

STUDI EVALUASI KUALITAS FISIKA-KIMIA TABLET AMLODIPIN GENERIK (BERLOGO DAN BERMEREK) SERTA ORIGINATOR

Febrianti¹, Mufrod²

INTISARI

Latar Belakang: Hipertensi merupakan penyakit kronis yang prevalensinya terus meningkat dan menjadi masalah kesehatan global, termasuk di Indonesia. Amlodipin sebagai obat golongan calcium channel blocker termasuk lini pertama terapi antihipertensi dan umumnya diformulasikan dalam bentuk tablet. Tablet merupakan sediaan padat yang stabil, praktis, dan dipilih sesuai untuk penggunaan jangka panjang. Proses produksi tablet harus memenuhi prinsip Cara Pembuatan Obat yang Baik (CPOB). Perbedaan formulasi dan proses produksi antar produsen, seperti pada sediaan generik berlogo, generik bermerek, dan originator, dapat memengaruhi mutu fisika-kimia tablet. Evaluasi terhadap karakteristik fisika dan kimia tablet amlodipin diperlukan guna memastikan kesesuaian produk terhadap standar Farmakope Indonesia Edisi VI.

Tujuan Penelitian: Mengevaluasi karakteristik fisika-kimia tablet amlodipin generik (berlogo dan bermerek) serta originator menurut Farmakope Indonesia Edisi VI.

Metode Penelitian: Tablet amlodipin generik berlogo (A dan B), generik bermerek (C dan D) serta originator (E) dilakukan uji keseragaman bobot, keseragaman ukuran, kerapuhan, kekerasan, waktu hancur, kadar dan keseragaman kandungan menurut prosedur kerja yang ditetapkan. Kadar dan kandungan amlodipin dalam tablet ditentukan menggunakan metode spektrofotometri UV-Vis.

Hasil Penelitian: Pengujian yang dilakukan pada sampel A, sampel B dan sampel D didapati hasil memenuhi syarat evaluasi sifat fisika-kimia sesuai standar Farmakope Indonesia Edisi VI. Hasil uji sampel C dan sampel E didapati tidak memenuhi syarat pada evaluasi uji kekerasan.

Kesimpulan: Tablet amlodipin 5 mg sampel A, B dan D memenuhi persyaratan sifat fisika-kimia. Sampel C dan E tidak memenuhi persyaratan pada uji kekerasan. Hasil analisis statistik menunjukkan adanya variasi antar sampel pada beberapa parameter yang diuji.

Kata Kunci: Tablet, Amlodipin, Generik, Bermerek, Originator

¹Mahasiswa Farmasi Universitas Jenderal Achmad Yani Yogyakarta

²Dosen Farmasi Universitas Jenderal Achmad Yani Yogyakarta

A PHYSICOCHEMICAL QUALITY EVALUATION STUDY OF GENERIC (BRANDED AND NON-BRANDED) AND ORIGINATOR OF AMLODIPINE TABLETS

Febrianti¹, Mufrod²

ABSTRACT

Background: Hypertension is a chronic disease with increasing prevalence and has become a global health problem, including in Indonesia. Amlodipine, a calcium channel blocker, is one of the first-line therapies for hypertension and is commonly formulated as a tablet. Tablets are solid dosage forms that are stable, practical, and suitable for long-term use. The manufacturing of tablets must follow the principles of Good Manufacturing Practices (GMP). Variations in formulation and manufacturing processes between different producers, such as generic products with logo, branded generics, and originator products, may affect the physical and chemical quality of the tablets. Evaluation of the physical and chemical characteristics of amlodipine tablets is necessary to ensure compliance with the standards set by the Indonesian Pharmacopoeia, Sixth Edition.

Objective: The objective of this study was to evaluate the physical and chemical characteristics of amlodipine tablets from generic (with logo and branded) and originator products based on the standards of the Indonesian Pharmacopoeia, Sixth Edition.

Method: Generic amlodipine tablets with logo (A and B), branded generics (C and D), and the originator product (E) were tested for uniformity of weight, uniformity of size, friability, hardness, disintegration time, drug content, and content uniformity according to established procedures. The amlodipine content in the tablets was determined using the UV-Vis spectrophotometry method.

Result: The results showed that samples A, B, and D met the requirements for physical and chemical evaluation in accordance with the standards of the Indonesian Pharmacopoeia, Sixth Edition. Samples C and E did not meet the requirements for the hardness test evaluation.

Conclusion: Amlodipine 5 mg tablets from samples A, B, and D met the requirements for physical and chemical properties. Samples C and E did not meet the requirements for the hardness test. Statistical analysis showed variations among samples in several evaluated parameters.

Keywords: Tablet, Amlodipine, Generic, Branded, Originator

¹Student of Pharmacy Universitas Jenderal Achmad Yani Yogyakarta

²Lecturer of Pharmacy Universitas Jenderal Achmad Yani Yogyakarta