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STRESS DEGRADATION STUDIES AND DEVELOPMENT OF A VALIDATED RP-UHPLC METHOD OF LEDIPASVIR

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ABSTRACT

The intent of the research work was to develop and validate a simple, selective and precise reversed phase ultra-high performance liquid chromatography (RP-UHPLC) method for the determination of ledipasvir. A forced degradation study was performed as per International Conference on Harmonisation (ICH) guidelines Q1A (R2) and Q1B. Ledipasvir was found to be well separated from degradation products using an analytical C18 column (150 mm × 4.6 mm i.d., 5 µm particle size) with a ratio of mobile phase (75:25 v/v) consisting of methanol and 0.1% trifluoroacetic acid (TFA) kept at ambient temperature. The average retention time of ledipasvir was found 4.45 min at 254 nm wavelength with 1.6 mL/min isocratic flow rate and 10 µL injection volume. Linearity, accuracy, precision, sensitivity, robustness, and ruggedness were studied according to ICH guideline Q2 (R1) to validate the method. Then, this validated method was applied for forced degradation studies of ledipasvir. In conclusion, the developed method has been successfully used to study degradation behaviour of ledipasvir and may be useful to quantify the drug in different pharmaceutical dosage forms.

***Keywords*:** Ledipasvir, RP-UHPLC, ICH, Validated method, Degradation

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