PERBANDINGAN KARAKTERISTIK FISIK, KIMIA, DAN DISOLUSI TABLET DEKSAMETASON GENERIK DAN BERMEREK DI KECAMATAN MLATI YOGYAKARTA

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INTISARI

Latar Belakang: Persepsi masyarakat terhadap perbedaan kualitas obat generik dan bermerek seringkali disebabkan oleh faktor harga dan kurangnya pengetahuan. Uji dilakukan terhadap tablet deksametason 0.5 mg di apotek Kecamatan Mlati, Yogyakarta untuk menjamin kesesuaiannya dengan standar mutu.
Tujuan Penelitian: Mengevaluasi karakteristik fisik, kimia, dan disolusi tablet Deksametason 0.5 mg generik dan bermerek yang beredar di Kecamatan Mlati, Yogyakarta.
Metode Penelitian: Penelitian ini bersifat deskriptif komparatif menggunakan 2 sampel generik dan 2 sampel bermerek yang paling banyak tersedia di Kecamatan Mlati. Setiap sampel dilakukan uji karakteristik fisik (keseragaman bobot, keseragaman ukuran, kerapuhan, kekerasan, dan waktu hancur) menurut prosedur kerja yang ditetapkan, karakteristik kimia (penetapan kadar dalam tablet), serta uji disolusi menggunakan metode spektrofotometri UV-Vis
Hasil penelitian: Bobot tablet keempat sampel berkisar antara 80.645 – 192.38 mg, diameter berkisar antara 0.6 – 0.82 cm, dan tebal berkisar antara 0.266 – 0.29 cm, kekerasan berkisar antara 2.407 – 5.384 kg, kerapuhan berkisar antara 0.000% – 0.606%, waktu hancur berkisar antara 3.09 – 6.56 menit, kadar Deksametason berkisar antara 100.131% – 103.772%, Q45 berkisar antara 87.54% – 94.58%, dan F2 berkisar antara 49.071 – 68.751. Semua parameter memenuhi persyaratan Farmakope Indonesia dan USP, Hasil uji statistik (*One Way ANOVA* atau *Kruskal-wallis*) menunjukkan keempat sampel memiliki perbedaan yang signifikan pada semua parameter fisik, kimia fisik, kimia, disolusi ($p < 0.05$) kecuali pada kerapuhan tablet ($p > 0.05$)
Kesimpulan: Hasil penelitian menunjukkan seluruh sampel tablet deksametason 0.5 mg generik dan bermerek memenuhi persyaratan karakteristik fisik , kimia dan disolusi yang telah ditetapkan. Perbedaan signifikan antar keempat sampel pada semua parameter karakteristik fisik, kimia, dan disolusi kecuali pada parameter kerapuhan tablet

Kata kunci: Deksametason, Tablet, Generik, Bermerek

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COMPARISON OF PHYSICAL, CHEMICAL, AND DISSOLUTION CHARACTERISTICS OF GENERIC AND BRANDED DEXAMETHASONE TABLETS IN MLATI DISTRICT, YOGYAKARTA.

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ABSTRACT

Background: This study examines the comparison of physical, chemical, and dissolution characteristics between branded and generic Dexamethasone tablets.Public perception of quality differences is often influenced by price and limited knowledge.Testing was conducted on 0.5 mg Dexamethasone tablets from pharmacies in Mlati District, Yogyakarta to assess compliance with quality standards.

Objective: To evaluate the physical, chemical, and dissolution characteristics of 0.5 mg generic and branded Dexamethasone tablets available in Mlati District, Yogyakarta.

Method: This study is a descriptive-comparative research using 2 generic and 2 branded samples that are most widely available in the Mlati District. Each sample was subjected to physical characterization tests (weight uniformity, size uniformity, friability, hardness, and disintegration time) based on established procedures, chemical characterization (assay of active pharmaceutical ingredient in tablets), and dissolution testing using the UV-Vis spectrophotometry method.

Result: The tablet weights of the four samples ranged from 80.645 to 192.38 mg, with diameters between 0.6–0.82 cm and thicknesses between 0.266–0.29 cm. Hardness ranged from 2.407 to 5.384 kg, friability from 0.000% to 0.606%, disintegration time from 3.09 to 6.56 minutes, dexamethasone content from 100.131% to 103.772%, Q45 values from 87.54% to 94.58%, and F2 values from 49.071 to 68.751. All parameters met the requirements of the Indonesian Pharmacopoeia and USP. Statistical analysis (One Way ANOVA or Kruskal-Wallis test) showed significant differences ($p < 0.05$) in all physical, physicochemical, chemical, and dissolution parameters among the samples, except for tablet friability ($p > 0.05$).

Conclusion: The results of the study showed that all samples of 0.5 mg generic and branded Dexamethasone tablets met the established requirements. There were significant differences in tablet weight, size, hardness, disintegration time, Dexamethasone content, and dissolution profile. However, tablet friability did not differ significantly.

Keywords: Dexamethasone, Tablets, Generic, Branded

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