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Formulation Development, Characterization and Evaluation of a Topical Microemulgel containing *Tinospora cordifolia* leaf extract

Article History:

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Abstract: Background: Topical Drug Delivery Systems (TDDS) offer localized therapeutic effects while minimizing systemic side effects. Tinospora cordifolia (Guduchi), a medicinal plant with anti-inflammatory and wound-healing potential, faces limitations in oral formulations due to poor solubility and bioavailability. Developing a microemulgel formulation enables improved solubilization, enhanced skin permeation, and sustained release for topical application.**Objective:** To develop, optimize, and evaluate a topical microemulgel containing Tinospora cordifolia leaf extract with desirable physicochemical stability, controlled drug release, and therapeutic potential for dermatological use.**Methods:** The formulation was prepared using Liquid paraffin oil, Olive oil, Peceol and Eukalyptus oil as the oil phase, Span 20, Tween 80, Stearic acid, and Polyethylene glycol 1500 as surfactants, PEG 400, Polysorbate 80, Span 80 and Span 20 as co-surfactants, and Carbopol 934 as the gelling agent. Pseudo-ternary phase diagrams were constructed to optimize the surfactant-to-co-surfactant ratio (Smix = for 1:1, 1:2, 1:3, 2:1 and 3:1). The prepared microemulsion was incorporated into a gel base and evaluated for pH, viscosity, spreadability, extrudability, particle size, FTIR compatibility, and in-vitro drug release using Franz diffusion cells. Stability testing was performed under ICH guidelines.**Results:** The optimized formulation (A2) exhibited pH 5.48 ± 0.02, viscosity 67.8 cps, spreadability 42.58 g•cm/s, and extrudability 111 g/cm. FESEM revealed uniformly distributed spherical particles (1–2 µm), and FTIR confirmed compatibility. In-vitro diffusion studies showed sustained release (85.76% over 8 hr), following the Korsmeyer–Peppas model (r^2 = 0.999), indicating diffusion-controlled release. Stability tests confirmed no phase separation and physicochemical changes over 6 months.**Conclusion:** The developed Tinospora cordifolia microemulgel demonstrated optimum stability, uniformity, and sustained release, making it a promising topical herbal formulation for wound-healing applications. Future studies should include in-vivo and clinical evaluation to establish therapeutic efficacy.

Keywords: Tinospora cordifolia; Microemulgel; Topical drug delivery; Diffusion-controlled release; formulation

INTRODUCTION

Topical Drug Delivery Systems (TDDS) play a vital role in achieving localized therapeutic effects through direct application of medicated formulations to the skin (1). This route of administration offers several advantages, including the ability to bypass

gastrointestinal disturbances and first-pass hepatic metabolism, ensuring improved drug bioavailability and sustained release of active ingredients at the site of action (2). Topical formulations also enhance patient compliance due to their non-invasive nature, ease of administration, and ability to terminate therapy quickly if adverse reactions occur (3). These characteristics make TDDS an effective approach for treating a variety of dermatological, inflammatory, and musculoskeletal disorders while minimizing systemic side effects (4).

The growing need for Novel Drug Delivery Systems (NDDS) has led to the development of hybrid dosage forms such as emulgels and microemulgels, which combine the properties of emulsions and gels (5). These systems provide the dual advantages of improved solubilization of hydrophobic drugs and enhanced skin penetration due to their fine droplet size and gel matrix structure(6). Microemulgels, in particular, are thermodynamically stable, easy to formulate, and exhibit superior spreadability and aesthetic appeal compared to conventional creams or ointments(7). Their ability to deliver both hydrophilic and lipophilic drugs through controlled and sustained release makes them highly suitable for topical therapy in chronic conditions requiring prolonged contact and efficient drug diffusion through the skin (8).

Tinospora cordifolia (Menispermaceae), popularly referred to as Giloy or Guduchi, is a well-known medicinal plant in Ayurvedic and modern medicine(9). It contains several bioactive constituents such as alkaloids, glycosides, diterpenoid lactones, and steroids that contribute to its wide range of pharmacological properties including anti-inflammatory, antioxidant, antimicrobial, wound-healing, and immunomodulatory effects (10). Despite its therapeutic potential, the oral administration of Tinospora cordifolia extracts faces limitations due to poor solubility, low bioavailability, and degradation in the gastrointestinal tract (11). Therefore, developing a topical delivery system such as a microemulgel can overcome these challenges by enhancing drug permeation through the skin, providing localized effects, and maintaining stability of the herbal constituents (12).

