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Development and Validation of Stability indicating HPTLC Method for Estimation of Carbocisteine and Amoxicillin as Bulk Drug and in Drug Formulation by Derivatization

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Abstract : A new, accurate, selective and sensitive stability indicating high performance thin layer chromatographic (HPTLC) method for simultaneous estimation of carbocisteine and amoxicillin was developed and validated. The compounds were well separated on aluminum plates precoated with silica gel $60F_{254}$ using Butanol: Water: Ethanol: Acetic acid (5.5:1:2:1.5 v/v/v/v) as mobile phase. Developed plates were derivatized with ninhydrin reagent followed by heating at 110^0C for 5 min in a preheated oven and scanned at 366 nm. The retention factor for carbocisteine and amoxicillin were found to be 0.28 and 0.72, respectively. Validation of the proposed method was carried out according to International Conference on Harmonization (ICH) guidelines. The current method demonstrates good linearity with correlation coefficients values 0.9996 and 0.9985 for carbocisteine and amoxicillin, respectively. The method was validated for precision, recovery and robustness and the values obtained were within ICH limits. The drugs were subjected to oxidation, acid and base hydrolysis, dry heat and UV light to apply stress condition for degradation studies as per ICH guidelines. The degradation products were well resolved from pure drug with different R_f values. Since the method effectively separates the drug from its degradation products it could be used as stability indicating method for analysis of individual drugs and the combined dosage form.
Keywords : Carbocisteine, Amoxicillin, stability indicating, HPTLC, Validation.

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