FORMULATION DEVELOPMENT OF CARVEDILOL ORAL SELF-NANOEMULSION CONCENTRATE BY FULL FACTORIAL DESIGN

Kumaravelrajan R.[a]*, Murugan Muthukrishnan[b], Poojavarshini G.[a], Suba V.[c], Sathishkumar T.[a], Sivakumar R.[a] and Farzana Affrin M. F.[a]

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ABSTRACT

Poor solubility of new chemical entities often leads to low bioavailability. Addressing this, self-nanoemulsifying systems for drugs like carvedilol, a cardiovascular drug, offer promising solutions. This study used a 3^2 factorial design to optimize a carvedilol nanoemulsion for cardiovascular disease. CCTriglyceride, Kolliphor®, and PEG 400 were identified as optimal excipients to maximize solubility. Differential Scanning Calorimetry confirmed no drug-excipient interactions. A pseudo-ternary phase diagram guided the development of a stable system, with formulation F10 achieving 95 % drug release within 30 min and minimal precipitation (1.2 %). *In vitro* dissolution studies showed 70 % - 90 % release within 20 min. Zeta potential analysis confirmed stability (particle size: 38.3 nm; charge: -2.059 mV). Pharmacokinetic studies in Wistar rats showed C_{max} of 602.0 ng mL^{-1} and Tmax of 0.8 h. One-month stability tests indicated consistent appearance and drug release, with slight precipitation. This optimized nanoemulsion enhances carvedilol's bioavailability and stability, offering significant pharmaceutical potential.