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Development and Validation of a High Performance Liquid Chromatography with Ultraviolet Detector Method for Determination of Rosuvastatin in Rat Plasma

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SUMMARY. **Rosuvastatin is an effective 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor and it is widely prescribed in the treatment of patients with hypercholesterolaemia. A simple high performance liquid chromatography method for determination of rosuvastatin in rat plasma was developed over the range of 50-8000 ng/mL. Protein precipitation with acetonitrile was used as sample preparation. Chromatographic separation was achieved on a C18 (4.6 × 150 mm, 5 μm) column with acetonitrile-0.1% trifluoroacetic acid in water (40:60, v/v). The ultraviolet detector was used in this study, with the detection wavelength of 242 nm. Linear calibration was obtained with correlation coefficients r > 0.99. The CV of the precision measurements was less than 5%. The accuracy of the method ranged from 94.7 to 105.6%. Mean recoveries of rosuvastatin in rat plasma were in the range of 93.5-96.7%. The method was successfully applied to the pharmacokinetic study of rosuvastatin in rats after oral and intravenous administration. The absolute bioavailability of rosuvastatin was calculated to be 39.8%.**

RESUMEN. La rosuvastatina es una efectiva 3-hidroxi-3-metilglutaril-coenzima A (HMG-CoA) reductasa y se prescribe ampliamente en el tratamiento de pacientes con hipercolesterolemia. Fue desarrollado un método simple de cromatografía líquida de alto rendimiento para la determinación de la rosuvastatina en plasma de rata en el rango de 50 a 8000 ng/mL. la precipitación de proteínas con acetonitrilo se utilizó como preparación de la muestra. La separación cromatográfica se realizó en una columna C18 (4,6 × 150 mm, 5 μm) con acetonitrilo-0,1% ácido trifluoroacético en agua (40:60, v/v). En este estudio se utilizó un detector ultravioleta, con longitud de onda de detección a 242 nm. La calibración lineal se obtuvo con coeficientes de correlación r > 0,99. El CV de las mediciones de precisión fue < 5%. La exactitud del método osciló desde 94,7 hasta 105,6%. Las recuperaciones medias de rosuvastatina en plasma de rata se encontraban en el rango de 93,5 a 96,7%. El método se aplicó con éxito para el estudio farmacocinético de rosuvastatina en ratas después de la administración oral e intravenosa. La biodisponibilidad absoluta de la rosuvastatina se calculó que era 39,8%.

KEY WORDS: HPLC, pharmacokinetics, rat plasma, rosuvastatin, UV.

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