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Lipospheres for prolonged topical delivery of teriflunomide: Design, characterization and *ex vivo* -*in vivo* assessment

Swapnila Vanshiv, Priti S Raut and Supriya P Deshmukh
Sinhgad Institute of Pharmacy, India

Present research work aims to prepare nanostructured lipid carriers (NLC) based hydrogel and study its potential for the topical application of Teriflunomide (TFM). TFM is an active metabolite of Leflunomide which belongs to Disease Modifying Anti Rheumatic Drug (DMARDs) and considered as effective for treatment of Rheumatic Arthritis. In the present study TFM-NLCs were prepared using probe sonication technique. Glyceryl monostearate, Acrysol K150, Gellucire44/14 and PEG 600 were selected as the solid and liquid lipid, surfactant and co-solvent respectively. 33 Box Behnken factorial design was applied to obtain statistically optimize lipid formulation. The developed lipid formulation then dispersed in 1% (w/v) carbapol 934P gel medium to maintain the consistency of topical formulation. The average particle size, zeta potential and PDI for TFM loaded NLCs were found to be 95.85 ± 0.56 , $-21.95 \text{ mV} \pm 0.24$, and 0.12 ± 0.02 respectively. *Ex-vivo* permeation study revealed significant improvement in flux, apparent permeability coefficient, steady state diffusion coefficient and drug deposition of TFM in rat skin as compared to the plain TFM gel. These results have shown that the prepared TFM -NLCs has high potential to improve penetration of TFM through the stratum corneum with enormous retention which is pre-requisite for topical application of TFM-NLCs. *In vitro* drug release study has shown initial burst release followed by sustained release for prolong period of time. Anti-inflammatory and antirheumatic activity shown significant result as compared to plain TFM gel on CFA induced rat paw edema model. Stability study was performed as per ICH guidelines and the formulation was found to be physio-chemically stable.

swapnila84@rediffmail.com