Journal of Young Pharmacists, 2026; 18(2):409-418.
https://www.jyoungpharm.org

Original Article

A Novel Emulgel-Based Oral Delivery Approach for Amlodipine Besylate: Formulation, Evaluation, and Kinetic Modelling

Pawan Singh[1,*], Anuj Kumar[2,*], Pankaj Kumar[1], Arun Kumar[3], Mohd Fareed[2], Sunita Gangwar[4], Mohd Junaid[5]

[1]Pharmacy Academy, Faculty of Pharmacy, IFTM University, Moradabad, Uttar Pradesh, INDIA.
[2]Department of Pharmacy, Madhav University, Bharja, Abu Road, Pindwara, Rajasthan, INDIA.
[3]Teerthanker Mahaveer College of Pharmacy, Teerthanker Mahaveer University, Moradabad, Uttar Pradesh, INDIA.
[4]Department of Pharmacy, Bareilly international University, Bareilly, Uttar Pradesh, INDIA.
[5]Department of Pharmacy, Mohammad Ali Jauhar University, Rampur, Uttar Pradesh, INDIA.

ABSTRACT

Background: Oral drugs like amlodipine besylate commonly have problems such as low water solubility and high first-pass metabolism, leading to changing plasma concentrations. Emulgel formulations offer a great solution as they combine the penetration and solubilizing effects of emulsions with the stability and controlled release of gels. **Materials and Methods:** The present work entails the preparation of amlodipine besylate emulgel where Carbopol 934 has been used as the gelling agent. Pseudo, ternary phase diagrams were drawn using propane, 1, 2, diol, polyoxyethylene (20) sorbitan monooleate, and polyethylene glycol as the components to identify the microemulsion region. Stability tests indicated that a 2:1 ratio surfactant combination was most suitable. Six different formulations (F1, F6) were characterized for their physical characteristics, uniformity, pH, viscosity, spreadability, drug content, and drug release profile. **Results:** FTIR and DSC showed that drug and excipients were compatible and the stability of the formulation was ensured. **Conclusion:** The formulation F4 had, among others, a good viscosity (3941 cP), pH of 6.2, drug content of 98.4%, and it was homogeneous in consistency. Its *in vitro* drug release was both controlled and according to the Higuchi model with a regression coefficient close to 0.99.

Keywords: Amlodipine Besylate, Emulgel, Carbopol 934, Diffusion Mechanism, Higuchi Model.

Correspondence:
Dr. Pawan Singh
Associate Professor, Pharmacy Academy, Faculty of Pharmacy, IFTM University, Moradabad-244001, Uttar Pradesh, INDIA.
Email: pawansingh690@gmail.com

Dr. Anuj Kumar
Assistant Professor, Department of Pharmacy, Madhav University, Bharja, Abu Road, Pindwara-307032, Rajasthan, INDIA.
Email: anujpharmacy01@gmail.com

Received: 06-01-2026;
Revised: 23-02-2026;
Accepted: 16-04-2026.

INTRODUCTION

While the convenience, safety, and non-invasive nature of oral drug delivery make it the most commonly used method, when combined with the increased patient acceptance and compliance with this route, oral drug delivery does face several limitations that may limit its effectiveness. Some of these limitations are related to the low water solubility of many drugs and poor absorption from the GI tract due to degradation of the drug in the GI tract and high levels of first-pass metabolism. Due to these factors, the bioavailability and therapeutic effect from oral delivery systems are reduced, leading to ongoing pharmaceutical research to develop and apply new advanced drug delivery systems to improve solubility, stability, and release characteristics for medications administered through this route (Xie *et al*., 2026).

Amlodipine besylate, a calcium, channel blocker for hypertension and angina, suffers from low oral bioavailability (60-65%) because of poor solubility and first-pass metabolism. Hence, plasma levels fluctuate and the therapeutic effect gets diminished when one uses standard oral forms. Emulgel is a novel drug delivery system that combines the benefits of both emulsions and gels. It has been demonstrated to increase drug solubility and stability. Conventional oral tablets/capsules undergo first-pass metabolism and poor bioavailability for periodontitis drugs, whereas the emulgel system offers mucoadhesive, sustained-release delivery directly at the periodontal site for enhanced efficacy. This method has the potential to result in better therapeutic outcomes and increased patient adherence (Blum *et al*., 2022). Carbopol 934 was selected due to its excellent swelling capacity, pH compatibility, mucoadhesive potential, and ability to provide controlled drug release at low concentrations. These properties make it particularly suitable for oral emulgel systems. Amlodipine besylate is a drug that can be formulated as an oral emulgel. Amlodipine besylate has poor solubility in water and therefore a poor bioavailability; thus, the emulgel formulation will increase its bioavailability. In addition, because amlodipine is a lipophilic (fat-soluble) drug,

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Manuscript TECHNOMEDIA

DOI: 10.5530/jyp.20260404

the emulgel will provide a stable and uniform distribution of the drug, and because the emulsion is embedded in a gel matrix, it will provide a controlled release of the drug (Gaizeh *et al.* 2024).