Although several formulations of Tinospora cordifolia have been explored, limited studies focus on its topical application in the form of a microemulgel for controlled and sustained release [14]. Herbal extracts are often unstable in conventional formulations, and their poor aqueous solubility restricts effective transdermal absorption(13). Hence, there is a need to develop a stable and efficient microemulgel system that ensures uniform drug distribution, prolonged release, and enhanced therapeutic efficacy (14). The present study aims to develop and evaluate a stable topical microemulgel formulation of Tinospora cordifolia leaf extract, assessing its physicochemical properties, drug release characteristics, and stability profile to establish its potential as a novel herbal topical delivery system (15).

Materials and Methods

The materials included were the *Tinospora cordifolia* leaf extract (authenticated BSI/WRC/IDEN.CER/2024/62), Liquid paraffin oil, Olive oil, Peceol and Eukalyptus oil as the oil phase, Span 20, Tween 80, Stearic acid, and Polyethylene glycol 1500 as surfactants, PEG 400, Polysorbate 80, Span 80 and Span 20 as co-surfactants, and Carbopol 934 as the gelling agent, and methyl as preservative. Triethanolamine (TEA) was employed for pH adjustment, and all solvents were freshly prepared in distilled water before use. Analytical-grade reagents were used throughout the study

Formulation Optimization and Development of *Tinospora cordifolia* Leaf Extract Emulgel

Solubility Studies: Solubility studies were conducted to identify the most suitable oil, surfactant, and co-surfactant for the formulation. These studies ensured maximum solubility of *T. cordifolia* extract, thereby facilitating higher drug loading and stable microemulsion formation. For surfactant screening, an excess amount of the extract was added to 10 ml of each surfactant-Span 20, Tween 80, Stearic acid, and Polyethylene glycol 1500-contained in stoppered vials. The vials were placed in an incubator shaker at 37 ± 1 °C for 48 hours to attain equilibrium. After equilibration, each mixture was centrifuged at 1500 rpm for 10 minutes, and the supernatant was analyzed colorimetrically at 570 nm to determine the concentration of dissolved extract. Similarly, for co-surfactant selection, the extract was added in excess to 10 ml of each co-surfactant-PEG 400, Polysorbate 80, Span 80, and Span 20-and the same procedure was followed. For oil phase selection, the extract was added to 10 ml of various oils including liquid paraffin, olive oil, Peceol, and eucalyptus oil. After 48 hours of agitation and centrifugation, the concentration of the dissolved extract was measured at 570 nm and plot the graph as shown in fig.1 for surfactant, fig .2 for co-surfactant and fig.3 for oil phase and the values of obtained absorbance were noted in table no.1. Among all tested Tween 80 as surfactant, Span 80 as co- surfactant and olive oil was selected as the oil phase, as per the table no.1 due to its superior solubilising capacity and *in-vitro* drug release kinetics study by Franz diffusion cell.(6,7)

Table . 1. Solubility data of *Tinospora cordifolia* leaf extract in oils, surfactants, and co-surfactants (7)

Component Tested	Concentration of Drug (mg / 10 mL)	Absorbance (λ = 570 nm)
Oils		
Liquid Paraffin Oil	100 mg / 10 mL	0.74
Olive Oil	100 mg / 10 mL	1.22
Peceol Oil	100 mg / 10 mL	0.95
Eucalyptus Oil	100 mg / 10 mL	0.88
Surfactants		
Span 20	100 mg / 10 mL	0.8
Tween 80	100 mg / 10 mL	1.0
Stearic Acid	100 mg / 10 mL	0.19
PEG 1500	100 mg / 10 mL	0.76
Co-Surfactants		
PEG 400	100 mg / 10 mL	0.76
Polysorbate 80	100 mg / 10 mL	0.94
Span 80	100 mg / 10 mL	1.0
Span 20	100 mg / 10 mL	0.8

