

Penetapan Beyond Use Date (BUD) Sediaan Suspensi Asam Mefenamat dengan Kromatografi Cair Kinerja Tinggi-Detektor UV-Vis = Determination of Beyond Use Date (BUD) for Mefenamic Acid Suspension by High Performance Liquid Chromatography-UV-Vis Detector

Fara Fanesa Z., author

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Abstrak

Asam mefenamat adalah obat golongan anti inflamasi nonsteroid yang cukup sering digunakan sebagai pereda nyeri pada tingkat ringan hingga sedang. Meskipun prevalensi penggunaan asam mefenamat di Indonesia cukup tinggi, namun beyond use date (BUD) asam mefenamat masih belum diketahui. Penelitian ini bertujuan untuk mengetahui BUD dari sediaan suspensi asam mefenamat yang beredar di pasaran dengan melakukan pengujian berkala terhadap perubahan kadar sampel menggunakan instrumen kromatografi cair kinerja tinggi (KCKT) pada metode yang telah tervalidasi. Kondisi KCKT yang digunakan adalah fase terbalik dengan kolom C18, fase gerak asetonitril – air (75:25) pH 4, laju alir 1,0 ml/menit, mode isokratik, dan panjang gelombang UV 280 nm. Waktu retensi yang diperoleh asam mefenamat adalah 5,068 menit. Berdasarkan hasil validasi, metode analisis optimal yang digunakan menunjukkan hasil yang linear pada rentang 4 – 10 $\hat{1}/4$ g/mL dengan $r = 0,9993$. LOD dan LOQ yang diperoleh adalah 0,5157 $\hat{1}/4$ g/mL dan 1,5627 $\hat{1}/4$ g/mL. Hasil uji akurasi asam mefenamat yaitu 98,80 – 101,16% dengan nilai KV<2%. Metode analisis telah memenuhi seluruh parameter validasi menurut ICH Q2(R1) (2005) dan Harmita (2015), sehingga dapat digunakan untuk analisis kadar suspensi asam mefenamat. Penetapan kadar dilakukan selama 39 hari. Penetapan BUD mengacu pada nilai t90 dari seluruh sampel yang diuji dan diperoleh BUD pada 33 hari.

.....Mefenamic acid is a non-steroidal anti-inflammatory drug which is quite often used as a pain reliever at mild to moderate levels. Although the prevalence of mefenamic acid use in Indonesia is quite high, the beyond use date (BUD) of mefenamic acid is still unknown. This study aims to determine BUD of mefenamic acid suspension on the market by conducting periodic testing of changes in sample concentrations using a high performance liquid chromatography (HPLC) instrument with a validated method. The HPLC conditions used were reversed phase with column C18, mobile phase acetonitrile – water (75:25) pH 4, flow rate 1.0 ml/min, isocratic mode, and UV detection at 280 nm. The retention time obtained by mefenamic acid was 5.068 minutes. Based on the validation results, the optimal analytical method used showed linear results in the range of 4 – 10 μ g/mL with $r = 0.9993$. The LOD and LOQ obtained were 0.5157 μ g/mL and 1.5627 μ g/mL. This method had fulfilled the parameters of accuracy and precision with % recovery from 98.80 % to 101.16% and CV <2%. The analytical method complies with all validation parameters according to ICH Q2(R1) (2005) and Harmita (2015), so that it can be used to analyze the concentrations of mefenamic acid suspension. Determination of samples' concentrations carried out for 39 days. BUD determination refers to the t90 value of all samples tested and obtained BUD on 33 days.