Development and Characterization of Niosomal *In-Situ* Gel for Ocular Drug Delivery System of Ketorolac Tromethamine

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Abstract
This work deals with the formulation of ocular niosomal *in-situ* gel of Ketorolac tromethamine for improved bioavailability. Ketorolac tromethamine loaded niosomes were prepared by thin film hydration method using cholesterol and different surfactants. Niosomal *in-situ* gel was prepared using HPMC (K15M) and Carbopol (934P) to maintain the drug localization for extended period of time. The niosomes formulations were characterized for vesicle size, entrapment efficiency and *in-vitro* release and niosomal *in-situ* gel were evaluated for visual appearance, clarity, pH measurement, drug content measurement, rheological study, and stability testing. Niosomal vesicles were discrete and spherical in shape, 2.09µm-5.59µm in size, 19.32%-53.06% entrapment efficiency and showed sustained release behavior. The formulation F10 shows the highest entrapment efficiency with 53.06%. Drug loaded niosomal *in-situ* gel sustained the drug release (71.74%-86.20%) for 24 hours. The mechanism of drug release was non-Fickian diffusion controlled first order kinetics for niosomal *in-situ* gel formulation. Stability study indicated that the prepared niosomal *in-situ* gel remained more stable at refrigeration (4-8˚C) and room temperature (25±2˚C) as compared to (45±2˚C) in humidity control oven for 3 months. FT-IR and DSC studies revealed the integrity of the drug in the formulations. Thus, the present study conclusively demonstrates the feasibility of effectively formulating Ketorolac tromethamine niosomal *in situ* gels which are capable of releasing the drug for extended periods of time.

Keywords:
Niosomes, *in-situ* gel, thin film hydration, *in-vitro* release, stability study