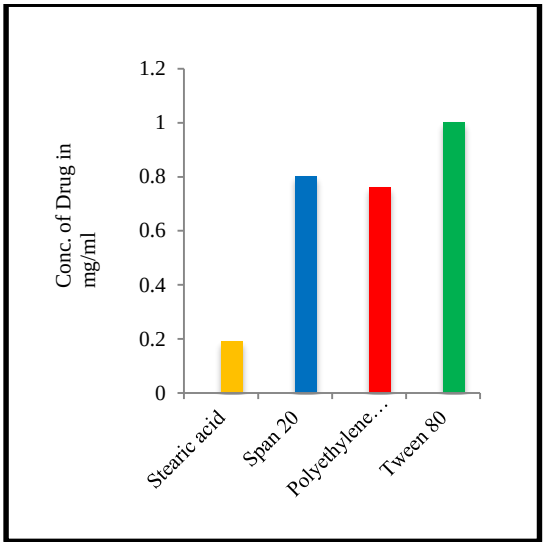

Figure .1.Solubility studies graph for selection of surfactant

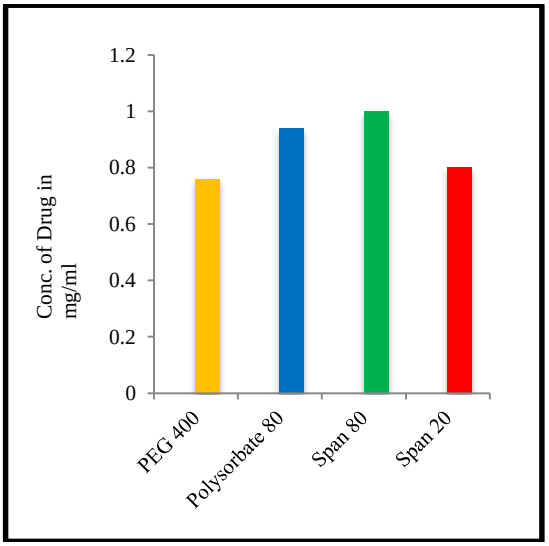

Figure .2.Solubility studies graph for selection of Co-surfactant

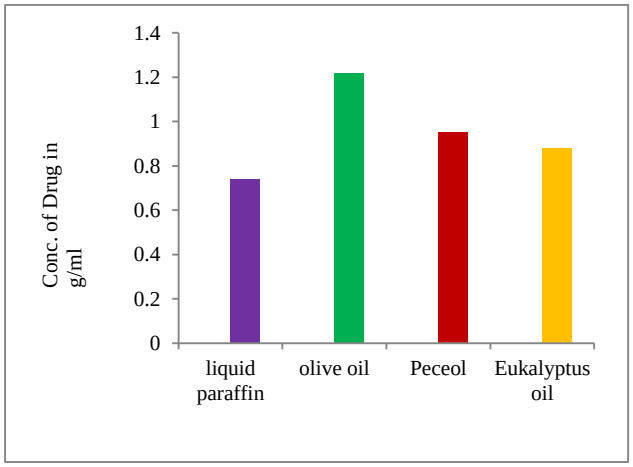

Figure .3.Solubility studies graph for selection of oil phase

Construction of Pseudo-Ternary Phase Diagrams

To identify the microemulsion region and optimize the ratio of surfactant to co-surfactant (Smix), pseudo-ternary phase diagrams were constructed using the water titration method. The surfactant and co-surfactant were mixed in weight ratios of 1:1, 1:2, 1:3, 2:1, and 3:1, and each Smix was vortexed for 5 minutes to ensure uniform blending. The oil phase was then added to each Smix in different proportions ranging from 1:9 to 9:1. Water was titrated gradually into each mixture with constant stirring until the system turned turbid, indicating phase separation as shown in fig.4. The clear and stable compositions were recorded and plotted using Chemix School 3.60 software to generate the pseudo-ternary phase diagrams as plotted in fig.5. Among the ratios tested, Smix 1:1 produced the largest isotropic region, suggesting its superior emulsification efficiency and stability.(13,16)

