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Method Development and Validation for Simultaneous Estimation of Ledipasvir and Sofosbuvir in Pharmaceutical Dosage Form by Using RP-HPLC

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ABSTRACT:

The study describes method development and subsequent validation of RP-HPLC method for simultaneous estimation of Ledipasvir and Sofosbuvir in combined tablet dosage form. Chromatographic separation was achieved on an Inspire C18 (4.6 x 150mm, 5.0µm) column using a mobile phase consisting of (25:75 v/v) Sodium phosphate buffer (pH-3.5): methanol at a flow rate of 1ml/min. The detection wavelength is 245 nm. The retention times of Ledipasvir and Sofosbuvir were found to be 1.974 min and 2.897 min respectively. The developed method was validated as per ICH guidelines .The developed and validated method was successfully used for the quantitative analysis of Ledipasvir and Sofosbuvir in tablet dosage forms.

Keywords: Ledipasvir, Sofosbuvir, RP-HPLC, Validation.

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