

DEVELOPMENT AND OPTIMIZATION OF A QBD-BASED HPTLC METHOD FOR FORCED DEGRADATION OF INOSINE PRANOBEX IN BULK AND TABLET FORMULATION

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ABSTRACT

A reliable, innovative and stability-indicating HPTLC method was successfully developed and validated for estimating inosine pranobex (IP) in both bulk drug and pharmaceutical formulations using a Quality by Design (QbD) approach. To achieve systematic optimization, a Box-Behnken Design was applied to identify and refine key method parameters. Variables such as mobile phase composition, saturation time, solvent front and band length were studied to enhance chromatographic efficiency. The separation was carried out on HPTLC plates precoated with silica gel 60 F254 using a mobile phase consisting of toluene, methanol, ethyl acetate and formic acid in the ratio 6:2:2:0.5 (V/V/V/V). Detection was performed at 272 nm using densitometry. The method underwent thorough validation to confirm its specificity, linearity, accuracy, precision, robustness and sensitivity. The drug showed a well-defined peak with an R_f value of 0.56 ± 0.02 . The method exhibited linearity in the range of 200–1200 ng band⁻¹ with a correlation coefficient (r^2) of 0.999. The limit of detection (LOD) and limit of quantification (LOQ) were found to be 1.15 ng band⁻¹ and 3.5 ng band⁻¹ respectively. The percentage recovery was found to be 98.6 % to 102.08%. Forced degradation studies under various stress conditions demonstrated method's stability by effectively separating the drug from its degradation products, proving its applicability for quality control analysis.