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A New RP-HPLC Method for the Simultaneous Assay of SOFOSBUVIR and LEDIPASVIR in Combined Dosage Form

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Abstract : A new RP-HPLC method was developed for the simultaneous assay of sofosbuvir and ledipasvir in combined dosage form, using Inertsil ODS column (Make: 150 mmx4.6 mm I.D; particle size 5µm and a mobile phase composed of TFA- Buffer(pH -2.0), Acetonitrile and Methanol (30:50:20% v/v/v) at a flow rate of 1.0mL/min. The retention times of sofosbuvir and ledipasvir were found to be 3.205 and 3.774 min, respectively. Linearity was established for sofosbuvir and ledipasvir in the concentration ranges of 40-120ìg/ml and 10-30ìg/ml, respectively. Regression analysis showed a correlation coefficient of greater than 0.999 for sofosbuvir and ledipasvir. The percentage recoveries of sofosbuvir and ledipasvir were found to be in the range of 99.2 to 100.9% and 98.40 to 100.9% respectively. This proposed RP-HPLC method can be successfully employed for simultaneous quantitative analysis of sofosbuvir and ledipasvir in various combined formulations available in the local pharmacies.
Keywords : Sofosbuvir, Ledipasvir and Validation.

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