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Investigation of anti-Hepatitis C virus, sofosbuvir and daclatasvir, in pure form, human plasma and human urine using micellar monolithic HPLC-UV method and application to pharmacokinetic study

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Abstract

Simultaneous determination of sofosbuvir (SOF), and daclatasvir (DAC) in their dosage forms, human urine and human plasma using simple and rapid micellar high performance liquid chromatographic method coupled with UV detection (HPLC-UV) had been developed and validated. These drugs are described as co-administered for treatment of Hepatitis C virus (HCV). HCV is the cause of hepatitis C and some cancers such as liver cancer (hepatocellular carcinoma) and lymphomas in humans. Separation and quantitation were carried out on anonyx^{TM} C_8 monolithic (100 × 4.6 mm (i.d.) analytical column maintained at 25 ºC. The mobile phase consisted of 0.1M sodium dodecyl sulfate (SDS) solution containing 20% (V/V) n-propanolol and 0.3% (V/V) triethylamine and pH was adjusted to 6.5 using 0.02 M phosphoric acid, respectively. The retention times of SOF and DAC were 4.8 min, and 6.5 min., respectively. Measurements were made at flow rate of 0.5 mL/min with injection volume of 20 µL and ultraviolet (UV) detection at 226 nm. Linearity of SOF and DAC was obtained over concentration ranges of 50-400, and 40-400 ng/mL, respectively in pure form, 60-300 and 50-300 ng/mL, respectively for human plasma and over 50-400, and 40-400 ng/mL, respectively for human urine with correlation coefficient > 0.999. The proposed method demonstrated excellent intra- and inter-day precision and accuracy. The suggested method was applied for determination of the drugs in pure, dosage form, and in real human plasma, real human urine and drug-dissolution test of their tablets. The obtained results have been statistically compared to reported method to give a conclusion that there is no significant differences.

Key words: HPLC-UV; human urine; human plasma; dissolution test; sofosbuvir; daclatasvir