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Development and Evaluation of Solid Fat Nanoemulsions of Anti-Tuberculosis Drug

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Formulations were prepared by modified lipid hydration method and evaluate the potential of solid fat nanoemulsion SFN for selective delivery of an anti-tuberculosis drug, rifabutin, to pulmonary tissues particularly alveolar macrophages as this is the densest site of tuberculosis infection. The formulations were characterized for zeta potential, polydispersity index, particle size, percent drug entrapment and in vitro drug release. Pharmacokinetics and biodistribution of formulations and plain drug upon nebulization of nanoparticles or intravenous administration to Balb/c mice were also investigated. The toxicity and targeting potential of the prepared formulation were assessed with alveolar macrophage viability, haematological, hepatotoxicity and lung histopathology studies. The nanoparticles were found to be spherical shape. The size of SFNs was found to be 250±12.4 nm with polydispersity index of 0.25±0.03 suggesting the moderate particle size distribution. Percent Drug entrapment and drug loading was found to be ~77% of initial drug added. The drug release showed the biphasic pattern of release i.e. initial burst followed by a sustained release pattern. The cytotoxicity studies revealed that SFNs are safe, non toxic as compared to free drug. In contrast to free drug, the nanoparticles not only sustained the plasma level but also enhanced the AUC and mean residence time (MRT) of the drug, suggesting improved pharmacokinetics of drug. Ex vivo cellular uptake studies of SFN formulations in alveolar macrophages depicted almost six times enhanced uptake as compared to free drug. Further, the serum level and organ distribution studies demonstrated efficiency of the system for prolonged circulation and spatial delivery of rifabutin to alveolar tissues. Finally, it is concluded that SFNs can be exploited for effective and targeted delivery of rifabutin compared to plain formulation and ultimately increasing the therapeutic margin of safety while reducing the side effects.

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