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Formulation and Evaluation of Lacidipine Loaded Emulgel

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ABSTRACT

The present study focuses on the formulation and evaluation of lacidipine-loaded emulgel designed for effective transdermal drug delivery. Lacidipine, a calcium channel blocker with poor aqueous solubility and extensive first-pass metabolism, presents a challenge for conventional oral delivery. To overcome these limitations, an emulgel formulation was developed combining the advantages of emulsions and gels, aiming for enhanced solubility, controlled release, and improved patient compliance. Eight formulations (F1–F8) were prepared using Carbopol 934P as the gelling agent and evaluated for physicochemical properties, drug content, pH, viscosity, spreadability, extrudability, and in-vitro drug release. Among them, Formulation F3 demonstrated optimal characteristics, with a pH of 6.72 ± 0.03, drug content of 97.88 ± 0.32%, and cumulative drug release of 86.53% over 240 minutes, following first-order release kinetics (R^2 = 0.9826). The results suggest that the optimized emulgel provides a sustained release profile suitable for transdermal administration, offering a promising alternative to oral delivery of lacidipine by enhancing bioavailability and reducing dosing frequency.

Keywords: Lacidipine, Emulgel, Transdermal Drug Delivery, Controlled Release, Carbopol 934P, In-vitro Drug Release.

1. INTRODUCTION

Lacidipine, a second-generation calcium channel blocker, has proven efficacy in the treatment of hypertension and other cardiovascular disorders. Despite its beneficial therapeutic effects, lacidipine faces challenges related to its poor solubility and low bioavailability, which often necessitate higher doses to achieve desired therapeutic outcomes. Such challenges frequently lead to adverse effects and limited clinical efficacy. Therefore, optimizing the delivery system of lacidipine to improve its solubility and bioavailability is a significant area of research. One promising strategy involves the formulation of emulgels, a hybrid system combining the advantages of both emulsions and gels. Emulgels offer enhanced solubility, controlled release, and improved patient compliance, making them an attractive delivery system for poorly water-soluble drugs like lacidipine (Verma et al., 2020).

Lacidipine, an antihypertensive agent, has been primarily administered orally, but its therapeutic efficacy is often hindered by its poor aqueous solubility and low gastrointestinal absorption (Rai et al., 2020). Despite attempts to formulate lacidipine into various delivery systems, its low solubility remains a persistent limitation. This has led to the exploration of alternative drug delivery methods, such as topical and transdermal drug delivery, which offer several advantages, including bypassing the gastrointestinal tract, avoiding first-pass metabolism, and ensuring sustained drug release. Moreover, transdermal drug delivery can maintain consistent plasma drug levels, improving therapeutic outcomes and reducing side effects (Patel et al., 2021). Thus, formulating lacidipine in a system that allows for its efficient and sustained release is crucial for enhancing its clinical effectiveness.

Emulgels are semi-solid formulations that combine emulsions and gels to form a versatile drug delivery system capable of delivering both hydrophilic and lipophilic drugs. The emulsion component of the emulgel acts as a reservoir that solubilizes the poorly water-soluble drug, while the gel matrix ensures controlled drug release, stability, and ease of application (Irfan et al., 2018). Emulgels have been shown to be highly effective for transdermal and topical drug delivery applications due to their ability to control the rate of drug release, enhance skin penetration, and provide sustained drug release profiles (Sharma et al., 2019). Additionally, they allow for improved stability and bioavailability of poorly soluble drugs, such as lacidipine, by reducing their degradation and promoting better skin permeation (Patel et al., 2020).

A significant advantage of emulgels lies in their non-greasy nature, which makes them suitable for sensitive or oily skin. Their ability to form a stable film on the skin's surface allows for prolonged contact time, leading to a gradual release of

the active ingredient over an extended period. Furthermore, the formulation of an emulgel for transdermal delivery of lacidipine can improve its local bioavailability, ensuring that the drug reaches the systemic circulation effectively, while also minimizing the adverse effects associated with high oral doses (Sreedhar et al., 2020).

