

KARAKTERISTIK FISIK DAN KIMIAWI TABLET PARACETAMOL GENERIK DENGAN BERMEREK DI KECAMATAN SEDAYU

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INTISARI

Latar Belakang: Tablet paracetamol merupakan salah satu bentuk sediaan yang banyak beredar di masyarakat sebagai obat analgesik dan antipiretik. Pengujian terhadap mutu tablet perlu dilakukan untuk membuktikan kualitas tablet generik dan bermerek. Pengujian mutu tablet dilakukan terhadap sifat fisik tablet dan sifat kimia tablet.

Tujuan Penelitian: Mengevaluasi sifat fisika kimia dari 6 tablet paracetamol generik dan bermerek terhadap standar yang ditetapkan.

Metode Penelitian: Sifat fisik tablet paracetamol bermerek maupun generik diuji terhadap keseragaman bobot, keseragaman ukuran, kerapuhan tablet, kekerasan tablet dan waktu hancur tablet. Sifat kimia tablet (kadar paracetamol) dievaluasi dengan metode spektrofotometri UV – Vis. Hasil evaluasi sifat fisik dan kimiawi dibandingkan dengan ketentuan yang telah ditetapkan dalam Farmakope Indonesia.

Hasil Penelitian: Keseragaman bobot keenam sampel berkisar antara 0,596 mg - 0,651 mg dan nilai CV < 5%. Diameter tablet berkisar antara 1,283 cm – 1,334 cm dengan CV < 5% dan ketebalan tablet berkisar antara 0,435 cm – 0,486 cm dengan CV < 5%. Nilai % kerapuhan tablet < 0,8 %. Kekerasan tablet berkisar 12,631 kg – 28,641 kg. Waktu hancur paracetamol tidak bersalut berkisar antara 2,497 menit – 20,433 menit. Kadar paracetamol dalam tablet memenuhi rentang 90% – 110% menurut persyaratan Farmakope Indonesia edisi VI.

Kesimpulan: Sifat fisik kimia pada tablet paracetamol generik dan bermerek memenuhi persyaratan menurut standar yang ditetapkan. Namun terdapat 1 sampel yang tidak memenuhi persyaratan sifat fisik yaitu pada waktu hancur. Hasil analisis statistik antara keenam sampel tablet paracetamol menunjukkan adanya variasi keseragaman bobot, keseragaman ukuran, kekerasan tablet, dan waktu hancur antar sampel kecuali pada kadar dan kerapuhan tablet.

Kata Kunci: Tablet, Paracetamol, Generik, Bermerek

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PHYSICAL AND CHEMICAL CHARACTERISTICS OF BRANDED AND GENERIC PARACETAMOL TABLETS IN SEDAYU SUB-DISTRICT

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ABSTRAK

Background: Paracetamol tablets are one of the dosage forms that are widely circulated in the community as analgesic and antipyretic drugs. Testing of tablet quality is very necessary to prove the quality of generic and branded tablets. Tablet quality testing is carried out on the physical properties of tablets and chemical properties of tablets.

Objective: Evaluate the physical chemical properties of 6 generic and branded paracetamol tablet brands against established standards

Method: The physical properties of branded and generic paracetamol tablets are tested against uniformity of weight, uniformity of size, friability test, hardness test and disintegration time test. The chemical properties of the tablets (paracetamol levels) were evaluated by the UV-Vis spectrophotometry method. The results of the evaluation of physical and chemical properties are compared with the provisions stipulated in the Indonesian Pharmacopoeia.

Results: The weight uniformity of the six samples ranged from 0.596 mg - 0.651 mg and CV values < 5%. The diameter of the tablet ranges from 1.283 cm – 1.334 cm with a CV of < 5% and the thickness of the tablet ranges from 0.435 cm – 0.486 cm with a CV of < 5%. The % value of the friability of tablets < 0.8 %. The hardness of tablets range from 12,631 kg – 28,641 kg. Disintegration time of uncoated paracetamol ranges from 2,497 minutes – 20,433 minutes. Paracetamol levels in tablets meet the range of 90% – 110% according to the requirements of the Indonesian Pharmacopoeia edition VI.

Conclusion: The physical-chemical properties of generic and branded paracetamol tablets meet the requirements according to established standards. However, there is 1 sample that does not meet the requirements of physical properties, namely at the time of destruction. The results of statistical analysis between the six paracetamol samples showed variations in weight uniformity, size uniformity, hardness, desintegration time between samples except for drug content and friability.

Kata Kunci: Tablets, Paracetamol, Generic, Branded

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