Quantification of sofosbuvir and ledipasvir in human plasma by UPLC-MS/MS method: Application to fasting and fed bioequivalence studies

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Abstract

A rapid and sensitive LCïMS/MS method was developed, optimized and validated for quantification of sofosbuvir (SF) and ledipasvir (LD) in human plasma using eplerenone as an internal standard (IS). Analytes and IS were extracted from plasma by simple liquidïliquid extraction technique using methyl tertiary butyl ether. The prepared samples were chromatographed on Acquity UPLC BEH C18 column. Separation was done using a mobile phase formed of 0.1% formic acid and acetonitrile (50:50, v/v) in an isocratic mode at a flow rate of 0.4 ml/min. The Xevo TQD LCïMS/MS was operated under the multiple-reaction monitoring mode using electrospray ionization. A full validation of the method was performed according to the FDA guidelines. Linearity was found to be in the range of 0.25ï3500 ng/ml for SF and 5ï2000 ng/ml for LD. The intra-day and inter-day precision and accuracy results were within the acceptable limits. A short run time of 2 min allows analysis of more than 400 plasma samples per day. The developed method was successfully applied to both fasting and fed bioequivalence studies in healthy human volunteers.

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