

PERBANDINGAN SIFAT FISIKA KIMIA TABLET AMBROXOL GENERIK DENGAN TABLET AMBROXOL BERMEREK DAGANG

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INTISARI

Latar Belakang: Ambroxol merupakan salah satu contoh obat yang tersedia dalam bentuk generik dan bermerek. Obat ini berfungsi sebagai mukolitik untuk mengurangi kekentalan dahak, sehingga mempermudah pengeluarannya dari saluran pernapasan. Evaluasi terhadap mutu fisik tablet Ambroxol, baik versi bermerek maupun generik, dilakukan untuk menyatakan kesesuaian kualitasnya. Selain uji mutu fisik, obat juga harus memenuhi standar kualitas lainnya sebelum dipasarkan dan selama masa peredarannya, termasuk memastikan kadar zat aktif sesuai dengan persyaratan yang ditetapkan.

Tujuan Penelitian: Melakukan perbandingan sifat fisika kimia dari sediaan tablet ambroxol generik dan bermerek dagang.

Metode Penelitian: penelitian ini dilakukan dengan membandingkan mutu tablet ambroxol generik dengan tablet bermerek. Metode yang digunakan penelitian dapat secara sistematis menguji berbagai aspek kualitas, seperti sifat fisik dan kimia. Pengujian sifat fisik tablet dilakukan terhadap keseragaman bobot, keseragaman ukuran, kerapuhan, kekerasan dan waktu hancur tablet. Sifat kimia tablet (kadar ambroxol) diuji menggunakan metode spektrofotometri UV-Vis.

Hasil Penelitian: Keseragaman bobot keempat sampel berkisar antara 204,698 mg hingga 259,318 mg dengan nilai CV < 5%. Diameter tablet berkisar antara 8,103 cm hingga 9,005 cm dengan nilai CV < 5%. Ketebalan tablet berkisar antara 3,102 cm – 4,768 cm dengan nilai CV < 5%. Nilai % kerapuhan tablet 0,038%. Kekerasan tablet berkisar antara 3,230 kg hingga 5,084 kg. Waktu hancur tablet ambroxol HCl berkisar antara 0,228 menit hingga 3,966 menit. Kadar Ambroxol HCl berkisar 100,21 % hingga 100,98 %.

Kesimpulan: Tablet ambroxol HCl generik berlogo dan generik bermerek memenuhi persyaratan yang ditetapkan antara lain Farmakope Indonesia, British Pharmacopeia dan United States Pharmacopoeia. Meskipun terdapat perbedaan signifikan pada beberapa parameter fisik seperti keseragaman bobot, ukuran, kekerasan dan waktu hancur. Parameter kerapuhan dan kadar zat aktif menunjukkan tidak ada perbedaan signifikan.

Kata Kunci: Ambroxol HCl, Bermerek, Generik, Tablet, Uji Sifat Fisika-Kimia

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ABSTRACT

Background: Ambroxol is an example of a medication available in both generic and branded forms. This medication functions as a mucolytic to reduce the viscosity of phlegm, thus facilitating its expulsion from the respiratory tract. An analysis of the physical quality of Ambroxol tablets, both branded and generic versions, was conducted to evaluate their physical quality. In addition to physical quality testing, medications must also meet other quality standards before being marketed and throughout their distribution period, including ensuring that the active ingredient content meets established requirements.

Objective: To compare the physicochemical properties of generic and branded ambroxol tablets.

Method: To analyze and compare the quality of generic and branded ambroxol tablets. This method allows the study to systematically examine various quality aspects, such as physical and chemical properties. Physical properties were assessed for content uniformity, size uniformity, tablet friability, tablet hardness, and disintegration time. The chemical properties of the tablets (ambroxol content) were evaluated using UV-Vis spectrophotometry.

Results: The weight uniformity of the four samples ranged from 204.698 mg to 259.318 mg with a CV value of <5%. Tablet diameter ranged from 8.103 cm to 9.005 cm with a CV value of <5%. Tablet thickness ranged from 3.102 cm to 4.768 cm with a CV value of <5%. The tablet friability percentage was 0.038%. Tablet hardness ranged from 3.230 kg to 5.084 kg. Ambroxol HCl tablet disintegration time ranged from 0.228 minutes to 3.966 minutes. Ambroxol HCl content ranged from 100.21% to 100.98%.

Conclusion: Both branded and branded generic ambroxol HCl tablets meet the requirements of the Indonesian Pharmacopoeia, the British Pharmacopoeia, and the United States Pharmacopoeia. Although there are significant differences in several physical parameters, such as weight uniformity, size, hardness, and disintegration time, friability and active ingredient content parameters show no significant differences.

Keywords: Ambroxol HCl, Branded, Generic, Tablets, Physical and Chemical Property Tests

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