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Formulation and Optimization of a Controlled-Release Tablets of Ketorolac Tromethamine

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SUMMARY. **This study was designed to optimize the role of polymer Eudragit (ES-100) as release retarding agent in direct compression & wet granulation techniques to design Ketorolac Tromethamine (KTM) controlled release tablets. Five different formulations of tablets were prepared by direct compression and wet granulation method with different ratio of KTM and ES-100. The compatibility studies were carried out using FTIR and DSC. Solubility study was performed using six different solvents. Physical evaluation included hardness, friability, disintegration and thickness. For *in vitro* drug release studies, dissolution studies were performed using dissolution media with HCl pH 1.2, phosphate buffer pH 6.8 and phosphate buffer pH 7.4 in order to simulate the pH change along the GIT at constant temperature of 37 ± 0.5 ºC. In order to analyze the drug release kinetics, different mathematical models were applied to the release data. The results proved that there was no incompatibility between drug and polymers. Non-Fickian *in vitro* drug release mechanism was found. The study successfully undertook the development of an optimized once-a-day formulation of KTM with ES-100 and controlled release characteristics.**

RESUMEN. Este estudio se diseñó para optimizar el papel del polímero Eudragit (ES-100) como agente retardante de la liberación en técnicas de compresión directa y granulación húmeda de comprimidos de liberación controlada de Ketorolac Tromethamina (KTM). Se prepararon cinco formulaciones diferentes de tabletas de KTM y ES-100. Los estudios de compatibilidad se realizaron con FTIR y DSC. El estudio de solubilidad se realizó utilizando seis disolventes diferentes. La evaluación física incluyó dureza, friabilidad, desintegración y espesor. Para los estudios de liberación de fármacos *in vitro* se realizaron estudios de disolución utilizando medio de disolución con HCl pH 1.2, tampón fosfato pH 6.8 y tampón fosfato pH 7.4 para simular el cambio de pH a temperatura constante de 37 ± 0.5 ºC. Para analizar la cinética de liberación del fármaco, se aplicaron diferentes modelos matemáticos a los datos de liberación. Los resultados demostraron que no hubo incompatibiliadad entre el fármaco y los polímeros. Se encontró que el mecanismo de liberación de fármaco *in vitro* era no fickiano. El estudio demostró que el método era exitoso para la preparación de una formulación de KTM con ES-100 y características de liberación controlada.

KEY WORDS: controlled release, Eudragit S100, Ketorolac Tromethamine.

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