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Nanostructured Lipid Carriers (NLC)-Based gel for the topical delivery of azelaic acid: Designing, characterization and *in-vitro* evaluation

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zelaic acid (AZA) is a naturally occurring dicarboxylic Acid, reported to be effective in management of mild to moderate acne vulgaris. However, few noticeable dose-related side effects limit its therapeutic applicability. Therefore, the study was directed towards the optimization, formulation and evaluation of the AZA loaded nano-structured lipid carrier (NLCs) to enhance its payloads and achieve sustained release at the target site. NLCs were prepared by melt emulsification and ultra-sonication method employing glyceryl monostearate and oleic acid as solid and liquid lipid, respectively. The formulation was optimized employing design expert software taking sonication time, amplitude and drug concentration as independent variables with particle size and drug entrapment as dependent variables. The optimized preparation so formed was incorporated into aloe-vera based carbopol gel and evaluated for its size, morphology, pharmacokinetic and pharmacodynamic

parameters. NLCs were found to possess mean particle size in a range of 45-48 nm with low polydispersity index value (~ 0.4) and encapsulation efficiency of ca. 82%. It was further verified employing transmission electron microscopy which depicted the formation of uniform surfaced spherical nanoparticles. *In-vitro* permeation and skin retention studies revealed significant retention of AZA within the skin with minimum penetration across the skin. Draize patch test exhibited no signs of irritation/lesion on the skin indicating its non-irritating nature. Skin distribution analysis employing rhodamine 6G as a fluorescent dye unveiled the deposition of NLCs preparation to the deeper layers of skin. Thus, as per experimental findings, NLCs may be explored as promising carriers for site specific targeting.

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