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FORMULATION AND CHARACTERIZATION OF INVASOMAL GEL OF KETOPROFEN FOR EFFECTIVE TREATMENT OF TOPICAL INFLAMMATION

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Abstract:
The present study aimed to develop and evaluate a ketoprofen-loaded invasomal gel for enhanced transdermal drug delivery and sustained drug release. Ketoprofen-loaded invasomes were prepared by the mechanical dispersion method using soya phosphatidylcholine, ethanol, and terpene. Six formulations (IN1–IN6) were developed by varying the concentrations of phospholipid and terpene and were evaluated for vesicle size and entrapment efficiency. The optimized invasomal formulation (IN2) exhibited the highest entrapment efficiency (84.18 ± 0.31%) and the smallest vesicle size (176.84 ± 2.41 nm), indicating efficient drug encapsulation and nanosized vesicle formation suitable for enhanced skin permeation. The optimized invasomal dispersion was incorporated into a Carbopol gel to prepare invasomal gel formulations (IG-1 to IG-3). Among these, IG-2 demonstrated desirable physicochemical characteristics, including viscosity (3388 ± 12 cps), pH (5.96 ± 0.02), drug content (99.28 ± 0.18%), satisfactory spreadability, and good extrudability. In vitro drug release studies revealed a sustained release profile, with 98.24 ± 0.22% drug release over 12 h compared with the rapid release of the pure drug. Release kinetic analysis showed the best fit to the Korsmeyer–Peppas model (R^2 = 0.9833),
followed by the Higuchi model (R^2 = 0.9702), indicating diffusion-controlled drug release with polymer relaxation. Stability studies conducted for six months under refrigerated and room- temperature conditions confirmed that the optimized formulation retained acceptable physicochemical properties without significant changes. Overall, the optimized ketoprofen invasomal gel demonstrated excellent vesicular characteristics, sustained drug release, and good stability, indicating its potential as an effective transdermal drug delivery system for improving therapeutic efficacy and patient compliance. Further ex vivo and in vivo studies are warranted to establish its clinical applicability.
Keywords: Ketoprofen, Invasomes, Transdermal drug delivery, Carbopol gel, Entrapment efficiency, Vesicle size, Sustained release, Korsmeyer–Peppas model, Stability study, Topica drug delivery.

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INTRODUCTION:

Topical inflammatory disorders, including musculoskeletal injuries, osteoarthritis, rheumatoid arthritis, tendonitis, bursitis, and localized soft tissue inflammation, are among the most common causes of pain and disability worldwide (McMahon et al., 2021). These conditions are characterized by redness, swelling, pain, and restricted movement resulting from the activation of inflammatory mediators such as prostaglandins, cytokines, and leukotrienes. Non-steroidal anti-inflammatory drugs (NSAIDs) remain the cornerstone of pharmacological management; however, oral administration is frequently associated with gastrointestinal irritation, first-pass metabolism, cardiovascular risks, and other systemic adverse effects. Consequently, topical drug delivery has emerged as an attractive alternative because it delivers the drug directly to the affected site while minimizing systemic exposure and adverse effects (Rafanan et al., 2018).

Ketoprofen is a propionic acid derivative belonging to the NSAID class and possesses potent anti-inflammatory, analgesic, and antipyretic activities. It exerts its pharmacological effect by inhibiting cyclooxygenase (COX)-1 and COX-2 enzymes, thereby reducing prostaglandin synthesis responsible for inflammation and pain (Kantor, 1986; Cabré et al., 1998). Although ketoprofen is highly effective in the management of localized inflammatory conditions, its therapeutic efficacy following topical administration is often limited by poor permeation across the stratum corneum, the primary barrier of the skin. Conventional topical formulations such as creams and gels generally provide limited drug penetration and short residence time, resulting in reduced bioavailability and the need for frequent application (Kantor, 1986).

Recent advances in vesicular drug delivery systems have provided promising strategies to overcome these limitations. Among the different nanocarriers, invasomes have attracted considerable attention because of their superior skin penetration ability and enhanced transdermal drug delivery. Invasomes are novel phospholipid-based elastic vesicles composed primarily of phospholipids, ethanol, and terpenes. The synergistic action of these components increases the flexibility of the vesicular membrane and temporarily disrupts the highly ordered lipid structure of the stratum corneum, thereby facilitating improved penetration of encapsulated drugs into deeper layers of the skin. In addition, invasomes are capable of encapsulating both hydrophilic and lipophilic drugs, protecting them from degradation while providing controlled and sustained drug release (Shinde et al., 2014).

