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(57) Abstract :
The present invention relates to a topical gel formulation comprising diclofenac sodium for the treatment of localized pain and inflammation. The gel formulation comprises diclofenac sodium in a concentration of 0.5 to 2.0 percent, carbomer as gelling agent, propylene glycol and ethanol as penetration enhancers and cosolvents, triethanolamine as neutralizing agent, preservatives, and purified water. The optimized formulation exhibits excellent physicochemical properties including appropriate viscosity, pH compatibility with skin, and good spreadability. In vitro drug release studies demonstrate sustained release characteristics with more than 80 percent drug release within 8 hours. Ex vivo permeation studies using excised goat skin confirm enhanced transdermal flux compared to marketed formulations. The formulation is non-irritating, stable for at least 24 months under recommended storage conditions, and demonstrates improved anti-inflammatory efficacy in animal models. The invention provides a cost-effective, patient-compliant topical therapy for musculoskeletal pain with minimized systemic side effects.

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