Title: Impact of Statistical Central Composite Face Centered Design Approach on Method and Process Optimization of Metformin Hydrochloride Loaded PLGA Nanoformulation

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Abstract: Background: In a conventional approach, development of nanoformulation necessitate significant amount of time, effort and cost.

Objective: The current investigation was aimed at studying the impact of statistical central composite face centered (CCF) design on method and process optimization of metformin HCl (MH) loaded poly (D,L-lactide-co-glycolide) (PLGA) nanoformulation.

Method: MH loaded PLGA nanoformulations were prepared by solvent evaporation method (SEV) and nanoprecipitation method (NPT) within a validated design space of 2-factor, 3-level CCF design. The effect of independent variables, PLGA and Poloxamer-188 on response variables such as particle size, zetapotential, entrapment efficiency and drug release were evaluated. Desirability approach, contour plots, surface response plots, perturbation plots and sweet spot analysis of graphical optimization technique were employed in nanoformulation.

Results: Comparative study of optimized nanoformulations of SEV, NPT methods by CCF design reveal that both methods produce spherical shape particles of nanosize, with homogenous distribution and good drug entrapment efficiency. Nanoprecipitation method is proven as the best optimized method, composed of nanoformulation of 1.0%, w/v PLGA and 0.680%, w/v Poloxamer exhibited mean particle size of 110.8 nm, entrapment efficiency of 71.62% and drug release 88.85% at 12hrs, in comparison to solvent evaporation method.

Conclusion: These research findings not only emphasize the understanding of CCF design as a promising optimization tool for method and formulation process development of MH loaded PLGA nanoformulations, but are also a worthwhile option time and efforts involved in complex and complicated formulation development process of nanoformulations for successful commercialization.