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DEVELOPMENT AND VALIDATION OF RP-HPLC FOR THE SIMULTANEOUS ESTIMATION OF SOFOSBUVIR AND DACLATASVIR IN BULK AND COMBINED TABLET DOSAGE FORM

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ABSTRACT

A rapid, sensitive and accurate method for simultaneous estimation of Daclatasvir and Sofosbuvir in drug product by liquid chromatography is developed. The chromatographic separation was achieved on C₁₈(Cosmosil)(250 ×4.6mm, 5.0μ). The separation achieved employing a mobile mobile phase consists of Methanol: Water (0.1% ortho phosphoric acid) (90:10%v/v). The flow rate was 0.7ml/ minute and ultraviolet detector range at 275nm. The average retention time for Daclatasvir and Sofosbuvir found to be 3.36min and 5.74 min. The proposed method was validated for selectivity, precision, linearity, and accuracy. All validation parameters were within the acceptable range. Linearity studies for Sofosbuvir was performed (30-120μg/ml) and for Daclatasvir(5-25μg/ml). The %RSD for accuracy found to be less than 2%. Assay was found to be 99.17 to 101.65 respectively.

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