Assay of naproxen by high-performance liquid chromatography and identification of its photoproducts by LC-ESI MS

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Abstract

A rapid, accurate and reliable reversed-phase high-performance liquid chromatographic (HPLC) method for the determination of naproxen and its photodegradation products in methanol was developed and validated. An Inertsil 5-ODS-3V column (5 μm, C18, 250 x 4.6 mm i.d.) was used with a mobile phase of acetonitrile-methanol-1% HOAc in H2O (40:20:40, v/v/v). UV detection was set at 230 nm. The developed method satisfies system suitability criteria, peak integrity and resolution for the parent drug and its photoproducts. The intraday and interday standard deviations of five replicate determinations for five consecutive days at the working concentrations of 5.0, 10, 25, 50, and 100 HM were 0.23-0.98 with coefficients of variance (CVs) of between 0.96 and 4.56% for the former, and 0.14-1.15 with CVs of between 1.13 and 3.82% for the latter. The percentage recoveries were determined to be 98.34, 99.19, 100.18, 102.97 and 99.81%, respectively, at the five concentrations between 5.0 and 100 μM. The limit of quantitation of naproxen was determined to be 0.29 μg/mL, while the detection limit was 64 ng/mL. Four major photoproducts were observed from the HPLC chromatogram using a Panchum PR-2000 reactor which equipped with 8 W x 16 low-pressure quartz mercury lamps as the light source for irradiation of a naproxen sample in methanol. The structures of the photoproducts were confirmed by LC-ESI MS.