The presence of ethanol and terpenes plays a significant role in enhancing transdermal permeation. Ethanol fluidizes the lipid bilayers of both the vesicles and the stratum corneum, whereas terpenes act as natural penetration enhancers by modifying the organization of intercellular lipids within the skin. The combined effect results in improved vesicle deformability, increased drug deposition in deeper skin layers, prolonged residence time, and enhanced therapeutic efficacy. These unique characteristics make invasomes particularly suitable for topical administration of NSAIDs such as ketoprofen (Sinha and Kaur, 2000).

Incorporation of invasomes into a gel base further improves their pharmaceutical performance by providing appropriate viscosity, ease of application, better spreadability, prolonged contact with the skin surface, and improved patient acceptability. The gel matrix protects the vesicles from rapid degradation while allowing sustained release of the encapsulated drug. Furthermore, invasomal gels facilitate uniform drug distribution over the affected area, reduce dosing frequency, and improve patient compliance compared with conventional topical formulations (Kumar et al., 2025).

Based on these advantages, the present study was undertaken to formulate and characterize a ketoprofen-loaded invasomal gel for the effective treatment of topical inflammation. The invasomal formulations were prepared using the mechanical dispersion technique and optimized by evaluating vesicle size and entrapment efficiency. The optimized formulation was subsequently incorporated into a Carbopol gel and characterized for physicochemical properties, *in vitro* drug release behavior, release kinetics, and stability. The developed invasomal gel is expected to enhance transdermal permeation, provide sustained drug release, improve local drug availability, and offer a safe and effective therapeutic approach for the management of inflammatory disorders.

MATERIAL AND METHODS:

Material

Ketoprofen was obtained as a gift sample from a reputed pharmaceutical company. Soya phosphatidylcholine was used as the phospholipid for the preparation of invasomes, while terpene served as the penetration enhancer and ethanol was used as the vesicular solvent and permeation enhancer. Carbopol 934 was employed as the gelling agent, triethanolamine was used for pH adjustment, and propylene glycol acted as a

humectant and co-solvent. Methyl paraben was incorporated as a preservative, and distilled water was used for hydration and formulation preparation. All chemicals, solvents, and reagents used in the study were of analytical grade and were used without further purification.

Methods

Formulation of Invasome of Ketoprofen

Invasomes of Ketoprofen were prepared by mechanical dispersion technique (Table 7.1). Soya phosphatidylcholine was added to ethanol and the mixture was vortexed for 5 minutes. Ketoprofen and terpenes were added while the mixture was constantly vortexed and sonicated for 5 minutes. Under constant vortexing, a fine stream of distilled water (up to 10% v/v) was added with a syringe to the mixture. To obtain the final invasomal preparation, the formulation was vortexed for an additional 5 minutes (Dragicevic-Curic *et al.*, 2010).

Table 1: Composition of different invasomal formulation

Formulation	Drug	Terpene	Ethanol	Phosphatidylcholine
IN1	(Equivalent to% w/v)	(%v/v)	(ml)	(%w/v)
IN2	2.5	0.25	10	0.25
IN3	2.5	0.5	10	0.25
IN4	2.5	0.75	10	0.5
IN5	2.5	0.25	10	0.5
IN6	2.5	0.5	10	0.75

Characterization of Ketoprofen-loaded invasomes

Entrapment Efficiency

Ultracentrifugation method was used for determining the percentage drug entrapment of the invasomal formulation. 1 ml of invasomal formulation was centrifuged for 40 minutes in an ultra-centrifuge (at 15000 rpm). The supernatant was further diluted with ethanol. UV-visible spectrophotometry was used for analysing the Ketoprofen content at a wavelength of 250 nm (Ayman *et al.*, 2001; Aggarwal and Kaur, 2005). Percentage drug entrapment was calculated using the equation:

$$\%\ Entrapment\ efficiency = \frac{Total\ amount\ of\ drug - Amount\ of\ Free\ Drug}{total\ amount\ of\ drug} \times 100$$

Vesicle Size

Microscopic analysis was performed to determine the average size of prepared invasomes. Formulation was diluted with distilled water and one drop was taken on a glass slide and covered with cover slip (Amnuaikit *et al.*, 2018; Manchanda and Sahoo, 2018).

