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Chromatographic analysis of ledipasvir and sofosbuvir: New treatment for chronic hepatitis C infection with application to human plasma

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A RP-HPLC/DAD method was developed and validated for the first time for the analysis of the newly formulated anti-HCV combination, in pure form, pharmaceutical formulation and in human plasma. In the developed method separation was carried out on Zorbax® Eclipse C18 column using a gradient mixture of acetonitrile: water as a mobile phase and scanning was performed at 260 nm (for SOF) and 330 nm (for (LED). The two drugs were completely separated from each other and from plasma, where plasma peak appeared at 2.76±0.05 min, SOF at 4.25±0.05 and LED at 7.35±0.05. The developed method showed high sensitivity, the drugs showed linearity in the range of 1-45 µg/mL for both pure form and spiked human plasma. Three freeze-thaw cycles were carried out separately at two different temperatures, -8oC and -20oC. No significant loss of the studied drugs was observed during repeated thawing and freezing. Validation parameters such as accuracy, precision, robustness and ruggedness were tested in compliance with USP recommendations, where acceptable results were obtained. Applying to pharmaceutical formulation showed no interference from tablet excipients.

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A novel mesogenic ether crown stationary phase for reversed-phase liquid chromatography

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The development of new bonded stationary phases is an important aspect in reversed-phase liquid chromatography (RPLC) the most used mode in high-performance LC. A novel mesogenic ether crown stationary phase has been synthesized and characterized (figure 1). The phase was obtained by coupling between Lichrospher Si 100 NH2 and the mesogenic carboxylic ether crown acid liquid crystal ECLC. Characterization of ECLC was made with proton NMR, and the nematic state was determined by DSC. Thermal study of the new material exhibit transitions in Van't Hoff plots indicating changes of the structure of the phase during heating. Analytical chromatographic behaviors of the new bonded liquid crystal stationary phase BLCSP were investigated by reversed phase LC. Separation of poly-aromatic hydrocarbons (PAHs) is described using high water content mobile phase. Bonded materials exhibit a liquid crystal-like behavior and molecular shape recognition toward planar and non-planar solutes probably due to the mesogenic state. The long nematic chain combined with a terminal ether crown imparted the new stationary phase fine selectivity towards PAH isomers. The shape selectivity demonstrated by the BLCP is higher before the transition occurring around 40°C. Using acetonitrile/water (35/65), reversed phase data of polyaromatic hydrocarbons showed significant solute planarity recognition of anthracene/o-terphenyl. The shape discrimination was evaluated by some pairs of isomers like phenanthrene/anthracene and chrysene/tetracene. The linear solute with the high length to bread ratio L/B is more retained on the new stationary phase.

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