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Development and Characterization of Topical 5-Fluorouracil Solid Lipid Nanoparticles for the Effective Treatment of Non-Melanoma Skin Cancer

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Abstract : Background: The topical and systemic toxicity associated with present nonmelanoma skin cancer (NMSC) treatment therapy using 5-Fluorouracil (5-FU) make it necessary to develop a novel delivery system having lesser toxicity and better control over drug release. Solid lipid nanoparticles offer many advantages like: controlled and localized release of entrapped actives, nontoxicity, and better tolerance. Aim:-To investigate safety and efficacy of 5-FU loaded solid lipid nanoparticles as a topical delivery system for the treatment of nonmelanoma skin cancer. Method: Topical solid lipid nanoparticles of 5-FU were prepared using Compritol 888 ATO (Glyceryl behenate) as lipid component and pluronic F68 (Poloxamer 188), Tween 80 (Polysorbate 80), Tyloxapol (4-(1,1,3,3-Tetramethylbutyl) phenol polymer with formaldehyde and oxirane) as surfactants. The SLNs were prepared with emulsification method. Different formulation parameters viz. type and ratio of surfactant, ratio of lipid and ratio of surfactant:lipid were investigated on particle size and drug entrapment efficiency. Results: Characterization of SLNs like–Transmission Electron Microscopy (TEM), Differential Scannig calorimetry (DSC), Fourier transform infrared spectroscopy (FTIR), Particle size determination, Polydispersity index, Entrapment efficiency, Drug loading, ex vivo skin permeation and skin retention studies, skin irritation and histopathology studies were performed. TEM results showed that shape of SLNs was spherical with size range 200-500nm. Higher encapsulation efficiency was obtained for batches having higher concentration of surfactant and lipid. It was found maximum 64.3% for SLN-6 batch with size of 400.1±9.22 nm and PDI 0.221±0.031. Optimized SLN batches and marketed 5-FU cream were compared for flux across rat skin and skin drug retention. The lesser flux and higher skin retention was obtained for SLN formulation in comparison to topical 5-FU cream, which ensures less systemic toxicity and better control of drug release across skin. Chronic skin irritation studies lacks serious erythema or inflammation and histopathology studies showed no significant change in physiology of epidermal layers of rat skin. So, these studies suggest that the optimized SLN formulation is efficient then marketed cream and safer for long term NMSC treatment regimens. Conclusion: Topical and systemic toxicity associated with long-term use of 5-FU, in the treatment of NMSC, can be minimized with its controlled release with significant drug retention with minimal flux across skin. The study may provide a better alternate for effective NMSC treatment.

Keywords : 5-FU, topical formulation, solid lipid nanoparticles, non melanoma skin cancer
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