CHAPTER 3
AIM OF WORK
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The NSAIDs have prominent anti-inflammatory, analgesic and antipyretic properties. They are used in the treatment of osteoarthritis and rheumatoid arthritis. Oral therapy of NSAIDs is very effective, but the clinical use is often limited because of its potential to cause adverse effects such as irritation and ulceration of the gastro-intestinal mucosa. Patient noncompliance is also a common therapeutic problem in the management of chronic inflammatory diseases, because most NSAIDs must be administered in multiple daily doses to maintain therapeutic blood levels. Administration of these agents via the dermal route can bypass these disadvantages of the oral route and may maintain relatively consistent plasma levels for long-term therapy.

In the present study piroxicam, ketoprofen and aceclofenac were selected. Topically these NSAIDs are usually administered in viscous formulations such as creams, ointments or gels. Gel formulations generally provide faster drug release compared with ointments and creams. A major obstacle to percutaneous drug delivery is the low penetration of drugs through the skin. The stratum corneum provides the principal barrier to the percutaneous permeation of topically applied substances. One of the different approaches for increasing the penetration of drugs through the skin is the use of vesicular systems such as liposomes and niosomes. Both liposomes and niosomes have attracted a great deal of attention in the delivery of dermal drugs because of many advantages, like they are biodegradable, non-toxic, amphiphilic nature, penetration enhancers and effective in the modulation drugs release properties.

Niosomes as drug carriers have shown advantages such as cheap and chemically stable alternatives to liposomes but associated with problems related to physical stability such as fusion, aggregation, sedimentation and leakage on storage.
The proniosome approach minimizes these problems as dry, free flowing product, which is more stable during sterilization and storage.

In the present study vesicular system, i.e. niosomes/proniosomes were selected in order to circumvent the undesirable effects of the drug and to maximize its therapeutic indices. Niosomes are supposed to give desirable interactions with human skin when applied in topical preparations by improving especially the horny layer characteristics, both by reducing trans-epidermal water loss and by increasing smoothness via replenishing lost skin lipids.

Hence, aim of the present work was formulation and characterization of niosomes containing non-steroidal anti-inflammatory drugs for developing a niosome-based topical formulation with their in-vitro & in vivo evaluation, to achieve better penetration of drug with minimum undesired side effects.

RESEARCH ENVISAGED

The project focuses on the preparation and characterization of niosomes and proniosomes containing nonsteroidal anti-inflammatory drugs, and selected batches of niosomes were embedded in to gel matrix to obtain niosome-based gel formulations that were evaluated for in vitro permeation and in vivo studies in animals.

The present research work include

I. Literature reviews covering various factors influencing characteristics of niosomes, findings of various investigators on niosome-based transdermal formulations.

II. Niosomes containing different NSAIDs were prepared by thin film hydration technique and characterized for the percentage drug entrapment and vesicles size. Optimization of niosomes was carried out to find out optimum level of
formulation variables by using Factorial design. Optimum batches were checked for stability.

III. Proniosomes containing different NSAIDs were prepared by slurry method and characterized for scanning electron microscopy, percentage drug entrapment and vesicle size. Optimization of proniosomes was carried out to find out optimum level of formulations variables by using different experimental design. Optimum batches were checked for stability.

IV. Niosome-based gel formulations containing different NSAIDs were developed by two different approaches. These prepared gel formulations were evaluated for in vitro skin permeation and in vivo animal studies.