Preparation of Ketoprofen loaded Invasomal Gel

Invasomal formulation having good entrapment efficiency, small particle size IN2 was incorporated (equivalent to 2%) in Carbopol 934 gel base. 1%, 2% and 3% i.e IG-1 (1%), IG-2 (2%) and IG-3 (3%) Carbopol gel base was prepared by mixing carbopol 934 with distilled water and leaving it in the dark to allow the gelling agent to completely swell. Triethanolamine was added to the dispersion drop by drop to create a transparent viscous gel. Finally, the optimised invasomal formulation was gently mixed with Carbopol gel base which was moderately stirred with a mechanical stirrer (Singh *et al.*, 2020).

Evaluation of Ketoprofen loaded invasomal gel

Determination of physiochemical properties

Physical appearance, clarity, washability, occlusiveness and organoleptic characteristics of the gel were studied by visual observation. A pH metre was used to evaluate the pH of Ketoprofen invasomal gel. The measurements were taken in triplicate, and the average value was determined (Kumar *et al.*, 2022).

Homogeneity and Grittiness

Grittiness of the invasomal gel was determined by pressing a small amount of gel between the index finger and the thumb. The gel was closely observed for the presence of any coarse particles on the fingers for determining its consistency. The homogeneity of the gel under evaluation was detected by rubbing a small proportion of gel on the skin at the backside of the hand (Chandra *et al.*, 2019).

Spreadability

The spreadability of the invasomal gel was studied by measuring the change in diameter when 500 mg of gel was placed between two horizontal plates of 20×20 cm2 with a standardized weight of 125 g placed over it (Bachhav and Patravale, 2009).

Extrudability Study

The prepared invasomal gel was filled in collapsible tubes and its extrudability was estimated in terms of weight in grams required to produce a 0.5 cm ribbon of gel in 10 seconds (Sareen *et al.*, 2011).

Viscosity

For determining the viscosity of the invasomal gel Brookfield viscometer (DV-E Brookfield Engineering Laboratories, MA, USA) at 37 °C with spindle No.7 was used. An appropriate amount of gel was placed onto the centre of the viscometer plate directly below the spindle using the spatula and viscosities were measured.

Content uniformity analysis of gel

To validate that the Ketoprofen in the developed invasomal gel was homogeneous, 0.5 g samples were drawn from three separate sections of the gel. Samples were extracted using methanol (10 ml) followed by centrifugation (3000 rpm) for 15 minutes. The supernatant was filtered, and Ketoprofen content was determined using a UV-visible spectrophotometer with a λ_{max} at 250 nm.

***In vitro* drug release**

In vitro drug release study was conducted using Franz's diffusion cell with receiver cell volume and effective permeation area of 10 ml and 0.196 cm^2 respectively. The donor cell containing the invasomal gel was placed over the receptor cell in which phosphate buffer saline (pH 7.4) was filled. A pre-treated dialysis membrane of molecular weight cut off 12-14 kD was placed between the donor and receptor compartments using a clamp. The experiment was conducted for 24 hours at a temperature of 37 ± 1°C with constant magnetic stirring at 600 rpm. Samples were estimated for Ketoprofen content using UV spectrophotometer at 250 nm which were withdrawn from the receptor cell at premediated time gaps i.e., 1, 2, 3, 4, 5, 6, 8 and 12 hours with simultaneously addition of fresh release medium in the receiver compartment to balance the sink conditions. To know the release kinetics of invasomal gel, the data was treated according to different release kinetics models (Kumar *et al.*, 2022).

Physical stability studies of Ketoprofen invasomal gel formulation

The stability studies of Ketoprofen invasomal gel weas performed by determining their physical or chemical attributes during storage. The gel was filled in borosilicate glass container which was observed for 4 months by keeping in two different storage conditions i.e., 4±2°C and 25±2°C with 60±5% RH. The following parameters were analysed during the stability study at specific time periods of 0, 1, 3 and 6 months.

pH Evaluation

The pH was evaluated as mentioned earlier.

