

INTISARI

WICAKSANA, B.A., 2017, UJI DISOLUSI TABLET SALUT SELAPUT RIFAMPISIN ANTARA TABLET INOVATOR DENGAN TABLET GENERIK DAN BERMEREK YANG BEREDAR DI PASARAN, SKRIPSI, FAKULTAS FARMASI, UNIVERSITAS SETIA BUDI, SURAKARTA.

Rifampisin merupakan obat antibiotik dan efektif untuk pengobatan tuberkulosis yang disebabkan oleh *Mycobacterium tuberculosis*. Rifampisin golongan obat *Biopharmaceutical Classification System* (BCS) kelas II dengan permeabilitas tinggi namun sifat kelarutannya rendah. Obat ini tersedia dipasaran dalam sediaan generik dan bermerek, sehingga kemungkinan terjadi perbedaan formulasi dan metode fabrikasi. Penelitian ini bertujuan untuk mengetahui mutu fisik dan profil disolusi rifampisin antara inovator dengan beberapa produk yang ada di pasaran.

Produk uji menggunakan lima produk tablet rifampisin 450 mg yang beredar di pasaran, yaitu 1 inovator A, 2 bermerek B dan C, dan 2 produk generik D dan E. Uji disolusi menggunakan alat disolusi tipe 2 (dayung) kecepatan rotasi 50 rpm dalam 900 ml medium disolusi. Medium disolusi yang digunakan yaitu larutan HCl pH 1,2. Penentuan kadar disolusi menggunakan alat spektrofotometer *UV-Visible* pada panjang gelombang 470 nm.

Hasil penelitian untuk uji mutu fisik yaitu keseragaman bobot, kekerasan, dan waktu hancur bahwa semua produk tablet rifampisin memiliki perbedaan dan memenuhi persyaratan yang ditetapkan. Hasil nilai Q45 bahwa inovator A, bermerek B, dan generik D memenuhi syarat diatas 75%. Produk bermerek B dan generik D menunjukkan bahwa nilai F_1 kurang dari 15% dan nilai F_2 diatas 50% sehingga profil disolusinya mirip dengan inovator A.

Kata Kunci : Rifampisin, inovator, merek, generik, mutu fisik, disolusi

ABSTRACT

WICAKSANA, B.A., 2017, COMPARATIVE DISSOLUTION TEST RIFAMPICIN FILM COATED TABLET BETWEEN INNOVATOR TABLET WITH GENERICS AND BRANDS TABLET ARE SPREAD IN THE MARKET, THESIS, FACULTY OF PHARMACY, SETIA BUDI UNIVERSITY, SURAKARTA.

Rifampicin is an antibiotic drug and effective for the treatment of tuberculosis caused by *Mycobacterium tuberculosis*. Rifampicin included biopharmaceutical Classification System (BCS) class II with high permeability but a low solubility properties. It is available commercially in the preparation of generic and innovator, and therefore caused the different formulations and method of fabrication. This study aims to determine the physical quality and rifampicin dissolution profile between innovator with several brands are spread in the market.

Test products using five products rifampicin 450 mg tablets in the market, that one innovator product A, two brand products B and C, and two generic products D and E. Dissolution testing using dissolution apparatus type 2 (paddle) rotation speed of 50 rpm in 900 ml of the dissolution medium. Dissolution medium is used HCl solution pH 1.2. The dissolution assay using a UV-Vis spectrophotometer at a wavelength of 470 nm.

The Result of research for physical qualities were uniformity of weight, hardness, and disintegrate time showed that all of rifampicin tablet products had difference and fulfilled of established requirements. The result of Q_{45} value showed that generic A, brand B, and generic D qualified more than 75%. Brand B and generic D products showed that F_1 value less than 15% and F_2 value more than 50% so dissolution profiles were similar with innovator A.

Keywords : Rifampicin, innovator, brand, generic, physical quality, dissolution