Development and validation of spectrophotometric and high performance thin layer chromatographic methods for the determination of folic acid in the presence of its impurities (degradation products)

ABSTRACT

three accurate, sensitive, simple and precise spectrophotometric methods along with TLC-Densitometric methods were developed and validated for determination of Folic acid in presence of two impurities (photodegradation product) which is Pteroic acid and para-aminobenzoic acid. Method A is ratio difference (RDSM) spectrophotometric method, which depends on measuring the difference value in the ratio spectrum where the difference between 291 and 313 nm was used for determination of folic acid while the difference between 305 and 319 nm was selected for estimation of para-aminobenzoic acid, on the other hand pteroic acid can be determined using first derivative of ratio spectra spectrophotometric method at 262 nm. Method B is double divisor (DDSM) spectrophotometric methods, which based on using the ratio spectrum obtained by the division of the spectrum of ternary mixture by the spectrum of binary mixture containing two of the three mentioned components, in this method folic acid, para-aminobenzoic acid and pteroic acid were measured at 242, 313 and 258 nm, respectively. Method C is mean centering of ratio spectra spectrophotometric (MCR) method, in this method folic acid, para-aminobenzoic acid and pteroic acid can be determined using the mean centered second ratio spectra amplitudes at 317-318 (peak to peak), 264-265 (peak to peak) and 232 nm, respectively. While Method D is a TLC-Densitometric one that depends on separation and quantitation of the mentioned components on TLC silica gel 60 F_{254}

plates, using methanol: iso-propanol: water: acetic acid (9:0.5:0.5:0.2, by volume) as a developing system followed by Densitometric measurement of the separated bands at 280 nm. Methods validation were carried out according to ICH guidelines and the proposed methods were successfully applied to the analysis of Folic acid in pharmaceutical formulations where no interference from additives has been found. Results obtained by the proposed methods were statistically compared with those obtained by the official RP-HPLC method and no significant difference.