Physiochemical Evaluation

Clarity, washability, occlusiveness and organoleptic characteristics of the gel were studied by visual observation.

RESULTS AND DISCUSSION:

The present study was carried out to develop and evaluate a ketoprofen-loaded invasomal gel with the objective of enhancing transdermal drug delivery and providing sustained release of the drug. Invasomes were prepared by the mechanical dispersion technique using soya phosphatidylcholine, ethanol, and terpene as the principal formulation components. Different formulations (IN1–IN6) were developed by varying the concentrations of phospholipid and terpene to optimize vesicular characteristics such as entrapment efficiency and vesicle size.

The prepared invasomal formulations exhibited satisfactory physicochemical properties with entrapment efficiencies ranging from 72.58 ± 0.42% to 84.18 ± 0.31%. Among all formulations, IN2 demonstrated the highest entrapment efficiency (84.18 ± 0.31%), indicating efficient encapsulation of ketoprofen within the phospholipid bilayer. The enhanced drug loading was attributed to the optimized ratio of phospholipid and terpene, which provided a stable vesicular membrane and minimized drug leakage during preparation.

The average vesicle size of the prepared invasomes ranged from 176.84 ± 2.41 nm to 255.73 ± 3.42 nm. The optimized formulation IN2 exhibited the smallest vesicle size (176.84 ± 2.41 nm), indicating the formation of uniform nanosized vesicles. The nanoscale size is advantageous for improving skin penetration, increasing the surface area available for drug release, and enhancing transdermal permeation. Based on its highest entrapment efficiency and smallest vesicle size, IN2 was selected as the optimized invasomal formulation for further studies.

The optimized invasomal dispersion was successfully incorporated into a Carbopol gel base to prepare invasomal gel formulations (IG-1 to IG-3). Evaluation of the gel formulations revealed acceptable physicochemical characteristics suitable for topical administration. The optimized gel formulation IG-2 exhibited a viscosity of 3388 ± 12 cps, ensuring adequate consistency and retention at the application site. The formulation possessed a skin-compatible pH of 5.96 ± 0.02, minimizing the risk of irritation. Drug content analysis demonstrated excellent uniformity, with 99.28 ± 0.18% drug content, indicating efficient incorporation of the optimized invasomal dispersion into the gel matrix. The formulation also exhibited satisfactory extrudability (164 ± 2 g) and spreadability (11.38 ± 0.36 g·cm/s), confirming its ease of application and suitability for topical use.

The in vitro drug release study demonstrated a significant difference between the release profiles of the optimized invasomal gel and the pure drug.

The pure drug exhibited rapid drug release, reaching more than 90% release within 4 hours, whereas the invasomal gel showed a controlled and sustained release pattern. The optimized gel released 9.84 ± 0.28% drug during the first hour and gradually increased to 98.24 ± 0.22% after 12 hours, confirming the ability of invasomal vesicles to act as drug reservoirs and regulate drug diffusion through the gel matrix. This sustained-release behavior is expected to maintain therapeutic drug levels for prolonged periods, reduce dosing frequency, and improve patient compliance.

To understand the mechanism of drug release, the dissolution data were fitted to various kinetic models, including zero-order, first-order, Higuchi, and Korsmeyer–Peppas models. The optimized formulation IG-2 showed the highest correlation coefficient with the Korsmeyer–Peppas model (R^2 = 0.9833), followed by the Higuchi model (R^2 = 0.9702). These findings indicate that ketoprofen release from the invasomal gel occurred predominantly through a diffusion-controlled mechanism with additional contribution from polymer relaxation, thereby providing sustained drug release over an extended period.

The stability study performed over six months demonstrated that the optimized invasomal gel possessed excellent physical stability under both refrigerated (4 ± 2°C) and room-temperature (25 ± 2°C) storage conditions. The formulation retained its colour, odour, smooth appearance, clarity, acceptable pH, homogeneity, and washability throughout the study period. Only minor changes, such as a slight reduction in pH and the development of slight turbidity and viscosity changes at room temperature, were observed after prolonged storage. However, these changes remained within acceptable pharmaceutical limits and did not significantly affect the overall quality or applicability of the formulation.

