Penetapan Beyond Use Date (BUD) Suspensi Oral Ibuprofen Menggunakan Kromatografi Cair Kinerja Tinggi – Detektor UV/Vis = Beyond Use Date (BUD) Determination of Ibuprofen Oral Suspension by High Performance Liquid Chromatography â UV/Vis Detector

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Abstrak

Suspensi oral ibuprofen yang diindikasikan sebagai penurun demam anak memiliki waktu kedaluwarsa yang tercantum pada kemasan sediaannya, namun belum ada data mengenai beyond use date (BUD) dari suspensi oral ibuprofen. Penelitian ini bertujuan untuk memperoleh data BUD suspeni oral ibuprofen berdasarkan penetapan kadar sediaan pada interval waktu yang telah ditentukan. Penetapan kadar dilakukan menggunakan Kromatografi Cair Kinerja Tinggi (KCKT) detektor UV/Vis pada panjang gelombang 220 nm dengan standar internal benzofenon. Analisis dilakukan menggunakan kolom C-18 Waters Spherisorb® (250 mm x 4,6 mm i.d; 5 m) dengan fase gerak asetonitril-asam fosfat 0,01 M (63:37, v/v). Mode elusi yang digunakan yakni isokratik dengan laju alir 1 mL/menit dengan waktu analisis 10 menit. Waktu retensi ibuprofen dan benzofenon berturut-turut adalah 6,92 dan 7,68 menit. Analisis bersifat selektif ditunjukkan oleh tidak adanya gangguan di sekitar waktu retensi ibuprofen dan benzofenon. Persamaan regresi linier kurva kalibrasi yaitu y = 0,9517x + 0,0433 dengan nilai koefisien korelasi (r) adalah sebesar 0,9998. LOD dan LOQ ibuprofen secara berturut-turut diperoleh sebesar 13,3021 g/mL dan 40,3094 g/mL. Metode bersifat akurat dan presisi (nilai perolehan kembali sebesar 99,49-100,76% dan nilai koefisien variasi sebesar 0,20-0,54%). Suspensi oral ibuprofen secara umum dan sampel E berturut-turut mencapai BUD setelah 124 dan 36 hari terhitung sejak pembukaan pertama kemasan primer.
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Ibuprofen oral suspension which is indicated as a fever reducer in children has an expiration date listed on the packaging, but there is no data on the beyond use date (BUD) of ibuprofen oral suspension. This study aims to obtain BUD data of ibuprofen oral suspension based on the determination of dosage levels at predetermined time intervals. Assays were carried out using a High-Performance Liquid Chromatography (HPLC) UV/Vis detector at a wavelength of 220 nm with an internal standard of benzophenone. Analysis was performed using a C-18 Waters Spherisorb® column (250 mm x 4.6 mm i.d; 5 m) with 0.01 M (63:37, v/v) acetonitrile-phosphoric acid as mobile phase (63:37, v/v). The elution mode used was isocratic with a flow rate of 1 mL/minute with an analysis time of 10 minutes. The retention time of ibuprofen and benzophenone were 6.92 and 7.68 minutes, respectively. Selective analysis was indicated by the absence of disturbances around the retention time of ibuprofen and benzophenone. The linear regression equation for the calibration curve was y = 0.9517x + 0.0433 with a correlation coefficient (r) was 0.9998. The LOD and LOQ of ibuprofen were 13.3021 g/mL and 40.3094 g/mL, respectively. The method is accurate and precise (recovery value was 99.49-100.76% and coefficient of variation value was 0.20-0.54%). The ibuprofen oral suspension in general and sample E reached BUD after 124 and 36 days, respectively, from the first opening of the primary pack.