Thin Layer Chromatography–Densitometric Determination of Some Non-Sedating Antihistamines in Combination with Pseudoephedrine or Acetaminophen in Synthetic Mixtures and in Pharmaceutical Formulations

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Abstract:

The combination of certain non-sedating antihistamines (NSA) such as fexofenadine (FXD), ketotifen (KET) and loratadine (LOR) with pseudoephedrine (PSE) or acetaminophen (ACE) is widely used in the treatment of allergic rhinitis, conjunctivitis and chronic urticaria. A rapid, simple, selective and precise densitometric method was developed and validated for simultaneous estimation of six synthetic binary mixtures and their pharmaceutical dosage forms. The method employed thin layer chromatography aluminum plates precoated with silica gel G 60 F254 as the stationary phase. The mobile phases chosen for development gave compact bands for the mixtures FXD–PSE (I), KET–PSE (II), LOR–PSE (III), FXD–ACE (IV), KET–ACE (V) and LOR–ACE (VI) [Retardation factor (Rf) values were (0.20, 0.32), (0.69, 0.34), (0.79, 0.13), (0.36, 0.70), (0.51, 0.30) and (0.76, 0.26), respectively]. Spectrodensitometric scanning integration was performed at 217, 218, 218, 233, 272 and 251 nm for the mixtures I–VI, respectively. The linear regression data for the calibration plots showed an excellent linear relationship. The method was validated for precision, accuracy, robustness and recovery. Limits of detection and quantitation were calculated. Statistical analysis proved that the method is reproducible and selective for the simultaneous estimation of these binary mixtures.

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