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Development of an Oral Naproxen-Loaded Microemulsion with Enhanced Solubility and Attenuated Gastric Mucosal Ulceration

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***SUMMARY*. Naproxen is poorly water-soluble and has an increased risk of serious gastrointestinal adverse events. In our study, a new oil-in-water (o/w) microemulsion delivery system has been successfully developed, with improved solubility and lessened adverse reactions to the gastric mucosa. Pseudo-ternary phase diagrams were constructed to obtain the phase regions of o/w microemulsion and the effects of different co-surfactants and mass ratios of surfactant to co-surfactant (K_m) on the phase regions were also assessed. Suitable compositions of naproxen-loaded microemulsion were screened *via* viscosity studies and microemulsion droplet size tests. *In vivo* histological changes of gastric mucosa were also evaluated with oral administration of naproxen-loaded microemulsion. The optimal formulation of naproxen-loaded microemulsion consists of naproxen 1.0 %, oil (MCT) 5.0 %, surfactant (polysorbate 80) 23.3 %, co-surfactant (PEG 400) 11.7 % and water 60.0 %, with the average particle size at approximately 68.31 nm. Transmission electron microscopy (TEM) revealed the spherical nature and size homogeneity of the microemulsion droplets. No significant variations (droplet size and naproxen content) in microemulsion were observed over a period of 14 days at 4 and 25 °C, respectively. The results of *in vivo* histological procedure of gastric tissue showed significant ameliorant in the gastric mucosal damage compared with its tablet formulation. The developed microemulsion revealed great potential as a possible alternative to conventional oral formulations of naproxen.**

KEY WORDS: Gastric mucosa damage, Naproxen, Nonsteroidal anti-inflammatory drug, O/W microemulsion, Solubility.

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