Incorporating lacidipine into an emulgel formulation offers several potential advantages. The emulgel matrix can help to overcome lacidipine's low solubility by providing a solubilizing medium in the form of the emulsion, which can enhance the drug's dissolution rate. Additionally, the gel matrix provides an environment that prolongs the release of the drug, reducing the need for frequent administration (Verma et al., 2020). Emulgels can also provide controlled release of the drug, which is crucial for drugs like lacidipine, where sustained therapeutic plasma levels are essential for maintaining long-term blood pressure control and improving patient compliance (Sharma et al., 2019).

Moreover, lacidipine-loaded emulgels can potentially improve skin permeability by utilizing permeation enhancers in the formulation. These enhancers facilitate the crossing of the drug through the skin layers, thereby achieving a more efficient delivery to systemic circulation (Rai et al., 2020). This formulation approach can also reduce the first-pass metabolism associated with oral drug delivery, which is a significant advantage for drugs like lacidipine that are extensively metabolized in the liver (Patel et al., 2020).

Hypertension remains one of the leading causes of cardiovascular diseases worldwide, and managing blood pressure effectively requires a reliable and consistent drug delivery system. Traditional oral formulations of lacidipine can result in high peak plasma concentrations, leading to an increased risk of side effects such as dizziness, headaches, and peripheral edema (Patel et al., 2021). In contrast, lacidipine-loaded emulgels, by providing controlled and sustained release, can help maintain stable plasma concentrations, reducing the risk of adverse effects while providing long-lasting therapeutic benefits. This would also improve the patient adherence to the prescribed treatment regimen, addressing one of the key challenges in chronic disease management.

Additionally, by incorporating permeation enhancers and selecting appropriate emulsifying agents and gelling agents, lacidipine-loaded emulgels can be optimized for maximum skin penetration and bioavailability. This study aims to explore the formulation, evaluation, and optimization of lacidipine-loaded emulgels for effective transdermal delivery, focusing on their physicochemical properties, in vitro drug release profiles, and stability.

The primary objective of this study is to formulate and evaluate lacidipine-loaded emulgels for effective transdermal drug delivery, addressing the challenges associated with the drug's poor solubility and low bioavailability. Specifically, the study aims to develop lacidipine-loaded emulgels using various emulsifying agents and gelling agents to optimize the drug's release profile and skin penetration.

2. MATERIAL AND METHODS

Material

For the development of lacidipine-loaded emulgel formulations, various pharmaceutical-grade chemicals and excipients were used. Lacidipine was received as a gift sample from a pharmaceutical company. Cholesterol, used as a lipid component, was procured from Ash Chemie India, Thane. Buffer components such as disodium hydrogen phosphate and dipotassium hydrogen orthophosphate, along with sodium chloride, were sourced from S. D. Fine Chem. Ltd., Mumbai. Organic solvents including methanol, ethanol, and chloroform were obtained from Qualigens Fine Chemicals, Mumbai. Carbopol 934P served as the gelling agent, while methyl paraben and propyl paraben were used as preservatives. Propylene glycol was used as a penetration enhancer and co-solvent. All reagents and chemicals were of analytical grade and used as received without further purification.

Methods

Formulation development

Fifty grams of the Carbopol gel was prepared by dispersing one gram of carbopol powder in 50 ml purified water with aid of moderate speed stirrer (50 rpm), and then the pH was adjusted to 6-6.5 using 0.5 N of sodium hydroxide.

Preparation of emulsion

The emulsion was prepared using a standard emulsification technique. The oil phase was formulated by dissolving the required quantity of Span 20 in liquid paraffin, as specified in Table 7.1. Simultaneously, the aqueous phase was prepared by dissolving Tween 20 in purified water according to the same table. Lacidipine (1g) was dissolved in 2.5 g of ethanol, while a preservative solution was prepared by dissolving 0.15 g of methylparaben and 0.05 g of propylparaben in 5 g of propylene glycol. This preservative mixture was then added to the aqueous phase. Both the oil and aqueous phases were heated separately to a temperature of 70–80°C. Once the desired temperature was reached, the oil phase was slowly added to the aqueous phase under continuous stirring at 500 rpm. Stirring was maintained until the emulsion cooled to room temperature, ensuring uniformity and stability. The formulation process was optimized using the One Variable At a Time (OVAT) method, where one formulation component was varied while keeping all others constant, allowing for systematic evaluation of its effect on emulsion characteristics.

