

Development and validation of stability indicating spectrophotometric methods for determination of sulbutiamine in tablet dosage form

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Abstract

Five sensitive, selective and precise stability-indicating spectrophotometric methods for the determination of Sulbutiamine (SUL) in the presence of its alkali-induced degradation product (DEG) were developed and validated. Method A is differential dual wavelength (D1DWL) applied in the analysis of SUL in binary mixture via its first derivative spectra using the difference between two points with equal amplitudes in the alkali-induced degradation product, thus DEG acts as zero contribution. Method B is second derivative spectrophotometry (D2), which allowed the determination of SUL at 300.0 nm. Method C is second derivative of the ratio spectra (DD2) in which SUL was determined by measuring the peak amplitude at 301.0 nm. Method D is the ratio difference spectrophotometry (RD), where the difference between amplitudes of the absorbance ratio spectra at 237.2 and 274.0 nm were recorded and Method E; Ratio subtraction (RSM) where the zero order spectra of pure SUL were extracted from their laboratory prepared mixtures, and consequently SUL can be analyzed at its maxima. The linearity for SUL was obtained within concentrations ranging from 5.00 - 50.00 µg/mL with percentage recovery of 100.58 ± 0.98 , 99.62 ± 1.16 , 100.70 ± 1.38 , 100.06 ± 1.00 and 99.56 ± 1.00 for the five methods, respectively.

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