Stability-indicating methods for the determination of famciclovir in the presence of its alkaline-induced degradation product

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Abstract

Five sensitive, selective and precise stability-indicating methods are presented for the determination of famciclovir (FCV) in the presence of its alkaline-induced degradation product. Method A utilizes the first derivative spectrophotometry at 321 nm. Method B depends on using the first derivative of the ratio spectrophotometry (DD(1)) by measurement of the amplitude at 256 nm. Method C is based on the reaction of FCV with hydroxylamine to form hydroxamic acid, causing the hydroxamic acid to react with triferric ion to form ferric hydroxamate that is measured at 503 nm. Method D is based on the separation of FCV from its degradation product followed by densitometric measurement of the bands at 304 nm. The separation was carried out on silica gel 60 F(254), using chloroform: methanol (70:30, v/v) as a mobile phase. Method E is based on a high performance liquid chromatographic (HPLC) separation of FCV from its degradation product using an ODS column with a mobile phase consisting of methanol-50 mM dipotassium hydrogen phosphate (25:75, v/v, pH 3.0) with UV detection at 304 nm. Regression analysis showed good correlation in the concentration ranges 16-72 microg/ml, 40-240 microg/ml, 40-240 microg/ml, 0.75-5.25 microg/band and 20-240 microg/ml with percentage recoveries of 99.65 +/- 0.85, 100.27 +/- 0.91, 99.72 +/- 0.84, 100.65 +/- 1.52 and 99.88 +/- 0.50 for methods A, B, C, D and E, respectively. These methods are suitable as stability-indicating methods for the determination of FCV in the presence of its degradation product either in bulk powder or in pharmaceutical formulation. Statistical analysis of the results has been carried out revealing high accuracy and good precision.