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.

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