Recent investigations reveal that emulgels, which were initially skin, based formulations, have the capability to increase the oral bioavailability of poorly soluble drugs by facilitating their dissolution and absorption. By selecting the right gelling agents, it is possible to impart mucoadhesive properties, thus extending the gastric retention time and also masking the unpleasant taste. This leads to better patient compliance. The present research intends to formulate and assess an oral emulgel of amlodipine besylate for potentiation of its therapeutic effectiveness (Jo *et al.*, 2024).

MATERIALS AND METHODS

Sources of Materials

Amlodipine besylate was obtained from Agron Pharmaceutical, Kashipur, India, as a complimentary sample. Other excipients, namely Carbopol 934, Tween 80, and methyl paraben, were purchased from CDH Ltd., India. Freshly distilled water was used in all the experiments.

Preformulation Study

Screening of Excipients by Solubility Studies

A shake-flask method was used to assess the solubility of amlodipine besylate in different solvent types. After 24 hr, spectrophotometric measurements taken at a wavelength of 271 nm demonstrated that propane-1,2-diol produced the greatest solubility of the drug and was therefore chosen as the oil phase of the formulation. Tween 80 served as the surfactant and polyethylene glycol the co-surfactant; Carbopol 934 acted as the gelling agent for stabilizing the finished formulation (Lin *et al.*, 2025).

Construction of Emulgel Phase Equilibrium Diagram

Tween 80 with polyethylene glycol and propane-1,2-diol formed the oleaginous phase while various S-mix ratios from 9:1 to 1:9 were mixed with the oleaginous phase and distilled water was added while maintaining constant mixing (Lee *et al.*, 2026). Used visual inspection and turbidity assessment to determine phase boundaries and the resulting data were used to construct pseudo-ternary phase diagrams using Chemix software which guided the development of optimized emulgel formulations F1 to F6.

Calibration curve of amlodipine Besylate

A stock solution of amlodipine was prepared as per the European Pharmacopoeia by dissolving 10 mg in 100 ml phosphate buffer (pH 5.5), yielding 100 µg/mL. It was then diluted to 2-10 µg/mL and analyzed at 271 nm to create a calibration curve by plotting absorbance against concentration (Badar *et al.*, 2023).

Determination of FTIR Analysis of Amlodipine Besylate

FTIR analysis was used to qualitatively identify amlodipine besylate. A sample weighing 3-5 mg was combined with 151 mg of KBr, ground, and then compressed into a pellet. This pellet was scanned on an FTIR spectrophotometer over the wavelength range 4000-400 cm^{-1} (Ubani-Ukoma *et al.*, 2025).

Determination of DSC Analysis of Amlodipine Besylate

Differential scanning calorimetry involves weighing 2-5 mg of Amlodipine Besylate, sealing it in an aluminium pan, and using an empty pan as a reference. The sample is heated at a controlled rate of 10°C/min under a nitrogen atmosphere. The resulting thermogram is analyzed to determine the melting endotherm, assessing the thermal behavior and purity of Amlodipine Besylate (Pezil *et al.*, 2021).

Method of Preparation of Emulgel

Six emulgel formulations (F1-F6) with 1% w/w amlodipine besylate were developed using a Carbopol 934 gel base with an oil-in-water emulsion system. The aqueous phase combined amlodipine besylate, propane-1,2-diol, and polyoxyethylene (20) sorbitan monooleate in distilled water at 80°C. The oleaginous phase included liquid paraffin, Span 20, and methyl paraben, mixed under heat. Both phases were heated to 70°C, then the aqueous was added to the oleaginous phase and homogenized at 2000 rpm for 1 hr to form a stable emulsion (Table 1) (Osman *et al.*, 2026).

The gel base was prepared by dispersing Carbopol 934 (0.24-0.25% w/w) in distilled water, stirring continuously, and hydrating for 30-40 min. Methyl paraben was dissolved in propane-1,2-diol as a preservative, and the pH was adjusted to 6.5-7.0 with triethanolamine to obtain a clear gel. The emulsion was then gradually incorporated into the gel base, stirred continuously, and homogenized at 1000-1500 rpm for 5-10 min to yield a smooth, uniform, and stable emulgel.

Evaluation Parameters

The following evaluation parameters were included in the study:

The Physical examination of Emulgel

The emulgel formulations were evaluated for their visual appearance and their ability to maintain uniform distribution of their components and their physical stability under testing which included checking for phase separation. The researchers conducted homogeneity studies to determine whether the components of the product were evenly distributed throughout the formulation. The viscosity measurements established the product's smoothness and consistency through assessment of its physical properties (Sirisha Mulukuri *et al.*, 2025).

The Determination of pH of Emulgel

The pH was calculated for all the formulations with the aid of a digitally calibrated pH meter, after thoroughly rinsing the electrode with distilled water prior to taking the pH reading (to ensure accuracy). A stable pH reading was taken after submerging the clean electrode into each product. The results show that all of the products have a pH that is acceptable for topical application (Ganea *et al.*, 2025).

The determination of particle size and zeta potential

Amlodipine besylate emulgel was characterised for particle size and zeta potential through a room-temperature diluted formulation with distilled water, as well as zeta potential determination using a zeta cell and the Smoluchowski equation to calculate zeta potentials from multiple (triplicate) measurements, based on the average values (mean ± SD) (Karimi *et al.*, 2025).

