A Validated HPLC Methods for Separation and Determination of Promethazine Enantiomers in Pharmaceutical Formulations

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Abstract

A simple, rapid, and validated method for separation and determination of promethazine enantiomers was developed. Promethazine was separated and quantitated on a Vancomycin Chirobiotic V column (250 × 4.6 mm), using a mixture of methanol, acetic acid, and triethylamine (100:0.1:0.1%, by volume) as a mobile phase at 20°C and at a flow rate of 1 mL/min. The UV-detector was set to 254 nm. Acetyl salicylic acid (Aspirin®) was used as an internal standard. The applied HPLC method allowed separation and quantification of promethazine enantiomers with good linearity (r > .999) in the studied range. The relative standard deviations (RSD) were 0.29 and 0.36 for the promethazine enantiomers with accuracy of 100.06 and 100.08. The limit of detection and limit of quantification of promethazine enantiomers were found to be 0.04 and 0.07 μg/mL, respectively. The method was validated through the parameters of linearity, accuracy, precision, and robustness. The HPLC method was applied for the quantitative determination of promethazine in pharmaceutical formulations

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