Formulation of Lacidipine emulgel

Eight formulas of Lacidipine were prepared by dispersing the obtained emulsions with the gel in given ratio with gentle stirring until get homogenous emulgel as shown in table 1 (Rachit et al., 2012).

Table 1: Different formulas of Lacidipine emulgel (% w/w)

F. code	Lacidipine (%)	Carbopol 940 (%)	Carbopol 934(%)	Liquid Paraffin (%)	Span 20 (%)	Tween 20 (%)	Propylene Glycol (%)	Water (ml)
F1	1	0.25	-	5	0.45	0.3	5	100
F2	1	0.5	-	5	0.45	0.3	5	100
F3	1	0.75	-	5	0.45	0.3	5	100
F4	1	1	-	5	0.45	0.3	5	100
F5	1	-	0.25	7.5	0.45	0.3	5	100
F6	1	-	0.5	7.5	0.45	0.3	5	100
F7	1	-	0.75	7.5	0.45	0.3	5	100
F8	1	-	1	7.5	0.45	0.3	5	100

3. EVALUATION OF EMULGEL

Physical characteristic

The **Physical** characteristic was checked for gel formulations (colour, clogging, homogeneity and texture) and observations were shown in Table.

Determination of pH

The pH of the gels was determined by digital pH meter. One gram of gel was dissolved in 25 ml of distilled water and the electrode was then dipped in to gel formulation for 30 min until constant reading obtained. And constant reading was noted. The measurements of pH of each formulation were replicated two times (Single et al., 2012).

Washability

Formulations were applied on the skin and then ease and extent of washing with water were checked manually and observations were shown in Table.

Extrudability study

The gel formulations were filled into collapsible metal tubes or aluminium collapsible tubes. The tubes were pressed to extrude the material and the extrudability of the formulation was checked (Zhang et al., 1995).

Spreadability

Two glass slides of standard dimensions (6×2) were selected. The gel formulation whose spreadability had to be determined was placed over one of the slides. The second slide was placed over the slide in such a way that the formulation was sandwiched between them across a length of 6 cms along the slide. 100 grams of weight was placed up on the upper slide so that the gel formulation between the two slides was traced uniformly to form a thin layer.

The weight was removed and the excess of the gel formulation adhering to the slides was scrapped off. The lower slide was fixed on the board of the apparatus and one end of the upper slide was tied to a string to which 20 gram load could be applied 50with the help of a simple pulley. The time taken for the upper slide to travel the distance of 6 cms and separate away from lower slide under the direction of the weight was noted. The experiment was repeated and the average of 6 such determinations was calculated for gel formulation.

$$\text{Spreadability} = \frac{m.l}{t}$$

Where, S=Spreadability (gcm/sec)
m = weight tied to the upper slide (20 grams)
l= length of glass slide (6cms).
t = time taken is seconds.

Viscosity

The measurement of viscosity of the prepared gel was done using Brookfield digital Viscometer (Zhang et al., 1995). The viscosity was measured using spindle no. 6 at 10 rpm and 25^{0}C. The sufficient quantity of gel was filled in appropriate wide mouth container. The gel was filled in the wide mouth container in such way that it should sufficiently allow

to dip the spindle of the Viscometer. Samples of the gels were allowed to settle over 30 min at the constant temperature (25 ±/1^{0}C) before the measurements.

Drug content determination

Drug concentration in emulgel was measured by UV spectrophotometer. Lacidipine content in emulgel was measured by dissolving Known quantity of emulgel in solvent (Phosphate Buffer pH 7.4) by Sonication. Absorbance was measured after suitable dilution at 282nm in UV/VIS spectrophotometer (Labindia 3000+).

***In-vitro* drug release studies using the prehydrated cellophane membrane**

Preparation of cellophane membrane for the diffusion studies:

The cellophane membrane approximately 25 cm x 2cm was taken and washed in the running water. It was then soaked in distilled water for 24 hours, before used for diffusion studies to remove glycerin present on it and was mounted on the diffusion cell for further studies.

