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Stability Indicating Method Development and Validation for the Simultaneous Estimation of Doxofylline and Montelukast in its pharmaceutical dosage form by HPLC.

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ABSTRACT

A simple, rapid, economical, precise and accurate stability indicting HPLC method for simultaneous estimation of Doxofylline and Montelukast In Their Combined Dosage Form has been developed.

A stability indicting high performance liquid chromatographic method was developed for the simultaneous estimation of Doxofylline and Montelukast In Their Combined Dosage Form has been developed. The separation was achieved by LC- 20 AT C18(250mm x 4.6 mm x 2.6 µm) column and Water (pH 4.0) : Methanol (50:50) at a flow rate of 1 ml/min. Detection was carried out at 236 nm. Retention time 3.273 min and 4.807 for Doxofylline and Montelukast respectively. The method has been validated for linearity, accuracy and precision. Linearity observed for Doxofylline 20-60 µg/ml and for Montelukast 0.5-1.5 µg/ml. Developed method was found to be accurate, precise and rapid for simultaneous estimation of Doxofylline and Montelukast In Their Combined Dosage Form The proposed method was successfully applied for the simultaneous estimation of both the drugs in commercial Combined dosage form.

KEYWORDS: Doxofylline, Montelukast, Simultaneous Estimation, HPLC Method, Validation.

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