

Formulation Study for Excipient Compositions of Pravastatin Tablet

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SUMMARY. The objective of this design of experiments (DoE) study was to identify the excipient compositions of microcrystalline cellulose (MCC)/lactose monohydrate (Lactose), croscarmellose sodium (CCS), and hydroxypropyl cellulose (HPC) in the screening of excipients of the reduced weight and size tablet for pravastatin by using 2^3 full factorial DoE. For the screening of excipients, 3-factorial (MCC/Lactose, CCS and HPC), 5-level (dissolution, disintegration time, assay, content uniformity and Carr's index) and 1-center ($n = 3$) points were listed as critical quality attributes (CQAs) and utilized for statistical analysis (analysis of variance; ANOVA) by means of the Design Expert software. All three factors significantly influenced the Carr's index, and disintegration and dissolution results ($P < 0.05$). The results showed that MCC/Lactose (10-20%), CCS (10-15%) and HPC (1-2%) for the excipient compositions were optimal for the reduced weight and size tablet for pravastatin. It can be concluded that the ideal ranges of excipient compositions in the screening of excipients were successfully identified.

RESUMEN. El objetivo de este estudio de diseño de experimentos (DoE) fue identificar las composiciones de excipientes de celulosa microcristalina (MCC)/lactosa monohidrato (Lactosa), croscarmelosa sódica (CCS) e hidroxipropil celulosa (HPC) en la detección de excipientes de la tableta pravastatina con reducción de peso y tamaño mediante el uso de 2^3 DoE factorial completo. Para el cribado de excipientes, 3-factorial (MCC/Lactosa, CCS y HPC), 5 niveles (disolución, tiempo de desintegración, ensayo, uniformidad de contenido e índice de Carr) y 1 centro ($n = 3$) se enumeraron como atributos de calidad críticos (CQA) y fueron utilizados para el análisis estadístico (análisis de varianza; ANOVA) por medio del software Design Expert. Los tres factores influyeron significativamente en el índice de Carr y los resultados de desintegración y disolución ($P < 0.05$). Los resultados mostraron que MCC/lactosa (10-20%), CCS (10-15%) y HPC (1-2%) para las composiciones de excipientes fueron óptimas para la tableta de pravastatina de peso y tamaño reducido. Se puede concluir que los intervalos ideales de composiciones de excipientes en el cribado de excipientes se identificaron con éxito.

KEY WORDS: design of experiment, formulation study, pravastatin, quality by design.

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