The Determination of Spreadability of Emulgel

In order to determine the spreadability, 350 mg of the emulgel was set on a 10.5 cm glass plate. Then a second glass plate weighing 5.81 g was gently dropped from a height of 5 cm. After 1 min of resting, the diameter of the diffusion circle formed was taken as a measure of the formulation's spreadability (Badaoui *et al.*, 2025).

The Determination of Swelling Index of Emulgel

The swelling behavior was determined by the Swelling Index (SI) method (Equation 1), where the initial Weight (W) of each emulgel was taken before being submerged in 0.1 N HCl at 370.5 C, and at specific times, the samples were taken out, the surface moisture was carefully wiped off, the swollen Weight (W) was measured, and the Swelling Index was calculated accordingly.

Equation 1

$$Swelling\ Index\ = \frac{Wt - W0}{W0} * 100$$

The initial weight (W_0) of the emulgel was taken along with its weight after a set time (W_t); these two weights were used to determine the % weight gain of the emulgel which shows how much fluid it absorbs, or is hydrophilic (Kola-Mustapha *et al.*, 2023).

The Determination of the Viscosity of the Emulgel

The viscosities of the formulations were measured by a Brookfield viscometer with spindle no. 5 at rotational speeds of 10, 53, 50, 60, and 100 rpm. Before measurement, the samples were first put in beakers and left to equilibrate at 25 ± 1°C for 30 min (Badaoui *et al.*, 2025).

The Determination of *in vitro* release of emulgel

Amlodipine release was tested with an Electrolab USP apparatus. 1 g of each formulation was in glass tubes sealed with cellophane, rotated in 750 mL phosphate buffer (pH 5.5) at 50 rpm and 37°C. Samples were taken at set times, and drug release was measured at 271 nm spectrophotometrically (de Souza *et al.*, 2025).

RESULTS

Preformulation Study

Screening of Excipients by Solubility Studies

The solubility study of Amlodipine besylate indicated variability among excipients, with propane-1,2-diol presenting high solubility, whereas liquid paraffin exhibited low solubility. Castor and olive oils demonstrated moderate solubility (Table 2).

Tween 80 had high solubility, while Span 20 and Cremophor RH40 were moderate, and Labrasol low. PEG 400 and propane-1,2-diol showed high solubility. Thus, propane-1,2-diol and PEG 400 were chosen to improve drug solubilization and emulsion stability in the oral emulgel.

Construction of Emulgel Phase Equilibrium Diagram

The pseudo-ternary phase diagram was constructed to identify the microemulsion regions suitable for the development of a stable emulgel formulation (Figure 1). The diagram illustrates the phase behaviour of the Oil phase (O), Aqueous phase (A), and surfactant-cosurfactant mixture (S-mix). Visual assessment of clarity, transparency, and isotropic nature was used to determine the formation of microemulsions.

Table 1: Formulation table of Emulgel.

Ingredient (% w/w)	F-1	F-2	F-3	F-4	F-5	F-6
Amlodipine besylate	1	1	1	1	1	1
Carbopol 934	0.25	0.25	0.25	0.25	0.25	0.24
Liquid Paraffin	3.70	3.72	3.75	3.75	3.78	3.80
Tween 80	0.45	0.45	0.45	0.45	0.45	0.45
Propane-1,2-diol	2.00	2.00	2.00	2.00	2.00	2.00
Methylparaben	0.005	0.005	0.005	0.005	0.005	0.005
Triethanolamine	pH Stabilizer	pH Stabilizer	pH Stabilizer	pH Stabilizer	pH Stabilizer	pH Stabilizer
Distilled Water	50	50	50	50	50	50

Table 2: Screening of Excipients by Solubility Studies.

Excipient Type	Excipient	Solubility of Amlodipine Besylate
Oils	Liquid paraffin	Low
	Castor oil	Moderate
	Olive oil	Moderate
	Propane-1,2-diol	High
Amphiphilic agents	Tween 80	High
	Span 20	Moderate
	Cremophor RH40	Moderate
	Labrasol	Low
Auxiliary amphiphilic agents	Polyethylene glycol (PEG 400)	High
	Propane-1,2-diol	High
	Ethanol	Moderate
	Glycerin	Low

Six formulations (F1-F6) were selected from the identified microemulsion region and evaluated for their compositional distribution (Table 3). Formulations F1-F5 showed a similar composition, containing approximately 6.59-6.72% oil phase, 4.36% S-mix, and 88.92-89.05% aqueous phase. These formulations produced clear and stable oil-in-water (o/w) microemulsions, indicating that a high aqueous phase with a low oil concentration favors the formation of a stable microemulsion system suitable for emulgel preparation (Table 3, Figure 1).

In contrast, formulation F6 contained a significantly higher proportion of oil (33.78%) and S-mix (21.78%) with a reduced aqueous phase (44.44%). This composition corresponded to a different region of the phase diagram, suggesting the formation of an alternative microemulsion zone with altered phase characteristics.

Calibration curve of amlodipine Besylate

Amlodipine besylate is white and soluble in methanol, acetone, and ethanol, with a melting point of 199°C to 201°C. A calibration curve was prepared in phosphate buffer (pH 6.5) at concentrations of 2-20 µg/mL, showing a strong linear relationship between concentration and absorbance (regression equation: $y = 0.0548x - 0.117$; $R^2 = 0.9981$) (Figures 2 and 3). Low standard deviations indicate good precision and reproducibility.

