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A novel validated RP-HPLC-DAD method for the simultaneous estimation of Phenylephrine and Ketorolac in bulk and pharmaceutical dosage form with forced degradation studies

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Abstract : A novel approach was used todevelop and validate a rapid isocratic Reversed Phase-High Performance Liquid Chromatographic method for the simultaneous estimation of Phenylephrine and Ketorolac in bulk and pharmaceutical dosage form with forced degradation studies. The separation was performed by BDS C_{18} (150mm×4.6 mm, 5µm particle size) column, Waters Alliance e2695 HPLC system with 2998 PDA detector and mobile phase contained a mixture of 0.01M Ammonium acetate (pH adjusted to 3.5 with orthophosphoric acid) and Acetonitrile (30:70, v/v). The flow rate was set to 1ml/min with responses measured at 259nm. The retention time of Phenylephrine and Ketorolac was 2.291min and 3.827min respectively with resolution of 11.11. Linearity was established in the range of 20-120µg/ml for Phenylephrine and 6-36µg/ml for Ketorolac with correlation coefficients (r^2=0.999). The percentage recoveries were between (100.30-101.03%) and (99.93-100.65%) for Phenylephrine and Ketorolac respectively. Validation parameters were evaluated according to the International Conference on Harmonization (ICH) Q2 R1 guidelines. The forced degradation studies were performed by using HCl, NaOH, H_2O_2, thermal, UV radiation and water. Phenylephrine and Ketorolac are more sensitive towards alkaline hydrolysis degradation condition. The developed method was successfully applied for the quantification and hyphenated instrumental analysis.
Key words: Phenylephrine, Ketorolac, PDA detector, Hyphenated, ICH.

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