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# Development and Optimization of Diclofenac Potassium Tablets Using Central Composite Design and Dissolution Profile Comparison

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***SUMMARY*. The objective of the present study was to develop and optimize diclofenac potassium immediate release tablets using response surface methodology (RSM). A four-factor, five-level rotatable central composite design was used for the optimization procedure. Twenty different formulations (F1-F25) were designed in such a way that sixteen formulations were on the factorial points and eight formulations were on axial points with one centre point using four independent variables: microcrystalline cellulose (Avicel PH-102, 30-70%), croscarmellose (Ac-di-sol, 1.5-7.5%), magnesium stearate (1.25-4.25%) and hydroxy propylmethyl cellulose (1-5%). The measured dependent response variables were friability and disintegration time. The regression equations obtained from experiment explain the main and interaction effects of factors for designed formulations. Ten different formulations were selected on acceptable weight basis *i.e.* F2, F4, F7, F12, F13, F17, F18, F20, F23, and F25. Powder blends of all the formulations were assessed by different parameters also test and reference formulations were assessed by different physico-chemical tests which were weight variation, diameter, thickness, assay, dissolution, disintegration, and friability tests. From these optimized formulations only four best formulations were selected such as F4, F12, F20, and F25 while remaining formulations were failed to choose due to their poor flow properties and delayed disintegration time. Dissolution profiles were also compared using different dissolution media, *i.e.* pH 1.2, phosphate buffer pH 4.5, and pH 6.8. Data were assessed by model dependent methods (Zero-Order, First Order, Higuchi model, Korsmeyer Peppas model, Hixson-Crowell cube root law and Weibull model) and model- independent methods $f_1$ (difference factor) and $f_2$ (similarity factor). Results showed that optimized formulations were fitted to Korsmeyer Peppas model and Weibull model at different dissolution media. Similarly, F12 showed smallest ($f_1$) values at pH 1.2 (6.52), pH 4.5 (2.42) and pH 6.8 (1.88), F4, F12, F20 and F25 at pH 6.8 were found similar with the reference product. Also the effects of different surfactants on the drug release rate of diclofenac potassium tablets using (1%) Sodium lauryl sulphate (SLS) and (1%) Polysorbate ester (Tween-80) was observed. Results showed that with SLS (1%) maximum drug release was obtained. It was also found that response surface methodology (RSM) showed good correlation between actual and predicted values.***

*KEY WORDS:* Central composite design, Diclofenac potassium, Direct compression, Dissolution profiles, Response surface methodology.

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