These results confirm the method follows Beer-Lambert's law within the studied range. is suitable for the quantitative estimation of amlodipine besylate in emulgel formulations.

Determination of FTIR Analysis of Amlodipine Besylate

The FTIR spectrum of Amlodipine besylate exhibited a characteristic absorption band at 3085.89 cm^{-1}, corresponding to N-H stretching vibrations. Distinct peaks observed at 2927.74 $cm^{-1}$and 2740.66 cm^{-1} were attributed to aliphatic C-H stretching. Prominent absorption bands at 1743.53 cm^{-1} and 1689.53 cm^{-1} were assigned to Carbonyl (C=O) stretching vibrations of the drug molecule (Figure 4).

Additionally, the presence of a band at 1612 cm^{-1} confirmed the aromatic ring structure, while a peak at 1238 cm^{-1} was indicative of C-O (aryl) stretching, confirming the structural integrity of the drug.

Determination of DSC Analysis of Amlodipine Besylate

The DSC thermogram of amlodipine besylate exhibited a sharp and well-defined endothermic peak at 210.55°C, corresponding to its melting point. The enthalpy change (ΔH) for this transition was 296.704 J/g, corresponding to a peak area of 296.704 mJ (Figure 5).

The presence of a single, sharp melting endotherm indicates that amlodipine besylate was crystalline and pure, with no polymorphic transformation or thermal degradation observed in the investigated temperature range.

Evaluation Parameters

The evaluation parameters results are provided below:

The Physical Examination of Emulgel

Table 4 shows that all emulgel formulations had a glossy, white, viscous, and uniformly smooth texture, with no signs of phase separation or precipitation. This indicates that all ingredients were evenly mixed to produce a stable, homogeneous formulation.

Formulation F4 showed strong uniformity and aesthetic quality, confirming effective emulsification and gel formation. It supports Chauhan *et al.* (2019), who highlighted Carbopol 934 role in maintaining Emulgel stability and uniformity.

The Determination of pH of Emulgel

All of the formulations' pH values were between 5.5 and 6.5, which means that they were compatible with physiological conditions and probably non, irritating. The pH didn't change even when the formulations were kept, which means that the active drug and the excipients are still stable. It is important to keep this pH level when the drug's solubility has to be preserved and its degradation is to be minimized.

These findings agree with Patel *et al.* (2013), showing that pH 5.5-6.5 in emulgels supports drug stability and safety for oral

delivery while reducing skin irritation risk. No significant pH changes occurred over time in any formulation.

The determination of particle size and zeta potential

Dynamic light scattering of formulation F4 showed an average particle size of nearly 1000 nm. Moreover, the low polydispersity index (0.555) pointed to a homogeneous droplet distribution. On the other hand, the zeta potential of 15.08 mV displayed a moderate level of electrostatic stabilization. Hence, it should provide the repulsion necessary to prevent droplet aggregation and phase separation during storage (Figure 6).

These results agree with findings made by Kumar *et al.* (2016) where they reported that nonionic amphiphilic agents, such as polyoxyethylene sorbitan monooleate, have the ability to successfully stabilise micro-emulsions. Additionally, the analysis of the size of the Amlodipine Besylate emulgel's (F4) particles, shows that this emulgel has a Z-average Particle Size of 1000 nm, which indicates that it has an extremely low degree of Polydispersity Index (PDI). As such, the results indicate that Amlodipine Besylate (F4) formed a stable and homogenous dispersal of emulgel particles.

The Determination of Spreadability of Emulgel

All emulgel formulations exhibited smooth and uniform spreadability, which is a vital factor for ease of administration and patient compliance in oral use. Moreover, an inverse relationship was noted between spreadability and polymer concentration, probably due to increased viscosity of the gel matrix. The formulation has a positive application attribute due to the low amount of shear force required to apply the formulation; however, it is only through assessment of their spreading ability that flow behaviours and usability during product administration are realised.

The Determination of Swelling Index of Emulgel

The swelling index corresponds to the ability of Carbopol 934 to absorb water and its cross, linking density, the formulation F4 showing a swelling pattern that is capable of a balanced prolonged retention and drug sustained diffusion within the hydrated polymer matrix, these facts are evidenced in Table 5.

The results of this study verified the stability and controlled release characteristics of the formulation, consistent with the findings of Chauhan *et al.* (2019). The swelling index of amlodipine besylate emulgel was assessed at regular intervals in order to better understand how much moisture is absorbed or retained by the emulgel fluid it absorbs, or is hydrophilic (Kola-Mustapha *et al.*, 2023).

