepine tablet products (C) were not equivalent to the innovator product (A) in the dissolution medium of phosphate buffer pH 6.8.

Keywords: Comparative Dissolution, Carbamazepine Tablet, Similarity Factor (f2), DD Solver.