DESIGN, DEVELOP AND CHARACTERIZE LEFLUNOMIDE ORGANOGEL FOR THE TREATMENT OF RHEUMATOID ARTHRITIS

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Problem statement: Arthritis is a disease of the joint that involves inflammation of one or more joints. The common Symptoms of arthritis disorders include varied levels of pain, swelling, joint stiffness, and sometimes a constant ache around the joints. More than 20 million individuals affected with rheumatoid arthritis on their daily basis. Conventional dosage forms of leflunomide having serious side effects while taking orally.

Purpose: The purpose of this study was to resolve conventional dosage forms related problems, which are at increased risk for serious side effects, when administered through oral route. Administration of leflunomide could deliver to the site of action in rheumatic diseases which would reduce the side effects of the drug. Organogel having potential to deliver drug topically, therefore the purpose of this study was formulating organogel for the topical delivery of leflunomide.

Methods: Based on preliminary study pseudoternary phase diagrams was constructed using isopropyl myristate (IPM), water and lecithin. The prepared Organogel were evaluated for organoleptic properties, appearance, in vitro drug release, ex vivo drug release, in vivo skin irritation study, and stability study

Results: The formulation F5 containing 40% of lecithin and 40% of IPM was the optimised batch with drug release 85.53 %(Dialysis membrane), 90.62 %(Egg membrane), and 92.24 %(Goat membrane). The formulation follows the higuchi model and release was done via fickian diffusion mechanism. Skin irritation test showed that there was no any type of irritation was produced. Stability study shows developed Organogel was stable at $30^{\circ}C \pm 2^{\circ}C$ at $65 \pm 5\%$ RH(room temperature, RT) and $40^{\circ}C \pm 2^{\circ}C$ at $75 \pm 5\%$ RH condition after three months.

Conclusions: So this organogel formula (F5) is considered to be a potential vehicle for a leflunomide for delivering drug topically.

Keywords: leflunomide, lecithin, Organogel, Arthritis