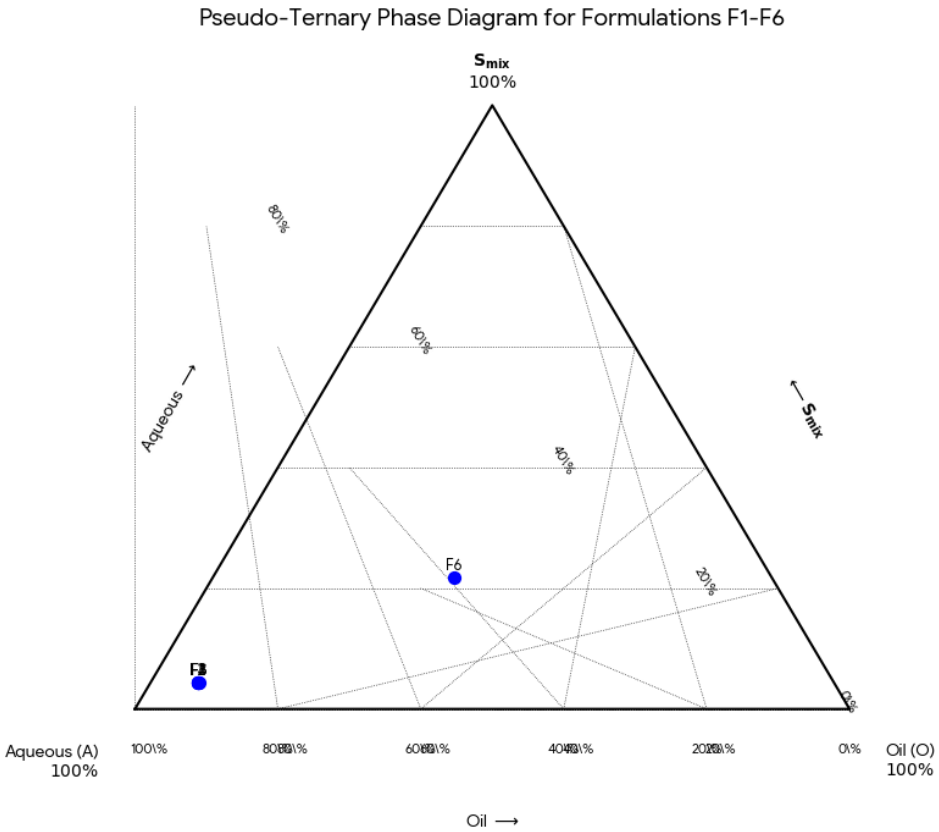

Figure 1: Pseudo-Ternary Diagram of Formulation F1-F6.

Table 3: Formulation table of Emulgel.

Formulation Code	Oil (O) %	S-mix (Amphiphilic agent + Auxiliary amphiphilic agent) %	Aqueous Phase (A) %
F-1	6.59	4.36	89.05
F-2	6.62	4.36	89.02
F-3	6.67	4.36	88.97
F-4	6.67	4.36	88.97
F-5	6.72	4.36	88.92
F-6	33.78	21.78	44.44

Figure 2: UV Spectroscopy of Amlodipine besylate.

The Determination of the Viscosity of the Emulgel

Viscosity measurement showed that all of the formulations are pseudoplastic flow, a typical feature of polymeric gels, with viscosity of the gels increasing as Carbopol concentration was increased, F4 had a viscosity that was moderate and on the one hand gave good spreadability and on the other hand-controlled drug diffusion, thus emphasizing that gel strength and fluidity have to be tuned in order to achieve release kinetics. Kumar *et al.* (2016) reported comparable rheological behavior, supporting that Carbopol-based emulgels possess appropriate flow characteristics, with the viscosities of all formulations in this study ranging from 1150 to 2060 centipoises. The value of 3941 cP corresponds specifically to formulation F4 measured at lower shear rates, whereas the earlier reported range represents average viscosities across formulations at higher rpm values.

The Determination of *in vitro* Drug Release of Emulgel

The *in vitro* drug release study demonstrated sustained release of amlodipine besylate from all emulgel formulations (F1-F6), as illustrated in Figure 7. The release behavior was found to be influenced by the concentration of the gelling polymer, Carbopol 934, where an increase in polymer content enhanced gel viscosity and strength, thereby reducing the rate of drug diffusion. Among all formulations, F4 exhibited an optimal sustained-release profile, indicating a balanced polymer concentration that allowed controlled drug diffusion. Conversely, formulation F2 showed the lowest drug release, suggesting that higher levels of polymer and the oleaginous phase significantly restrict drug diffusion through the matrix. The presence of liquid paraffin also contributed to slower drug release by increasing the hydrophobicity of

the emulgel system. These observations are consistent with previous studies reporting diffusion-controlled drug release from polymeric gel matrices (Patel *et al.*, 2013; Nair *et al.*, 2021).

To further understand the mechanism of drug release, kinetic modeling of the optimized formulation was performed using zero-order, first-order, Higuchi, Hixson-Crowell, and Korsmeyer-Peppas models. The regression coefficient (R^2) values for different models are presented in Table 6. Among these models, the Higuchi model showed the best fit ($R^2 \approx 0.99$), indicating that drug release from the emulgel primarily follows a diffusion-controlled mechanism.

Additionally, the Korsmeyer-Peppas model demonstrated a high correlation ($R^2 \approx 0.98$) with a release exponent (n) between 0.5 and 0.7, suggesting a non-Fickian (anomalous) transport mechanism in which both diffusion and polymer relaxation contribute to drug release. Overall, these results confirm that formulation F4 is the most suitable emulgel, providing controlled and sustained amlodipine besylate release.

