

PERBANDINGAN SIFAT FISIK DAN KIMIA TABLET KALIUM DIKLOFENAK GENERIK BERLOGO DAN GENERIK BERMEREK

Imelda Futri Zani¹ , Dwi Larasati²

INTISARI

Latar Belakang: Kalium diklofenak merupakan obat antiinflamasi nonsteroid (OAINS) yang mengandung garam kalium dari diklofenak. Pengujian sifat fisik dan kimia tablet penting dilakukan untuk menjamin mutu, keamanan dan efektivitas produk yang beredar di pasaran, sesuai standar mutu yang telah ditetapkan.

Tujuan Penelitian: Mengetahui pemenuhan syarat dan membandingkan sifat fisik dan kimia empat sampel tablet kalium diklofenak generik berlogo dan generik bermerek sesuai standar yang ditetapkan.

Metode Penelitian: Pengujian sifat fisik tablet kalium diklofenak generik berlogo maupun generik bermerek meliputi uji keseragaman bobot, keseragaman ukuran, kerapuhan, kekerasan dan waktu hancur tablet. Pengujian sifat kimia dilakukan melalui penetapan kadar zat aktif menggunakan metode spektrofotometri UV-Vis. Hasil evaluasi sifat fisik dan kimia dibandingkan dengan standar yang tercantum dalam Farmakope Indonesia atau sumber literatur lainnya yang relevan.

Hasil Penelitian: Keseragaman bobot keempat sampel tablet berkisar antara 203,185 mg – 209,445 mg dengan nilai koefisien variasi (CV) < 5%. Diameter tablet berkisar antara 0,808 cm – 0,825 cm dengan nilai CV < 5%. Ketebalan tablet berkisar antara 0,330 cm – 0,386 cm dengan nilai CV < 5%. Persentase kerapuhan tablet sebesar 0,038%. Kekerasan tablet berkisar antara 4,424 kg – 13,084 kg. Waktu hancur tablet berkisar antara 4,340 menit- 10,635 menit. Kadar kalium diklofenak berada dalam rentang antara 90% - 110% dan memenuhi persyaratan yang tercantum dalam Farmakope Indonesia edisi VI.

Kesimpulan: Sifat fisik kimia pada tablet kalium diklofenak generik berlogo dan generik bermerek memenuhi persyaratan yang telah ditetapkan. Hasil analisis statistik dari keempat jenis sampel tablet kalium diklofenak menunjukkan bahwa terdapat variasi keseragaman bobot, keseragaman ukuran, kekerasan tablet, dan waktu hancur tablet antar sampel, kecuali pada parameter kerapuhan dan kadar zat aktif yang tidak menunjukkan perbedaan signifikan.

Kata Kunci: Bermerek, Generik, Kalium Diklofenak, Tablet, Uji Sifat Fisik-Kimia

¹Mahasiswa Farmasi Universitas Jenderal Achmad Yani Yogyakarta

²Dosen Farmasi Universitas Jenderal Achmad Yani Yogyakarta

COMPARISON OF PHYSICAL AND CHEMICAL PROPERTIES OF LOGO GENERIC AND BRANDED GENERIC DICLOFENAC POTASSIUM TABLETS

Imelda Putri Zani¹ , Dwi Larasati²

ABSTRACT

Background: Potassium diclofenac is a type of nonsteroidal anti-inflammatory drug (NSAID) that contains potassium salts from diclofenac. Physical and chemical quality testing of tablets aims to ensure that tablets manufactured by the pharmaceutical industry meet the standards that have been set.

Objective: To know the fulfillment of the requirements and comparison of physical properties and Chemistry of 4 Generic Potassium Diclofenac Tablets Logo and Branded Generic Accordingly set standards.

Method: Physical properties test of branded generic potassium diclofenac tablets which includes weight uniformity, size uniformity, brittleness, hardness and crushed time of tablets. The chemical properties test of tablets includes a test for determining the level of active substances by the UV-Vis spectrophotometry method. The results of the evaluation of physical and chemical properties are compared with standards that have been set according to the requirements of the Indonesian pharmacopoeia or other literature.

Results: The uniformity of the weight of the four samples ranged from 203.185 mg – 209.445 mg with a CV value of 5%. The diameter of the tablet ranges from 0.808 cm – 0.825 cm with a CV value of 5%. The thickness of the tablets ranges from 0.330 cm – 0.386 cm with a CV value of 5%. The value % of the fragility of the tablet is 0.038%. The hardness of the tablets ranges from 4,424 kg – 13,084 kg. The crushed time of membrane-coated diclofenac potassium ranges from 4,340 minutes- 10,635 minutes. Potassium diclofenac levels range from 90% - 110% to meet the requirements of Pharmacopoeia Indonesia edition VI.

Conclusion: The physical and chemical properties of branded generic diclofenac potassium tablets meet the requirements that have been set. The results of statistical analysis of the four types of potassium diclofenac tablet samples showed that there were variations in weight uniformity, size uniformity, tablet hardness, and tablet crushed time between each sample type except for tablet brittleness and tablet content.

Keywords: Branded, Tablets, Diclofenac Potassium, Tablets, Physical and Chemical Property Tests

¹Student of Pharmacy University Jenderal Achmad Yani Yogyakarta

²Lecturer of Pharmacy University Jenderal Achmad Yani Yogyakarta