

Abstract:

A selective, repeatable, and robust isocratic liquid chromatographic method has been developed for the analysis of bulk samples of roxithromycin, a semi-synthetic macrolide antibiotic. The method involves the use of XTerra RP18 as stationary phase and acetonitrile-2.0m (NH₄)₂HPO₄, pH 6.4-water, 25:30:45, (v/v) as mobile phase, delivered at a flow rate of 1.0 mL min⁻¹. Detection was by UV absorbance at 215 nm. Sufficient separation of roxithromycin from its homolog containing one more methyleneoxy group (roxithromycin G) and from other related substances was achieved. The robustness of the method was evaluated by means of a full-factorial experimental design.