DISCUSSION

The current investigation demonstrates that amlodipine besylate emulgel can be effectively designed and developed through a rational approach. The results emphasised the importance of conducting preformulation studies and evaluating emulgel formulations to ensure proper incorporation of amlodipine besylate. Solubility screening of excipients aided in formulation design, revealing that propane-1,2-diol, Tween 80, and PEG 400 were superior solubilisers for amlodipipine besylate compared to other tested excipients. Therefore, selecting appropriate surfactants and co-surfactants is essential to enhance drug incorporation and the thermodynamic stability of the emulgel. Castor oil and olive oil showed moderate solubility for amlodipine besylate, whereas liquid paraffin was only slightly soluble. Hence, selecting the appropriate oil phase significantly affects drug incorporation and release from the emulgel. Constructing the pseudo-ternary phase diagram clarified the system's behaviour, indicating that higher water content and less oil lead to stable, clear oil-in-water microemulsions. Formulations F1 through F5 fell within this optimal range and exhibited desirable properties. In contrast, F6, which contained additional oil and surfactant, behaved differently. Excess oil disrupted the system's stability and uniformity (Osman *et al.*, 2026).

The method used to estimate drugs was checked using a calibration curve. The curve showed strong linearity with an R value of 0.9981. It performed well between 2 and 20 µg/mL. This fit Beer-Lambert's law, indicating that the results were accurate and consistent. FTIR showed clear signs of N, H, C-H, and C=O groups. No peaks were altered or vanished (Ubani-Ukoma *et al.*, 2025). This suggests no chemical reaction occurred between the drug and other ingredients. DSC revealed a sharp peak matching the known melting point of amlodipine besylate. That peak confirmed the drug was in crystalline form and pure. It also showed no changes in structure or breakdown during mixing. It is evident that all tests agree on the formulation's stability and quality (Pezil *et al.*, 2021).

The emulgel formulation evaluations showed that all batches had consistent and smooth textures without phase separation, demonstrating successful emulsification and gel formation. In all formulations, F4 exhibited the best uniformity and visually appealing characteristics, indicating a well-balanced formulation. All formulations had pH values between 5.5 and 6.5, which are suitable for physiological compatibility, cause minimal irritation, and allow for drug stability. Analysis of formulation F4 revealed uniformly sized droplets with a moderate polydispersity index,

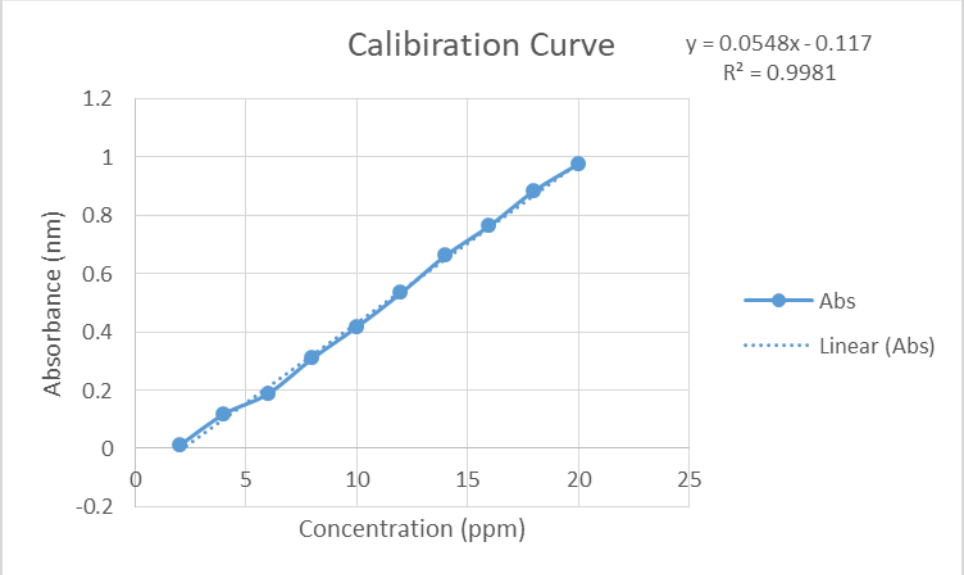

Figure 3: Calibration curve of amlodipine besylate in phosphate buffer at 6.5 pH.

and the zeta potential was adequate to enable electrostatic repulsion and ensure formulation stability (Ganea *et al.*, 2025).

Both the rheological and functional characteristics of the emulgel were significantly influenced by the amount of Carbopol 934 used in its preparation. All formulations exhibited pseudoplastic (also known as shear-thinning) behavior, which facilitates easier application and thus increases patient acceptance. The inverse relationship between spreadability and polymer concentration can be explained by the rise in viscosity as the polymer amount increases. The swelling index results further demonstrate the role of Carbopol in regulating water absorption and swelling capacity of the emulgel, with formulation F4 showing the optimal swelling capacity, which supports better retention and longer drug release (Kola-Mustapha *et al.*, 2023). Additionally, the viscosity of formulation F4 enabled a balance between gel strength and viscosity, ensuring both stability and ease of drug diffusion emulgel (Badaoui *et al.*, 2025).

