ABSTRACT

An accurate, simple and specific reverse phase HPLC analytical procedure is established and validated for simultaneous determination of Tramadol HCl, Diphenhydramine HCl and Fluoxetine HCl in pharmaceutical formulations. Good chromatographic separations between and stress induced degradations products were accomplished within 15 minutes using C18 column using 0.1% formic acid with TEA (triethylamine) pH at 3.6 as mobile phase A and acetonitrile as mobile phase B, (70-100 % v/v) at 224nm wavelength. The flow rate was 1.1 ml/min. Developed method was validated using ICH guidelines. Linearity was from (4-200 µg mL-1) for Tramadol HCl, (4-200 µg mL-1) for Diphenhydramine HCl and (4-200 µg mL-1) for Fluoxetine HCl. The LOD values were found to be 11µg/ml for tramadol HCl, 9µg/ml for diphenhydramine HCl and 11.8µg/ml for fluoxetine HCl. The LOQ values were found to be 33.8µg/ml for tramadol HCl, 28µg/ml for diphenhydramine HCl and 35.9µg/ml for fluoxetine HCl. All the analytes including the degradation products were separated with acceptable peak tailing and resolution. The established method can successfully be used for the routine and simultaneous determination of Tramadol HCl, Diphenhydramine HCl and Fluoxetine HCl in pharmaceutical formulations.