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KAJIAN PROFIL DISOLUSI TABLET ASAM MEFENAMAT

(xix + 195 halaman + 10 gambar + 14 tabel + 6 lampiran)

INTISARI

Latar Belakang : Asam mefenamat merupakan golongan obat *Biopharmaceutical Classification System (BCS)* kelas II, dengan kelarutan rendah dan permeabilitas tinggi, sehingga memiliki daya serap yang tinggi tetapi laju disolusi rendah. Tujuan penelitian ini untuk membandingkan profil disolusi tablet asam mefenamat sesuai parameter FI Edisi V atau *USP 37* serta mengevaluasi faktor-faktor yang berpengaruh terhadap profil disolusi.
Metode : Penelitian ini menggunakan metode literatur *review* dengan tema kajian profil disolusi tablet asam mefenamat menggunakan 5 jurnal yang terdiri dari 1 jurnal nasional terakreditasi SINTA dan 4 jurnal internasional terindeks scimago.
Hasil : Berdasarkan hasil uji disolusi tablet asam mefenamat menggunakan 23 sampel yang diuji menggunakan apparatus *USP* tipe I dan II, dengan kandungan zat aktif, media disolusi, formulasi dan metode pembuatan tablet yang berbeda menunjukkan hasil uji disolusi pada rentang 29,13- 98,52%. Kesesuaian hasil uji disolusi disebabkan karena adanya modifikasi dalam proses formulasi dan pembuatan tablet, kondisi uji disolusi yang sesuai dengan ketentuan uji disolusi sediaan tablet maupun dikarenakan tablet sudah menjalani proses uji disolusi tahap 2 (S2) sampai dengan tahap 3 (S3).
Kesimpulan : Profil disolusi 23 sampel tablet asam mefenamat menunjukkan hasil pada rentang 29,13-98,52%. Sebanyak 20 sampel menunjukkan profil disolusi memenuhi persyaratan Farmakope Indonesia Edisi V yaitu >65% maupun menurut *United States Pharmacopeia 37 (USP 37)* yaitu >75% dalam waktu 45 menit. Perbedaan hasil uji disolusi disebabkan oleh adanya perbedaan media disolusi, volume media disolusi, pH, kecepatan pengadukan, *excipients*, zat aktif, metode pembuatan tablet, spesifikasi alat, suhu, posisi dan waktu pengambilan sampel serta penentuan kadar zat terlarut.

Kata Kunci : Tablet asam mefenamat, Uji disolusi, Farmakope Indonesia Edisi V, *USP 37.*

Kepustakaan : 35 pustaka

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MEFENAMIC ACID TABLETS DISSOLUTION PROFILE STUDY

(xix + 195 pages + 10 pictures + 14 table + 6 attachments)

ABSTRACT

Background : Mefenamic acid is a class II Biopharmaceutical Classification System (BCS) drug, with low solubility and high permeability, so it has high absorption but low dissolution rate. The purpose of this study was to compare the dissolution profile of mefenamic acid tablets according to the parameters of FI Edition V or USP 37 and evaluate the factors that influence the dissolution profile.
Methods: This study used a literature review method with the theme of dissolution profile study of mefenamic acid tablets using 5 journals consisting of 1 SINTA accredited national journal and 4 scimago indexed international journals.
Results : Based on the results of the dissolution test of mefenamic acid tablets using 23 samples tested using USP apparatus type I and II, with the content of the active substance, dissolution media, formulation and method of making different tablets, the results of the dissolution test were in the range of 29.13 to 98.52 %. The suitability of the dissolution test results was due to modifications in the process of formulation and manufacture of tablets, the dissolution test conditions were in accordance with the provisions of the dissolution test for tablet preparations and because the tablets had undergone a dissolution test process stage 2 (S2) to stage 3 (S3).
Conclusion: The dissolution profile of 23 samples of mefenamic acid tablets showed results in the range of 29.13-98.52%. A total of 20 samples showed that the dissolution profile met the requirements of the Indonesian Pharmacopeia V Edition namely >65% and according to United States Pharmacopeia 37 (USP 37) which was >75% within 45 minutes. The difference in dissolution test results is caused by differences in dissolution media, volume of dissolution media, pH, stirring speed, excipients, active substance, tablet manufacturing method, equipment specifications, temperature, position and time of sampling and determination of solute levels.

Keywords: Mefenamic acid tablet, Dissolution test, Indonesian Pharmacopeia Edition V, USP 37.

Bibliography : 35 references