According to the *in vitro* tests conducted on the release of amlodipine besylate from all formulations, each exhibited sustained release, with an inverse relationship between polymer concentration and the rate of release (Suman *et al.*, 2026). The best formulation was F4, based on its drug release profile, supporting the conclusion that a balance among the polymer, oil, and surfactant is essential for optimal controlled drug delivery. Formulations with higher polymer and/or oil contents showed slower drug release rates due to their dense and hydrophobic

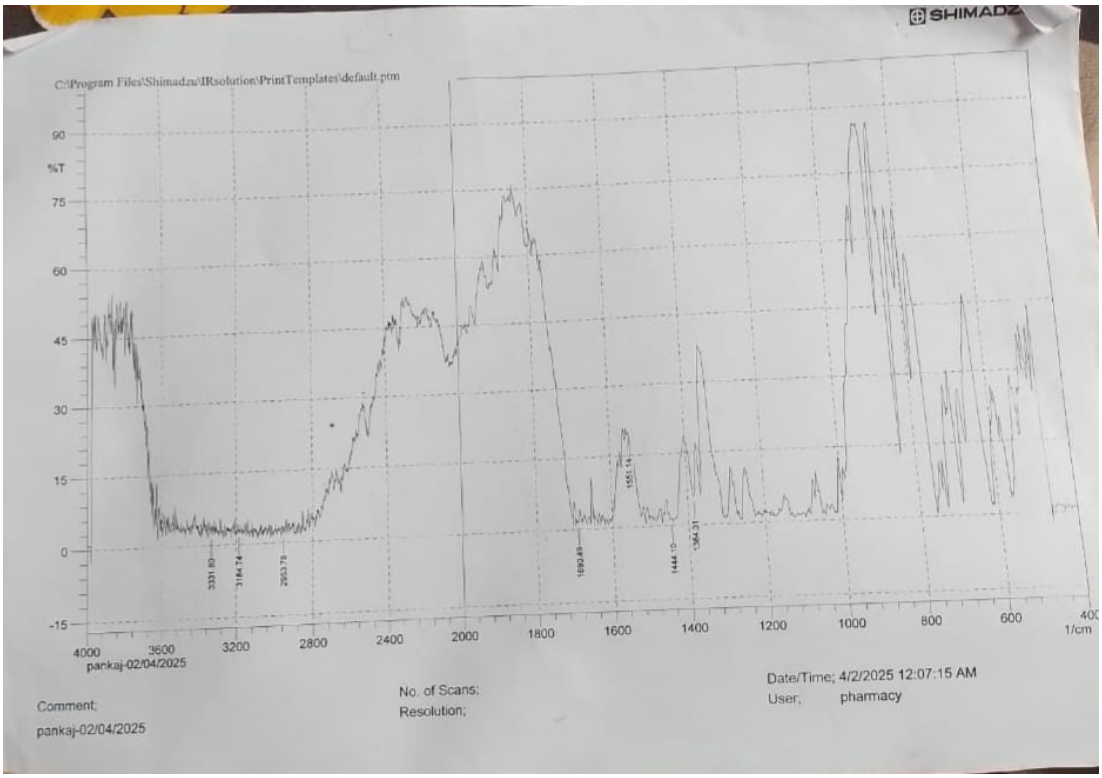

Figure 4: FTIR Analysis of Amlodipine Besylate.

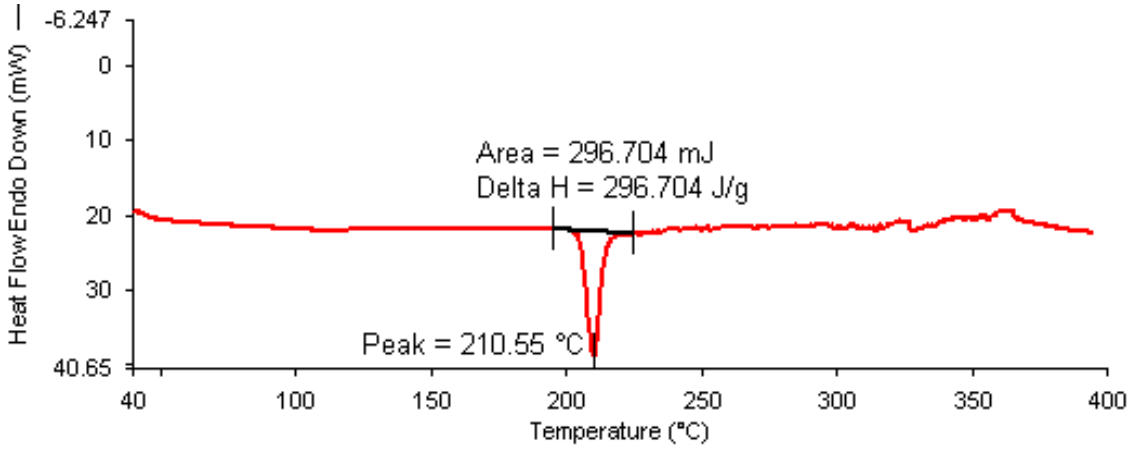

Figure 5: DSC analysis of Amlodipine Besylate.

