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A Rapid and Sensitive HPTLC Method for the Simultaneous Estimation of Sofosbuvir and Velpatasvir in Rat Plasma Samples and its Application to Pharmacokinetic Study

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***SUMMARY*. A rapid and sensitive high-performance thin-layer chromatography (HPTLC) bioanalytical assay was developed and validated for the simultaneous estimation of sofosbuvir (SBV) and velpatasvir (VLP) in rat plasma. Simultaneous densitometry estimation of SBV and VLP as well as internal standard (IS; cabzantinib) was carried out on glass coated silica gel 60 F254 TLC plates utilizing the combination of chloroform/methanol (90:10, v/v) as the solvent system. The entire analysis was performed at 264 nm. The calibrator's linearity was recorded in the range of 300-4000 ng/mL for SBV and VLP. The plasma samples were prepared by a simple protein precipitation method. The accuracy for SBV and VLP was obtained as 98.65-108.90 and 97.80-107.56%, respectively. The precision for SBV and VLP was recorded as 2.42-4.20 and 2.59-3.93%, respectively. The present bioanalytical HPTLC assay was applied for the evaluation of pharmacokinetic profiles of SBV and VLP in rats after single oral dose of SBV (6 mg/kg) and VLP (1.5 mg/kg). The maximum concentration in rat plasma was estimated as 1683.04 ng/mL and 560.80 ng/mL for SBV and VLP, respectively. The present HPTLC bioanalytical method could be utilized in pharmacokinetic assessment of various dosage forms having SBV and VLP.**

RESUMEN. Se desarrolló y validó un ensayo bioanalítico de cromatografía en capa fina de alto rendimiento (HPTLC) rápido y sensible para la estimación simultánea de sofosbuvir (SBV) y velpatasvir (VLP) en plasma de rata. La estimación densitométrica simultánea de SBV y VLP, así como el estándar interno (IS; cabzantinib) se llevó a cabo en placas de TLC de gel de sílice 60 F254 recubiertas de vidrio utilizando la combinación de cloroformo / metanol (90:10, v / v) como sistema disolvente. Todo el análisis se realizó a 264 nm. La linealidad del calibrador se registró en el rango de 300 a 4000 ng/mL para SBV y VLP. Las muestras de plasma se prepararon mediante un método simple de precipitación de proteínas. La precisión para SBV y VLP se obtuvo como 98,65-108,90 y 97,80-107,56%, respectivamente. La precisión para SBV y VLP se registró como 2,42-4,20 y 2,59-3,93%, respectivamente. El presente ensayo de HPTLC bioanalítica se aplicó para la evaluación de perfiles farmacocinéticos de SBV y VLP en ratas después de una dosis oral única de SBV (6 mg/kg) y VLP (1,5 mg/kg). La concentración máxima en plasma de rata se estimó en 1683.04 ng/mL y 560.80 ng/mL para SBV y VLP, respectivamente. El presente método bioanalítico de HPTLC podría utilizarse en la evaluación farmacocinética de diversas formas de dosificación que tienen SBV y VLP.

KEY WORDS: HPTLC, pharmacokinetics, sofosbuvir, validation, velpatasvir.

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