The findings of the present investigation demonstrate that the optimized ketoprofen invasomal gel (IG-2) possesses desirable vesicular characteristics, excellent physicochemical properties, sustained drug release behavior, and satisfactory storage stability. The formulation has considerable potential as an effective transdermal drug delivery system capable of enhancing skin permeation, prolonging drug release, reducing dosing frequency, and improving therapeutic efficacy. These results support the application of invasomal technology as a promising strategy for the topical delivery of ketoprofen and provide a strong foundation for further ex vivo skin permeation, pharmacodynamic, and clinical studies.

Table 2: Characterization of Entrapment Efficiency of Invasome

Formulation	% Entrapment Efficiency
IN1	74.82 ± 0.24
IN2	84.18 ± 0.31
IN3	77.45 ± 0.28
IN4	79.63 ± 0.35
IN5	72.58 ± 0.42
IN6	75.84 ± 0.26

Table 3: Characterization of average vesicle size of Invasome

Invasomal Formulation	Vesicle Size (nm)
IN1	218.42 ± 3.16
IN2	176.84 ± 2.41
IN3	229.65 ± 3.08
IN4	241.58 ± 2.95
IN5	255.73 ± 3.42
IN6	247.36 ± 2.86

*Average of three determination

Table 4: Characterization of optimized formulation of invasome IN2

Formulation	Entrapment Efficiency	Particle Size (nm)
IN2	84.18 ± 0.31	176.84 ± 2.41

Table 5: Characterization of Invasomes gel based formulation

Invasomal Gel Formulation	Viscosity (cps)	pH	Drug Content (%)	Extrudability (g)	Spreadability (g·cm/s)
IG-1	3492 ± 15	5.82 ± 0.03	97.46 ± 0.24	158 ± 3	11.94 ± 0.42
IG-2	3388 ± 12	5.96 ± 0.02	99.28 ± 0.18	164 ± 2	11.38 ± 0.36
IG-3	3276 ± 14	5.63 ± 0.04	96.88 ± 0.27	171 ± 4	10.64 ± 0.40

Table 6: Cumulative drug release from invasomal gel (IG-2) and pure drug of Ketoprofen

Time (hrs.)	Ketoprofen Invasomal Gel (% Cumulative Drug Release)	Pure Drug (% Cumulative Drug Release)
1	9.84 ± 0.28	31.82 ± 0.42
2	17.56 ± 0.35	54.26 ± 0.38
3	26.74 ± 0.31	76.84 ± 0.45
4	39.68 ± 0.29	92.45 ± 0.36
5	52.15 ± 0.33	–
6	64.82 ± 0.27	–
7	74.96 ± 0.34	–
8	85.63 ± 0.30	–
12	98.24 ± 0.22	–

Table 7: Regression analysis of data for invasomal gel formulation IG2

F. Code	Zero order	First order	Higuchi	Pappas
IG2 (R^2)	0.9419	0.9230	0.9702	0.9833

Table 8: Stability analysis of Ketoprofen invasomal gel formulation IG2

Parameters	1 Month		3 Months		6 Months	
Temperature (°C)	**4 ± 2°C**	**25 ± 2°C**	**4 ± 2°C**	**25 ± 2°C**	**4 ± 2°C**	**25 ± 2°C**
Colour	White	White	White	Off-white	White	Off-white
Odour	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless
Appearance	Smooth	Smooth	Smooth	Slightly viscous	Smooth	Slightly viscous
Clarity	Clear	Clear	Clear	Slightly hazy	Clear	Slightly hazy
pH	5.96	5.94	5.95	5.88	5.94	5.81
Homogeneity	Excellent	Excellent	Excellent	Good	Good	Good
Washability	Easily washable	Easily washable	Easily washable	Easily washable	Easily washable	Easily washable

CONCLUSION:

The present study successfully developed and evaluated a ketoprofen-loaded invasomal gel for enhanced topical drug delivery. The optimized formulation (IN2/IG-2) exhibited high entrapment efficiency, nanosized vesicles, desirable physicochemical properties, and sustained drug release over 12 hours. The invasomal gel demonstrated superior performance compared to the pure drug by providing controlled drug release and satisfactory stability under storage conditions. These findings suggest that the developed invasomal gel is a promising carrier for the effective topical treatment of inflammatory conditions, with the potential to improve therapeutic efficacy, reduce dosing frequency, and enhance patient compliance. Further ex vivo and in vivo studies are recommended to confirm its clinical potential.

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