

INTISARI

MAHARAI, D. DISOLUSI TERBANDING TABLET ASAM MEFENAMAT MERK DAGANG DAN GENERIK YANG BEREDAR DIPASARAN, SKRIPSI, FAKULTAS FARMASI, UNIVERSITAS SETIA BUDI, SURAKARTA.

Asam mefenamat merupakan analgetika dan anti radang yang poten untuk mengurangi nyeri ringan sampai sedang. Dipasaran beredar dalam obat merk dagang dan generik, keduanya berbeda dalam formulasinya dan metode pembuatannya. Asam mefenamat termasuk dalam *Biopharmaceutical Classification System* (BCS) kelas II, maka perlu dilakukan uji disolusi terbanding untuk memastikan kemiripan kualitas produk dengan membandingkan mutu fisik dan kemiripan profil disolusi (F_2).

Penelitian ini menggunakan dua jenis tablet asam mefenamat merk dagang (ODA dan ODB) dan tiga jenis obat generik (OGC, OGD dan OGE). Uji disolusi dilakukan sesuai standar dalam FI IV menggunakan alat disolusi tipe 2 (dayung), kecepatan rotasi 100 rpm dalam 950 ml dapar phospat 7,4, pada suhu $37 \pm 0,5$ ° C. Penentuan kadar terdisolusi tablet asam mefenamat menggunakan alat spektrofotometer UV pada panjang gelombang 284 nm. Parameter yang diamati adalah nilai jumlah zat yang terlarut (Q_{60}), *Dissolution Efficiency* (DE_{60}) dan faktor kemiripan (F_2).

Hasil penelitian untuk parameter Q_{60} dan DE_{60} menunjukan semua produk obat memenuhi persyaratan uji disolusi. Nilai kemiripan (F_2) antara obat merk dagang dan merk generik hampir sama dan nilai kemiripan terbesar pada OGC-OGD yaitu 70,090.

Kata kunci : Asam mefenamat, disolusi, faktor kemiripan (F_2), BCS II.

ABSTRACT

MAHARAI, D. COMPARATIVE DISSOLUTION OF BRAND AND GENERIC PRODUCTS OF MEFENAMIC ACID TABLETS COMMERCIAL PRODUCTS, THESIS, FACULTY OF PHARMACY, SETIA BUDI UNIVERSITY, SURAKARTA.

Mefenamic acid is used for analgesic and anti-inflammatory which potents to reduce mild to moderate pain. The commercial products include generic drugs and brand name, both are different in formulation and method of producing. Mefenamic acid is includes in the Biopharmaceutical Classification System (BCS) class II, it is necessary to comparative dissolution test to ensure the similarity of product quality and compairing the pysical quality and similarity of dissolution profiles (F2).

This study used two types of brand mefenamic acid tablets (ODA and ODB) and three types of generic products (OGC, OGD and OGE). Dissolution test was performed according to standard FI IV using dissolution apparatus type 2 (paddle), the rotation speed was 100 rpm in 950 ml of buffer 7,4, at 37 ± 0.5 ° C. Determination of dissolved mefenamic acid tablets used UV spectrophotometer at 284 nm wave length. The parameters observed were amount value of dissolved substances (Q_{60}), Dissolution Efficiency (DE60) and similarity factor (F2).

The results of the study for Q_{60} and DE60 parameters showed all that products met the requirements of the dissolution test. Similarity value (F2) between the brand and generic drugs almost the same and the largest similarity value on OGC-OGD was 70.090.

Keywords: Mefenamic acid, dissolution, similarity factor (F2), BCS II.