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Formulation and Evaluation of Aceclofenac Nanoemulsion

Shivkanya P. Palve[1] and Gajanan D. Mogal[2]
Raosaheb Patil Danve College of Pharmacy, Badnapur
Dr. Babasaheb Ambedkar Technological University, Lonere, Raigad, Maharashtra, India
[1] shivkanyapalve4@gmail.com

Abstract: *Aceclofenac is a non-steroidal anti-inflammatory drug (NSAID) widely prescribed for the management of pain, inflammation, osteoarthritis, rheumatoid arthritis, and enclosing spondylitis. However, its poor aqueous solubility and limited dissolution rate result in low and variable bioavailability, which can reduce therapeutic effectiveness. The present research focuses on the formulation and evaluation of aceclofenac nanoemulsion as an advanced drug delivery system to improve solubility, dissolution, and bioavailability. Nanoemulsions are isotropic colloidal systems consisting of oil, water, surfactant, and co-surfactant with droplet sizes generally ranging from 20–200 nm. Owing to their nanosized droplets and large interfacial surface area, nanoemulsions enhance drug solubilization and absorption. Aceclofenac nanoemulsion was prepared using suitable oils, surfactants, and co-surfactants through homogenization and ultrasonication techniques. The formulation was evaluated for droplet size, polydispersity index, zeta potential, pH, viscosity, drug content, stability, and in-vitro drug release. The optimized formulation exhibited nanoscale droplet size, good physical stability, and enhanced drug release compared with conventional formulations. The findings suggest that nanoemulsion technology represents a promising approach for improving the therapeutic performance and patient compliance of aceclofenac formulations.*

Keywords: Poorly water soluble, bioavailability, pseudo ternary phase diagram, nanoemulsion.

I. INTRODUCTION

Aceclofenac belongs to the phenylacetic acid group of NSAIDs and is extensively used for inflammatory disorders. Despite its therapeutic efficacy, poor aqueous solubility limits its dissolution and absorption. Nanoemulsion systems have emerged as a modern strategy to overcome these limitations. Nanoemulsions possess droplet sizes in the nanometer range, resulting in improved surface area, enhanced drug dissolution, and better permeability across biological membranes. The incorporation of aceclofenac into nanoemulsion systems can significantly improve bioavailability and therapeutic outcomes. Additionally, nanoemulsions offer advantages such as controlled drug release, protection from degradation, and enhanced stability.

Nonsteroidal anti-inflammatory drugs (NSAIDs) are among the most frequently prescribed medications for the management of pain, inflammation, and musculoskeletal disorders. Aceclofenac, a phenylacetic acid derivative NSAID, is widely used in the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, and other inflammatory conditions due to its potent anti-inflammatory, analgesic, and antipyretic properties. Despite its therapeutic effectiveness, oral administration of aceclofenac is associated with several limitations, including gastrointestinal irritation, ulceration, bleeding, and reduced patient compliance during long-term therapy. To overcome these drawbacks, alternative drug delivery approaches have been explored. Transdermal drug delivery offers significant advantages over oral administration by bypassing the gastrointestinal tract and hepatic first-pass metabolism. It provides sustained drug release, maintains consistent plasma drug concentrations, improves patient convenience, and minimizes systemic adverse effects. Therefore, the development of a transdermal aceclofenac formulation with enhanced skin permeation is of considerable pharmaceutical interest.

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In recent years, researchers have focused on advanced topical delivery systems capable of improving drug transport across the skin barrier. Conventional topical formulations often require chemical penetration enhancers to facilitate drug absorption; however, prolonged use of these agents may cause skin irritation and toxicity. Consequently, there is a growing need for safer and more efficient carrier systems. Nanoemulsion technology has emerged as a promising strategy for transdermal drug delivery. Nanoemulsions are thermodynamically stable, transparent or translucent dispersions consisting of oil, water, surfactants, and co-surfactants, with droplet sizes generally below 100 nm. Their nanoscale droplet size provides a large surface area, resulting in improved drug solubilization, enhanced skin permeation, and increased bioavailability. Moreover, the components of nanoemulsions can themselves act as permeation enhancers, reducing the need for additional chemical agents. Several studies have demonstrated that nanoemulsion-based formulations significantly improve the dermal and transdermal delivery of poorly water-soluble drugs compared to conventional creams, gels, and emulsions. Therefore, the formulation and evaluation of aceclofenac nanoemulsion represent an effective and innovative approach for achieving enhanced therapeutic efficacy in the treatment of localized pain, inflammation, and musculoskeletal disorders while minimizing adverse effects associated with oral therapy.

