Validated stability-indicating spectrophotometric methods for the determination of Silodosin in the presence of its degradation products

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Abstract

Five simple, rapid, accurate, and precise spectrophotometric methods are developed for the determination of Silodosin (SLD) in the presence of its acid induced and oxidative induced degradation products. Method A is based on dual wavelength (DW) method; two wavelengths are selected at which the absorbance of the oxidative induced degradation product is the same, so wavelengths 352 and 377 nm are used to determine SLD in the presence of its oxidative induced degradation product. Method B depends on induced dual wavelength theory (IDW), which is based on selecting two wavelengths on the zero-order spectrum of SLD where the difference in absorbance between them for the spectrum of acid induced degradation products is not equal to zero so through multiplying by the equality factor, the absorption difference is made to be zero for the acid induced degradation product while it is still significant for SLD. Method C is first derivative (1D) spectrophotometry of SLD and its degradation products. Peak amplitudes are measured at 317 and 357 nm. Method D is ratio difference spectrophotometry (RD) where the drug is determined by the difference in amplitude between two selected wavelengths, at 350 and 277 nm for the ratio spectrum of SLD and its acid induced degradation products while for the ratio spectrum of SLD and its oxidative induced degradation products the difference in amplitude is measured at 345 and 292 nm. Method E depends on measuring peak amplitudes of the first derivative of the ratio (1DD) where peak amplitudes are measured at 330 nm in the presence of the acid induced degradation product and measured by peak to peak technique at 326 and 369 nm in the presence of the oxidative induced degradation product. The proposed methods are validated according to ICH recommendations. The calibration curves for all the proposed methods are linear over a concentration range of 5ï70 εg/mL. The selectivity of the proposed methods was tested using different laboratory prepared mixtures of SLD with either its acid induced or oxidative induced degradation products showing specificity of SLD with accepted recovery values. The proposed methods have been successfully applied to the analysis of SLD in pharmaceutical dosage forms without interference from additives.

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