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Liquid Chromatography Technique for Simultaneous Estimation of Metformin and Vildagliptin. Application to Pharmacokinetic in Healthy Rabbits

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***SUMMARY*. Metformin hydrochloride is biguanide drug and vildagliptin is dipeptidyl peptidase 4 (DPP4) inhibitor which are orally administered as a primary medication to cure Type 2 Diabetes mellitus (T2DM), a widely spread chronic disease. Studies of vildagliptin have shown prominent improvements in glycemic control as an add-on to metformin. This research work is focused to acquire and authenticate a precise method to determine metformin and vildagliptin in rabbit plasma and to implement it for pharmacokinetic studies in healthy rabbits. The method provides recoveries between the range of 100.13-100.29%, successfully determined the MTF and VLD concentration in rabbit plasma after oral examination of these drugs. The AUC_{0-24}, $AUC_{0-\infty}$ of metformin of reference versus test formulation were 14504.5, 14952.1 ng·h/mL versus 14779.6, 16046.17 ng.h/mL for MTF and 4372.4,3588.6 ng.h/mL versus 3317.8,3433.7 ng·h/mL for VLD and MRT, Vd and CL of reference versus test formulation were 5.7, 568.5 and 68.9 versus 5.1, 564.3, and 67.7 for MTF while 5.67, 42.33 and 14.4 versus 5.5, 46.7, and 15.1 for VLD, which showed no significance difference between pharmacokinetics parameters of both test and reference formulations.**

RESUMEN. El clorhidrato de metformina es un fármaco de biguanida y vildagliptina es un inhibidor de la dipeptidil peptidasa 4 (DPP4) que se administra por vía oral como medicamento primario para curar la diabetes mellitus tipo 2 (DM2), una enfermedad crónica muy extendida. Los estudios de vildagliptina han demostrado mejoras notables en el control glucémico como complemento de la metformina. Este trabajo de investigación se enfoca en adquirir y autenticar un método preciso para determinar metformina y vildagliptina en plasma de conejo e implementarlo para estudios farmacocinéticos en conejos sanos. El método proporciona recuperaciones entre el rango de 100.13-100.29% y se determinó con éxito la concentración de MTF y VLD en plasma de conejo después del examen oral de estos medicamentos. El AUC_{0-24}, $AUC_{0-\infty}$ de metformina de referencia versus formulación de prueba fueron 14504.5, 14952.1 ng.h/mL versus 14779.6, 16046.17 ng.h/mL para MTF y 4372.4,3588.6 ng.h mL versus 3317.8,3433.7 ng.h/mL para VLD y MRT, Vd y CL de referencia versus formulación de prueba fueron 5.7, 568.5 y 68.9 versus 5.1, 564.3 y 67.7 para MTF, mientras que 5.67, 42.33 y 14.4 versus 5.5, 46.7 y 15.1 para VLD, que no mostraron diferencia significativa entre los parámetros farmacocinéticos de las formulaciones de prueba y de referencia.

KEY WORDS: Diabetes mellitus, metformin, vildagliptin, HPLC, pharmacokinetic, Bioavailability, postprandial glucose, plasma glucose.

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