II. AIM & OBJECTIVES

1. To formulate and evaluate an Aceclofenac nanoemulsion for improving the solubility, stability, permeability, and bioavailability of Aceclofenac.
2. To select suitable oil, surfactant, and co-surfactant for the preparation of Aceclofenac nanoemulsion.
3. To determine the solubility of Aceclofenac in various oils, surfactants, and co-surfactants.
4. To construct a pseudo-ternary phase diagram for identification of the nanoemulsion region.
5. To prepare Aceclofenac nanoemulsion using high-pressure homogenization and ultrasonication techniques.
6. To optimize the formulation based on droplet size, clarity, and physical stability.
7. To evaluate the nanoemulsion for particle size, polydispersity index (PDI), zeta potential, pH, viscosity, and refractive index.
8. To determine the drug content and entrapment efficiency of the developed formulation.
9. To perform thermodynamic stability studies including centrifugation, heating-cooling cycles, and freeze-thaw cycles.
10. To study the in-vitro drug release profile of the formulated nanoemulsion.
11. To enhance the transdermal permeation and bioavailability of Aceclofenac.
12. To reduce gastrointestinal side effects associated with conventional oral administration of Aceclofenac.
13. To develop a stable and effective nanoemulsion system for improved therapeutic efficacy and patient compliance.

III. MATERIAL AND METHODS

Table1: Materials Used for Formulation of Aceclofenac Nanoemulsion

Sr. No.	Material	Category	Function
1	Aceclofenac	Active Pharmaceutical Ingredient (API)	Anti-inflammatory drug
2	Oleic Acid	Oil Phase	Solubilizer and permeation enhancer
3	Tween 80	Surfactant	Emulsifying agent
4	PEG 400	Co-surfactant	Stabilizer and co-emulsifier
5	Distilled Water	Aqueous Phase	Vehicle
6	Ethanol	Solvent	Solubilizer
7	Methanol	Analytical Reagent	Drug estimation
8	Phosphate Buffer pH 7.4	Dissolution Medium	In-vitro release study

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IV. EXPERIMENTAL WORK

Table 2: Composition of Optimized Nanoemulsion Formulation

Ingredients	Quantity (% w/w)
Aceclofenac	1
Oleic Acid	10
Tween 80	25
PEG 400	10
Distilled Water	q.s. to 100

Solubility Study

The solubility of Aceclofenac was determined in different oils, surfactants, and co-surfactants to identify suitable excipients for nanoemulsion formulation. Excess amount of drug was added separately into selected vehicles and kept in an orbital shaker at 37 ± 1°C for 72 hours to attain equilibrium. The samples were centrifuged and filtered through a membrane filter. The concentration of dissolved drug was analyzed using UV-visible spectrophotometry. Based on the solubility results, Oleic Acid was selected as the oil phase, Tween 80 as the surfactant, and PEG 400 as the co-surfactant.

Preparation of Nanoemulsion

Accurately weighed Aceclofenac was dissolved in Oleic Acid to prepare the oil phase. Tween 80 and PEG 400 were mixed in a fixed ratio to form the surfactant mixture (Smix). The oil phase was slowly added to the Smix under continuous magnetic stirring. Distilled water was then added dropwise to the mixture while maintaining constant stirring to obtain a coarse emulsion.

The resulting emulsion was subjected to high-speed homogenization at 6000 rpm for 10 minutes to reduce droplet size. Further size reduction was achieved by ultrasonication for 10 minutes at 20 kHz frequency. The prepared nanoemulsion was cooled to room temperature and stored in airtight containers for further evaluation.

Evaluation of Nanoemulsion

The formulated nanoemulsion was evaluated for various physicochemical parameters. Droplet size and polydispersity index (PDI) were determined using Dynamic Light Scattering (DLS) to assess particle size distribution. Zeta potential analysis was performed to determine formulation stability. The pH of the formulation was measured using a digital pH meter, while viscosity was evaluated using a Brookfield viscometer.

Drug content was determined by UV spectrophotometric analysis to ensure uniform drug distribution within the formulation. The refractive index was measured to confirm the transparent and isotropic nature of the nanoemulsion. Thermodynamic stability studies, including centrifugation, heating-cooling cycles, and freeze-thaw cycles, were carried out to evaluate physical stability.

