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

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Abstract : The objective of the method was to develop and validate a sensitive stability indicating high performance thin layer chromatographic (HPTLC) method for simultaneous estimation of glucosamine and diacerein. The chromatographic separation was done on aluminum plates precoated with silica gel $60F_{254}$ using n-butanol: Water: Glacial Acetic Acid (7:1.5:1.5 v/v/v) as mobile phase. Developed plates were scanned at 254 nm for spot of diacerein followed by derivatization with ninhydrin reagent by heating at 110^0C for 5 min in a preheated oven and scanned at 366 nm for spot of glucosamine. The retention factor for glucosamine and diacerein were found to be 0.23 and 0.81, 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 0.9995 for glucosamine and diacerein, respectively. The method was validated for different parameters like precision, recovery and robustness and the values obtained were within ICH limits. For forced degradation studies the drugs were subjected to oxidation, acid and base hydrolysis, dry heat and UV light as per ICH guidelines. Forced degradation studies indicated the suitability of the method for stability studies. 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 : Glucosamine, diacerein, HPTLC, stability indicating, Validation.

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