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Development and Validation of Stability Indicating RP-HPLC Method for Simultaneous Estimation of NSAIDS-Antiulcer Agent Combination

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Abstract : A specific, accurate, precise and reproducible stability-indicating HPLC method has been developed and subsequently validated for the simultaneous determination of Paracetamol (PCM), Pantoprazole (PPZ) and Ibuprofen (IBU) in pharmaceutical dosage forms. The separation was performed on a Rankem Princeton Spher-100, C_{18} (150×4.6mm), 100A, 5µm column using methanol: disodium hydrogen phosphate buffer (adjusted to pH 7 using orthophosphoric acid) in the ratio of 60:40 (v/v) as the mobile phase. The flow rate was adjusted to 1ml/min for PCM, PPZ and 1.5ml/min for IBU. Quantitation was achieved with UV detection at 222 nm, based on peak area with linear calibration curves, at seven concentration levels ranging from 1-64µg/ml for PCM, PPZ and IBU in individual as well as in combined dosage form. It demonstrated good linearity with r^2 >0.998 for all the drugs. The method was validated in terms of accuracy, precision, linearity, limit of detection, limit of quantitation and robustness. The proposed method was successfully applied for the analysis of pharmaceutical formulations containing PCM, PPZ and IBU, in the presence of degradation products formed under various stress conditions, and no interference from the excipients was observed.
Keywords: RP-HPLC, Paracetamol, Pantoprazole, Ibuprofen, Stability-indicating method.

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