Improving tadalafil dissolution via surfactant-enriched tablets approach: Statistical optimization, characterization, and pharmacokinetic assessment.

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Abstract

Tadalafil suffers from poor aqueous solubility that could lead to fluctuating blood levels and unreproducible effect. Thus, this work aimed at improving tadalafil dissolution utilizing the approach of surfactant-enriched tablets. The feasibility of minimizing various surfactants quantities was investigated by establishing the ratio of the surfactant to drug that is required for drug solubilization in micellar solutions. Based on the computed ratios, Tween was precluded from formulation studies due to its poor solubilizing capacity towards the drug. 23 factorial design was employed to assess the impact of formulation attributes on tablets' characteristics. Based on the statistical analysis and the desirability function approach, tablet formulation F6 prepared using CTAB, Avicel PH 102, and 5% Ac-Di-Sol was selected as the optimum formulation. The selected formulation showed adequate stability after storage at 40 ÁC and 75% R.H. for twelve weeks. Pharmacokinetic study revealed that the selected surfactant-enriched tablet formulation F6 showed enhanced bioavailability compared to the market product CialisÈ.

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