In-vitro Drug Release Study

The in-vitro drug release study was performed using a dialysis membrane method. The nanoemulsion was placed inside the dialysis membrane and immersed in phosphate buffer pH 7.4 maintained at 37 ± 0.5°C under continuous stirring. Samples were withdrawn at predetermined time intervals and analyzed spectrophotometrically. The nanoemulsion showed enhanced and sustained drug release compared to conventional formulations due to improved solubilization and nanosized droplets.

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Optimized Formulation

The optimized aceclofenac nanoemulsion exhibited nanosized droplets with uniform distribution and good physical stability. The formulation showed acceptable pH, high drug content, and excellent thermodynamic stability without phase separation. Enhanced drug release and improved solubility indicated the suitability of the nanoemulsion system for efficient transdermal and topical drug delivery.

Figure 1: Formulation of Nanoemulsion.

V. RESULT AND DISCUSSION

The developed Aceclofenac nanoemulsion was successfully formulated using Oleic Acid as the oil phase, Tween 80 as the surfactant, and PEG 400 as the co-surfactant. The optimized formulation exhibited desirable physicochemical characteristics suitable for transdermal drug delivery. The droplet size analysis revealed an average globule size of approximately **120 nm**, indicating successful formation of a nanoemulsion system. The polydispersity index (PDI) was found to be less than **0.3**, demonstrating a narrow particle size distribution and uniformity of the dispersed phase. Zeta potential measurements showed a value of approximately **−25 mV**, suggesting adequate electrostatic stabilization and good physical stability of the formulation.

The drug content of the optimized nanoemulsion was found to be greater than **98%**, indicating efficient incorporation and uniform distribution of Aceclofenac within the formulation. The pH of the formulation was within the acceptable range for topical application and did not show any signs of instability during storage. In-vitro drug release studies demonstrated a sustained release profile over a period of **8 hours**. The nanoemulsion exhibited significantly higher drug release compared to conventional formulations due to improved solubilization and increased surface area of the nanosized droplets. Enhanced diffusion characteristics indicated the potential of the formulation for prolonged therapeutic action.

Skin irritation studies were carried out to assess the safety of the formulation. No signs of erythema, edema, or skin irritation were observed during the study period, confirming the suitability of the formulation for topical administration. Overall, the results suggest that the developed nanoemulsion system effectively enhanced drug solubility, permeation, and release characteristics while maintaining excellent stability and safety. The formulation can therefore serve as a promising carrier system for the transdermal delivery of Aceclofenac.

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VI. SUMMARY & CONCLUSION

The present study focused on the formulation and evaluation of Aceclofenac nanoemulsion for improving its solubility, permeability, and bioavailability. Suitable excipients were selected based on solubility studies, and a stable nanoemulsion was prepared using high-speed homogenization followed by ultrasonication. The optimized formulation contained Aceclofenac, Oleic Acid, Tween 80, PEG 400, and distilled water. The prepared nanoemulsion was evaluated for droplet size, polydispersity index, zeta potential, drug content, pH, stability, and in-vitro drug release. The optimized formulation exhibited nanosized droplets, uniform particle distribution, excellent drug content, and good thermodynamic stability. Sustained drug release was observed over eight hours, indicating its suitability for prolonged therapeutic action. Skin irritation studies confirmed the safety of the formulation for topical use.

The findings of this study demonstrate that nanoemulsion technology can effectively overcome the limitations associated with the poor aqueous solubility of Aceclofenac and enhance its therapeutic performance.

Aceclofenac-loaded nanoemulsion was successfully formulated and evaluated as an effective transdermal drug delivery system. The optimized formulation showed nanosized droplets, good physical stability, high drug content, and sustained drug release characteristics. The nanoemulsion significantly improved the solubility and permeation of Aceclofenac while minimizing the potential gastrointestinal side effects associated with conventional oral administration. The absence of skin irritation and the enhanced release profile indicate that the developed formulation is safe and suitable for topical application. Therefore, Aceclofenac nanoemulsion represents a promising approach for improving patient compliance, therapeutic efficacy, and localized treatment of inflammatory and painful conditions. Further in-vivo and clinical studies are recommended to establish its long-term safety and therapeutic effectiveness.

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