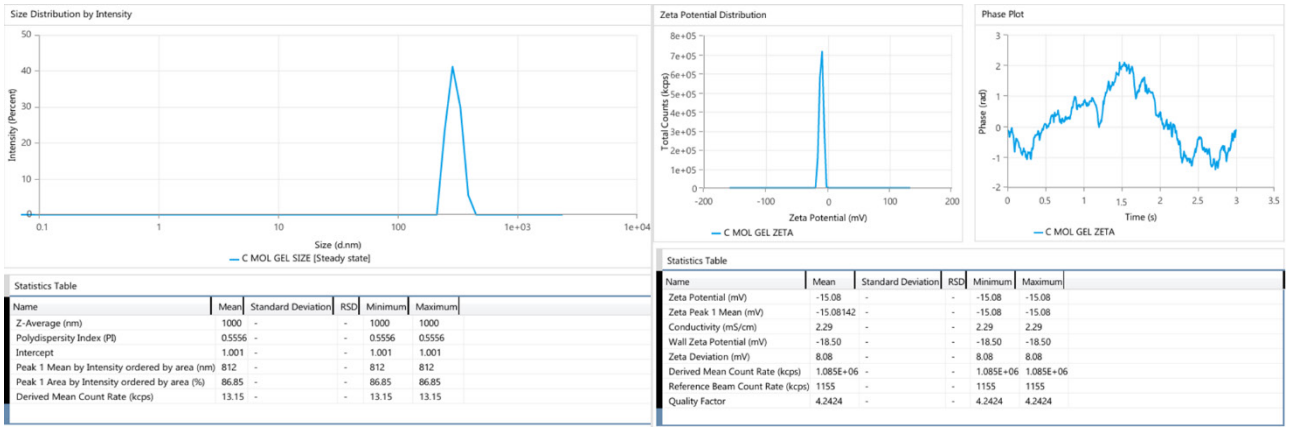

Figure 6: Particle size and zeta potential of emulgel.

Table 4: Physical Appearance of Formulation.

Formulation	Color	Phase Stability	Uniformity	Viscosity
F-1	Whitish	No separation	Highly uniform	Good
F-2	Off-Whitish	No separation	Highly uniform	Good
F-3	Whitish	No separation	Good	Optimal
F-4	Whitish	No separation	Highly uniform	Optimal
F-5	Whitish	No separation	Good	Good
F-6	Off-Whitish	No separation	Highly uniform	Good

Table 5: Swelling Index of Emulgel Formulations.

Sl. No.	Formulation	Swelling extent (%) across time intervals (%)		
		10 min	20 min	30 min
1	F-1	23	35	47
2	F-2	26	42	55
3	F-3	20	30	35
4	F-4	28	45	70
5	F-5	38	58	61
6	F-6	26	37	45

Table 6: R^2 values for different models in optimized formulation.

Formulation	Zero-order R^2	First-order R^2	Higuchi R^2	Korsmeyer-Peppas R^2
F-1	~0.95	~0.97	~0.98	~0.99
F-2	~0.94	~0.96	~0.97	~0.99
F-3	~0.94	~0.97	~0.98	~0.99
F-4	~0.92	~0.95	~0.96	~0.98
F-5	~0.93	~0.95	~0.97	~0.99
F-6	~0.95	~0.97	~0.98	~0.99

matrices, respectively, which hindered diffusion. Kinetic modeling of the optimized formulation indicated that drug release followed the Higuchi model with a high correlation coefficient, confirming a diffusion-controlled mechanism. Additionally, the Korsmeyer-Peppas model further demonstrated that the drug release mechanism was non-Fickian (anomalous), with both polymer relaxation and drug diffusion contributing to the release.

CONCLUSION

The present study successfully developed and optimised Amlodipine Besylate emulgel formulations for oral delivery, effectively overcoming the challenges posed by low aqueous solubility and pre-systemic elimination. Among the formulations, F4 was identified as the most promising, exhibiting excellent

physical stability, homogeneity, optimal pH (6.2), and suitable viscosity (3941 cP) for ease of administration. The *in vitro* release profile confirmed a time-dependent, sustained-release behaviour, with kinetic modelling indicating a diffusion-controlled mechanism consistent with the Higuchi model. In contrast, Korsmeyer-Peppas analysis suggested anomalous (non-Fickian) transport. In general, formulation F4 is indicative of a stable, high, drug, content, and efficient emulgel platform for controlled oral delivery, which can lead to better bioavailability, therapeutic performance, and patient compliance. Subsequent investigations are necessary to support *in vivo* pharmacokinetic and bioavailability assessments and to establish the clinical significance of this innovative delivery system.

ACKNOWLEDGEMENT

The authors express their gratitude to IFTM University for their academic guidance and institutional support throughout the conduct of this research.

ABBREVIATIONS

pH: Potential of Hydrogen; **FTIR:** Fourier Transform Infrared Spectroscopy; **DSC:** Differential Scanning Calorimetry; **Cp:** Centipois; **GI:** Gastrointestinal Track; **CDH:** Central Drug House; **nm:** Nanometer; **mL:** Millimeter; **mg/mL:** Microgram Per Milliliter; **mg:** Milligram; **SI:** Swelling Index; **RPM:** Round per Minute.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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Cite this article: Singh P, Kumar A, Kumar P, Kumar A, Fareed M, Gangwar S, *et al*. A Novel Emulgel-Based Oral Delivery Approach for Amlodipine Besylate: Formulation, Evaluation, and Kinetic Modelling . J Young Pharm. 2026;18(2):409-18.