Validasi metode analisis rebamipid dalam plasma in vitro secara kromatografi cair kinerja tinggi-ultraviolet

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Abstrak

Rebamipid tergolong suatu obat antiulkus yang masuk dalam kategori obat wajib uji Bioekivalensi (BE) menurut Food and Drug Administration (FDA). Penelitian ini bertujuan untuk memperoleh kondisi optimum untuk analisis rebamipid dalam plasma in vitro menggunakan Kromatografi Cair Kinerja Tinggi (KCKT) detektor ultraviolet dan melakukan validasi metode analisis tersebut. Kromatografi dilaksanakan dengan teknik isokratik pada kolom fase terbalik Kromasil® C18 (5 μm, Akzo Nobel) panjang kolom 250 x 4,6 mm, fase gerak asetonitril-dapar fosfat pH 3,0 (40:60), dengan kecepatan alir 1,0 ml/menit, dan dideteksi pada panjang gelombang 230 nm. Teknik penyiapan sampel dilakukan dengan cara ekstraksi cair-cair menggunakan asam fosfat dan etil asetat. Karbamazepin digunakan sebagai baku dalam. Metode ini valid menurut FDA dalam Bioanalytical Method Validation, dengan nilai koefisien korelasi r = 0,9993 dan linier pada kisaran konsentrasi 0,04 ? 1,2 ìg/ml, batas terendah kuantitasi (LLOQ) 42,0 ng/ml, presisi kurang dari 6%, dan nilai perolehan kembali antara 90,32 sampai 113,45%. Rebamipid stabil dalam plasma selama 14 hari penyimpanan pada suhu -200C.
<hr>Rebamipide is antiulcer agent and it is one of the drug that have to be evaluated with bioequivalency test according to Food and Drug Administration (FDA). The objective of this research is to find out the optimum condition of rebamipide in human plasma in vitro analysis by High Performance Liquid Chromatography (HPLC) with ultraviolet detector, and then the method was validated. The chromatography was carried out by isocratic technique on a reversed-phase Kromasil® C18 (5 μm, Akzo Nobel), column length was 250 x 4.6 mm, with mobile phase consisted of acetonitrile - phosphate buffer pH 3.0 (40:60) at flow rate of 1.0 ml/min, and detection was performed at wavelength of 230 nm. The sample preparation technique was liquidliquid extraction by phosphoric acid and ethyl acetate. Carbamazepine was used as the internal standard. The method was valid according to FDA in Bioanalitycal Method Validation, with coefficient correlation of 0.9993 and linear in the range concentration of 0.04 ? 1.2 μg/ml, the lower limit of quantitation was 42.0 ng/ml, precision less than 6% and recovery percentage was 90.32 to 113.45%. Rebamipide in plasma was stable for 14 days storage in -200C.