Stability Indicating Analytical method Devlopment and Validation for Simultaneous Estimation of Paracetamol and Zaltoprofen in Solid Dosage Form

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Abstract

Objective: Stability Indicating Analytical method Devlopment and Validation for Simultaneous Estimation of Paracetamol and Zaltoprofen in Solid Dosage Form.

Experimental work done: UV spectrophotometric estimation was carried out by First order derivative method. Methanol was used as a solvent for UV spectrophotometric method. HPLC method was performed by using C_{18}, 5µ, 250 mm x 4.6 mm. Various trials were performed for optimization of mobile phase. All these methods were validated as per ICH guidelines.Various Stability parameters were also checked for the degradation of drugs.

Results and Discussion: The selected optimized wavelength for spectrophotometric methods, in First order derivative method were 268 nm and 248 nm, for estimation of ZALTO, and PCM respectively. The optimized mobile phase for HPLC method phosphate buffer : Acetonitrile pH 3.0 with OPA in the ratio of 65: 35 v/v gave peak of ZALTO and PCM at Retention Time of 4.83 min. and 2.79 min. at λmax=260 nm. % RSD for precision, accuracy and robustness for all methods was less than 2. In Stability study HCl, NaOH, H_2O_2 were used in acid, Base and Oxidation and Thermal Degradation respectively.

Conclusion: The spectrophotometric and chromatographic methods developed are sensitive, precise, accurate and reproducible for analysis of pharmaceutical formulation. Results of method suggest that all the methods are repeatable and specific for the estimation of ZALTO and PCM. Stability study suggest that no any interference observed from any degradant peaks at retention time of ZALTO and PCM.

Key Words: First order derivative method, High performance liquid chromatography, Force Degradation study, Zaltoprofen, Paracetamol.

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