Title: HPTLC method for the simultaneous estimation of Amlodipine and Benazepril in their formulations

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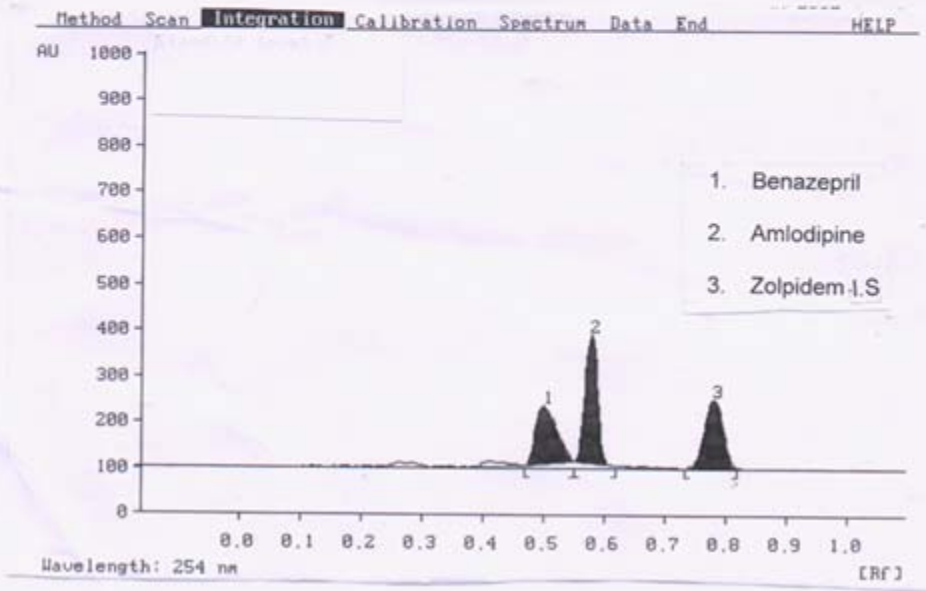
Abstract: Amlodipine, a dihydro pyridine derivative and Benazepril, a benzazepine derivative are used as antihypertensive agents. A combination of 10 mg of Amlodipine and 10 mg of Benazepril is commercially available as tablets. Literature survey reveals that only one HPLC method is available for its estimation in their dosage forms. The present work describes the application of high performance thin layer chromatographic estimation of Amlodipine and Benazepril from its formulations. Chromatography was performed on aluminium backed silica gel $60F_{254}$ HPTLC plates. Plates were developed with Ethyl acetate: Methanol: Ammonia (10%) in the volume ratio of 8.5:2:1 in a Camag twin trough chamber. Standard solutions of Amlodipine and Benazepril were transferred into different 10 mL volumetric flasks and diluted to volume with the methanol such that the final concentrations of Amlodipine and Benazepril were 0.1 to 0.8 $\mu g\ \mu L^{-1}$ and 0.2 to 2.0 $\mu g\ \mu L^{-1}$ containing 0.8 μg Zolpidem as an internal standard. Standards and samples (0.2 $\mu g\ \mu L^{-1}$ containing 0.8 μg Zolpidem) were applied to the plates as 6 mm bands by means of a Camag Linomat IV sample applicator. After development it was then scanned densitometrically under deuterium lamp at 254 nm. The Rf values are 0.58, 0.50 and 0.78 for Amlodipine, Benazepril and Zolpidem respectively. The linearity range of the drugs Amlodipine and Benazepril were 0.1 to 0.8 $\mu g\ \mu L^{-1}$ and 0.2 to 2.0 $\mu g\ \mu L^{-1}$ respectively. Percentage assay of Amlodipine was 105.1% and percentage assay of Benazepril was 101.2%. The percentage recovery of Amlodipine and Benazepril were 99.79% and 100.25% which indicates that the method is precise and accurate. The developed method was suitably validated using various validation parameters such as LOD, LOQ, robustness and ruggedness. The simplicity, accuracy, sensitivity and precision of the developed method make it as choice for routine quality control analysis for the simultaneous estimation Amlodipine and Benazepril in their formulations.

Typical chromatogram of Amlodipine, Benazepril and Zolpidem (I.S)



Calibration graph of Amlodipine and Benazepril (HPTLC)