

PENETAPAN KADAR DAN SIFAT FISIK TABLET FUROSEMIDA 40 MG GENERIK BERLOGO DAN GENERIK BERMEREK

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INTISARI

Latar Belakang: Furosemida merupakan obat diuretik kuat yang umum digunakan dalam pengobatan penyakit kronis seperti gagal jantung, hipertensi, dan gangguan ginjal. Tablet furosemida tersedia dalam bentuk generik berlogo dan generik bermerek. Untuk menjamin kualitas dan efektivitas terapi, perlu dilakukan evaluasi terhadap mutu fisik dan kimia tablet, serta perbandingan antara kedua jenis generik tersebut.

Tujuan Penelitian: Mengetahui pemenuhan persyaratan mutu dan perbandingan sifat fisik dan kimia tablet furosemida 40 mg generik berlogo dan generik bermerek berdasarkan standar Farmakope Indonesia dan USP.

Metode Penelitian: Penelitian dilakukan secara deskriptif terhadap empat sampel tablet furosemida (dua generik berlogo dan dua generik bermerek). Evaluasi meliputi uji keseragaman bobot, keseragaman ukuran, kekerasan, kerapuhan, waktu hancur, dan penetapan kadar zat aktif dengan metode spektrofotometri UV-Vis. Analisis statistik dilakukan menggunakan software SPSS.

Hasil Penelitian: Keseragaman bobot keempat sampel berkisar 124,195-163,845 mg dengan nilai CV <5%. Tebal tablet berkisar 0,271-0,311 cm dengan nilai CV <5%. Diameter tablet berkisar 0,704-0,804 cm dengan nilai CV <5%. Kekerasan berkisar 4,762-6,583kg. Kerapuhan berkisar 0,000-0,467 %. Waktu hancur 2,45-7,07 menit. Kadar furosemida dalam tablet memenuhi rantang 90,0%-110,0% menurut persyaratan Farmakope Indonesia Edisi VI. Terdapat perbedaan signifikan pada sifat fisik antara tablet furosemida 40 mg generik berlogo dan generik bermerek meliputi keseragaman bobot, keseragaman ukuran, kekerasan, dan waktu hancur tetapi tidak ada perbedaan signifikan pada uji kerapuhan dan penetapan kadar zat aktif.

Kesimpulan: Tablet furosemida 40 mg generik berlogo dan generik bermerek memenuhi standar mutu fisik-kimia. Perbedaan signifikan ditemukan pada beberapa parameter fisik, namun tidak memengaruhi mutu keseluruhan, sehingga keduanya dapat memberikan efek terapi yang setara.

Kata Kunci: Berlogo, Bermerek, Furosemida, Tablet, Sifat fisik-kimia

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DETERMINATION OF THE CONTENT AND PHYSICAL PROPERTIES OF FUROSEMIDE TABLETS 40 MG GENERIC AND GENERIC BRANDED

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ABSTRACT

Background: Furosemide is a potent diuretic commonly used in the treatment of chronic diseases such as heart failure, hypertension, and kidney disorders. Furosemide tablets are available in both branded and generic forms. To ensure the quality and effectiveness of therapy, it is necessary to evaluate the physical and chemical quality of the tablets, as well as to compare the two generic forms.

Objective: To determine whether the quality requirements are met and the physical and chemical properties of 40 mg generic and branded furosemide tablets are compared based on the Indonesian Pharmacopoeia and USP standards.

Method: A descriptive study was conducted on four samples of furosemide tablets (two branded and two branded generics). The evaluation included tests for weight uniformity, size uniformity, hardness, friability, disintegration time, and determination of active ingredient content using UV-Vis spectrophotometry. Statistical analysis was performed using SPSS software.

Results: The weight uniformity of the four samples ranged from 124,195 to 163,845 mg with a CV value of <5%. The tablet thickness ranged from 0,271 to 0.311 cm with a CV value of <5%. The tablet diameter ranged from 0,704 to 0.804 cm with a CV value of <5%. The hardness ranged from 4.762 to 6,583 kg. The friability ranged from 0,000 to 0.467%. The disintegration time was 2,45 to 7,07 minutes. The furosemide content in the tablets met the 90,0% to 110,0% range according to the requirements of the Indonesian Pharmacopoeia Edition VI. There were significant differences in the physical properties between the generic 40 mg furosemide tablets with a logo and the branded generic tablets including weight uniformity, size uniformity, hardness, and disintegration time but there were no significant differences in the friability test and determination of active substance levels.

Conclusion: The 40 mg generic furosemide tablets with a logo and branded generics met the physical and chemical quality standards. Significant differences were found in several physical parameters, but these did not affect the overall quality, so both can provide equivalent therapeutic effects.

Keywords: Generic, Branded, Furosemide, Tablets, Physico-chemical properties

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