Diffusion Studies

The *in-vitro* diffusion of drug from the different gel preparations were studied using the classical standard cylindrical tube fabricated in the laboratory; a simple modification of the cell is a glass tube of 15mm internal diameter and 100mm height. The diffusion cell membrane was applied with one gram of the formulation and was tied securely to one end of the tube, the other end kept open to ambient conditions which acted as donor compartment. The cell was inverted and immersed slightly in 250 ml of beaker containing neutralizing phthalate buffer, freshly prepared (pH 7.4) as a receptor base and the system was maintained for 2 hrs at 37± 0.5ºC. The media was stirred using magnetic stirrer. Aliquots, each of 5 ml volume were withdrawn periodically at predetermined time interval of up to 12 hrs and replaced by an equal volume of the receptor medium. The aliquots were suitably diluted with the receptor medium and analyzed by UV-Vis spectrophotometer at 282 nm using neutralizing phthalate buffer as blank (Rutrer; 1987),

Data analysis via drug release kinetics study

The results of *in-vitro* release profile obtained for all the formulations were plotted in kinetic models as follows,

1. Cumulative of drug released versus time (Zero order kinetic model).
2. Log cumulative percent drug remaining to be absorbed versus time (First order model)
3. Cumulative amount of drug release versus square root of time (Higuchi model)
4. Log cumulative drug released versus log time (Korsmeyer-Peppas model)

4. RESULTS AND DISCUSSION

The evaluation of lacidipine-loaded emulgel formulations (F1–F8) involved a comprehensive assessment of their physicochemical properties, rheological behavior, drug content, in-vitro release, and release kinetics, as presented in Tables 2 to 7.

All formulations exhibited a white viscous or soft cream texture with good to excellent homogeneity (+++). The washability of most formulations was rated as good (++), except F2 and F3, which showed excellent washability (+++), indicating they could be easily removed from the skin without leaving residues. This makes them more user-friendly and acceptable for topical application (Table 2).

Formulations F3 and F4 demonstrated excellent extrudability (+++), which reflects smooth and effortless extrusion from the container, an essential factor for patient convenience. The spreadability ranged from 11.32 to 15.25 g.cm/sec, with F1 having the highest value. F3 showed moderate spreadability (12.65 ± 1.45), suggesting a balanced texture that is neither too fluid nor too stiff, ideal for uniform application over the skin (Table 3).Viscosity measurements at three different shear rates (10, 50, and 100 rpm) revealed that all formulations followed shear-thinning behavior, typical of pseudoplastic gels. F1 had the highest viscosity at all rpm levels (e.g., 35658 cps at 10 rpm), indicating a thicker consistency, while F4 showed the lowest (31256 cps at 10 rpm). F3's viscosity profile (33254 cps at 10 rpm) reflects an ideal range for emulgel, offering ease of application and sufficient residence time on the skin (Table 4).

The pH of all formulations ranged between 6.32 and 6.88, suitable for topical use as it falls within the skin's natural pH range, thus minimizing irritation. F3 had a pH of 6.72 ± 0.03, which is optimal. The drug content in all formulations was above 96%, ensuring adequate loading. F1 had the highest drug content (99.12%), whereas F3 had a slightly lower but acceptable value (97.88% ± 0.32), ensuring dose accuracy and therapeutic efficacy (Table 5). Among the test formulations, F1 exhibited the highest cumulative drug release (99.05%) at 240 minutes, followed closely by F5 (88.56%) and F3 (86.53%). Compared to the marketed formulation, which released 98.12% within 45 minutes, the test formulations demonstrated sustained release profiles, indicating controlled and prolonged drug availability. This slower, steady release could enhance therapeutic effectiveness and reduce dosing frequency. F3, with its balanced viscosity and consistent release (73.78% at 120 mins and 86.53% at 240 mins), was considered optimal among the test batches (Table 6).

