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Nano-Colloidal gel for the topical delivery of azelaic acid: Designing, characterization, and *in vitro* evaluation

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The study is directed towards the formulation, optimization and evaluation of Azelaic acid loaded nano-structured lipid carrier (NLCs) to enhance its payloads, achieve sustained release at target site and reduce the drug linked side effects. NLCs were formulated by melt emulsification and ultra-sonication technique employing glyceryl monostearate, oleic acid and cremophor RH-40 as solid lipid, liquid lipid, and surfactant, respectively. The formulation was optimized employing 33 full factorial design taking lipid:drug ratio, surfactant concentration and sonication time as independent variables with particle size (PS) and entrapment efficiency (EE) as dependent variables. The optimized formulation (F23) exhibited PS of 49.6 ± 1.24 nm with low polydispersity index (~ 0.4) and EE of 83.4 ± 2.14 %. Transmission electron microscopy studies confirmed the formation of uniform surfaced spherical nano size particles. The F23 was then incorporated into aloe-vera based carbopol gel and evaluated for its physiological properties, drug content, stability, *in vitro* release and skin distribution (fluorescent microscopy) analysis. The NLCs emulgel was found to be nonirritating, homogenous, with optimum moisture content, spreadability and occlusivity and was found to be stable both under room and accelerated temperature conditions over a period of 3 months. *In vitro* permeation studies showed NLC preparation to markedly enhance the drug's skin retention in comparison to drug suspension and marketed preparation. The skin distribution studies employing rhodamine 6G further confirmed the permeation of NLCs to the deeper layers of skin. The experimental findings suggested that NLCs could serve as a promising carrier for site specific targeting with better skin retention abilities.

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