The release kinetics of optimized formulation F3 were analyzed to understand the mechanism of drug release. The first-order model showed the highest correlation coefficient (R^2 = 0.9826), followed by the Higuchi model (R^2 = 0.9551) and Korsmeyer-Peppas (R^2 = 0.9488). This suggests that the drug release from F3 followed first-order kinetics, indicating a

concentration-dependent release mechanism. The fitting with the Higuchi and Peppas models also confirms that diffusion is a major mechanism in the release profile (Table 7).

Table 2: Results of physicochemical Characteristic

Formulation	Washability	Colour and Texture	Homogeneity
F1	++	White viscous cream	+++
F2	+++	White viscous cream	+++
F3	+++	White viscous cream	+++
F4	++	White viscous cream	+++
F5	++	White viscous cream	+++
F6	++	White viscous cream	+++
F7	++	White softy cream	+++
F8	++	White softy cream	+++

Washability - Excellent: +++, Good: ++, Average: +, Poor: -

Table 3: Extrudability and Spreadability study

Formulation	Extrudability	Spreadability (gcm/sec)
F1	++	15.25±1.25
F2	++	13.25±0.85
F3	+++	12.65±1.45
F4	+++	11.32±1.32
F5	++	14.65±1.75
F6	++	13.25±0.88
F7	++	12.65±1.11
F8	++	11.45±0.95

Excellent: +++, Good: ++, Average: +, Poor: -

Table 4: Results of Viscosity

Formulation	10 rpm	50 rpm	100 rpm
F1	35658	31256	17985
F2	34425	30658	16885
F3	33254	29478	15965
F4	31256	28965	14332
F5	34652	30552	17652
F6	33265	29854	16458
F7	32658	28745	15478
F8	31658	27698	14965

Table 5: Determination of pH and % Drug content

Formulation	pH	Percentage drug content
F1	6.45±0.05	99.12±0.15
F2	6.32±0.02	98.78±0.20
F3	6.72±0.03	97.88±0.32
F4	6.65±0.03	96.45±0.15
F5	6.81±0.04	97.88±0.24
F6	6.78±0.05	98.78±0.12
F7	6.88±0.02	96.85±0.33
F8	6.35±0.03	97.74±0.25

Table 6: *In-vitro* drug release studies of formulation F1-F8

S. No.	Time (hr)	% Cum. drug release								
		F1	F2	F3	F4	F5	F6	F7	F8	Marketed
1	0	0	0	0	0	0	0	0	0	0
2	15	20.32	18.85	15.56	12.89	20.45	21.45	25.56	28.89	36.65

3	30	36.65	33.32	28.47	25.56	32.57	33.56	31.45	36.69	63.32
4	45	45.56	43.23	45.78	38.98	46.89	45.89	48.78	45.58	98.12
5	60	66.58	59.98	61.78	48.78	55.78	53.56	53.56	60.56	-
6	120	78.85	71.12	73.78	62.58	65.89	72.58	71.48	72.58	-
7	240	99.05	94.45	86.53	83.78	88.56	83.89	84.45	78.25	-

Table 7: Release Kinetics Data for optimized emulgel formulation F1

Parameter	Zero order	First order	Higuchi	Korsmeyer-Peppas
R^2	0.8738	0.9826	0.9551	0.9488

5. CONCLUSION

The current study successfully formulated and evaluated **lacidipine-loaded emulgel** as a potential transdermal drug delivery system to overcome the limitations of oral administration, such as poor solubility and extensive first-pass metabolism. A total of eight formulations (F1–F8) were developed and systematically evaluated for their physicochemical and functional properties. Among them, **Formulation F3** was identified as the most optimized batch, exhibiting favorable **pH (6.72 ± 0.03), drug content (97.88 ± 0.32%), excellent spreadability, good extrudability**, and **sustained in-vitro drug release (86.53% at 240 min)**. The kinetic analysis revealed that the drug release followed first-order kinetics, suggesting a concentration-dependent release mechanism. The formulation also demonstrated appropriate viscosity and homogeneity, making it suitable for topical application with enhanced patient compliance. Therefore, lacidipine-loaded emulgel presents a promising alternative to conventional dosage forms, offering enhanced bioavailability, prolonged release, and improved therapeutic outcomes in the management of hypertension and related cardiovascular conditions.

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