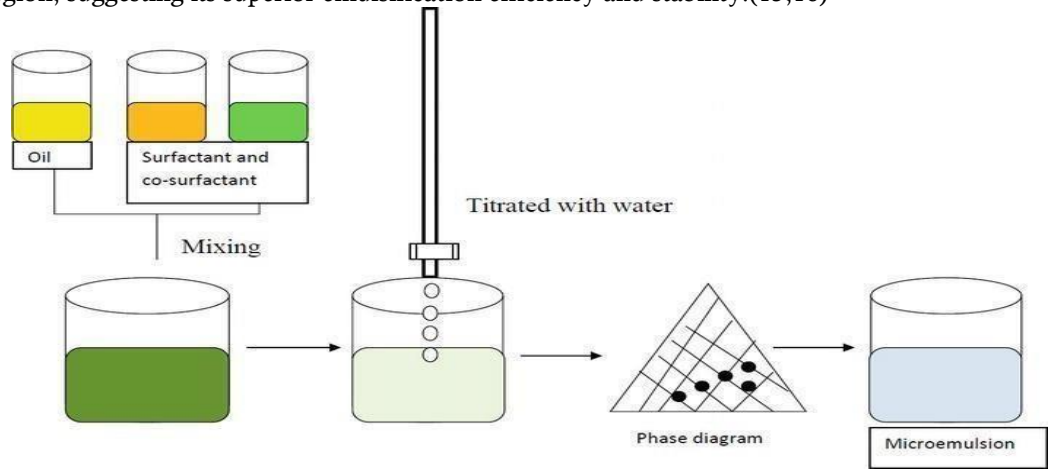

Figure .4. Pseudo-ternary phase Diagrams of surfactant, co-surfactant, oil and water Phase with the ratio of 1:1, 1:2, 1:3, 2:1 and 3:1.(13,16)

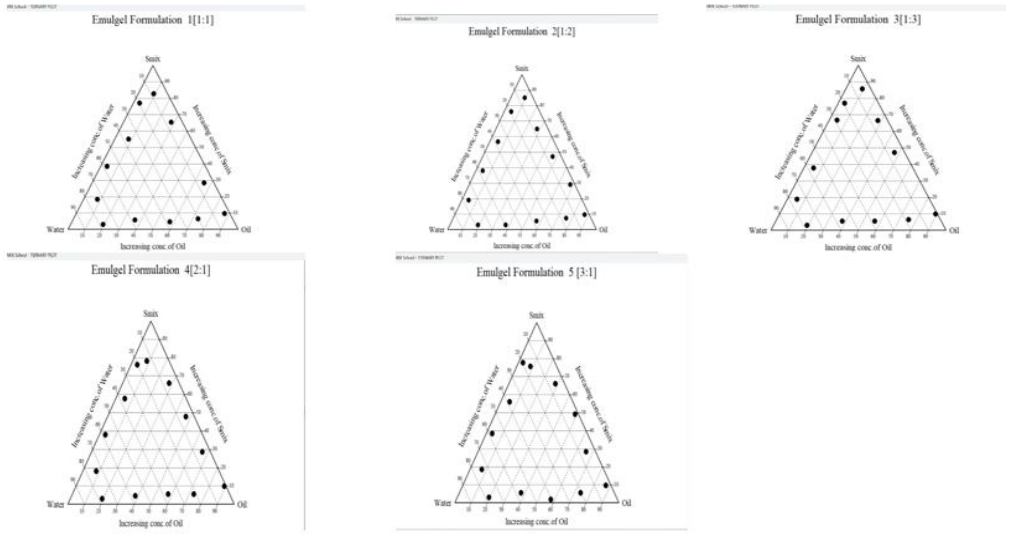

Figure .5 Pseudo ternary phase diagram for 1:1, 1:2, 1:3, 2:1 and 3:1 indicates more emulsion region, microemulsion

Preparation of *Tinospora cordifolia* Microemulgel

After the Pseudo-ternary phase study (Smix) of surfactant, co-surfactant, oil and water Phase with the ratio of 1:1, 1:2, 1:3, 2:1 and 3:1, total 45 formulations were prepared as per given flowchart in fig.5 and prepared 45 formulations of microemulsion among which only four were found to be stable (A-2, B-9, C-9, D-1) which were further prepared as emulgel by varying the proportions of oil, surfactant, and co-surfactant while keeping the drug and polymer content constant as per the formulation which is given in table no.2.

The formulation of the microemulgel was carried out in a stepwise manner consisting of five key stages:

1. Preparation Gel
2. Preparation Aqueous Phase of Emulsion
3. Preparation Oil Phase of Emulsion
4. Emulsion Formation
5. Final Emulgel Formation

Carbopol 934 (1 g) was dispersed in cold distilled water (q.s. 50 ml) under continuous stirring until a clear, uniform gel was obtained. The dispersion was left overnight for complete hydration, and the pH was adjusted

to 5.0–5.5 using triethanolamine. This ensured that the gel base was compatible with the physiological pH of the skin. For the aqueous phase, Tween 80 was dissolved in distilled water, while methyl paraben was dissolved in propylene glycol. The T. cordifolia extract was dissolved in ethanol and added to the aqueous phase under gentle stirring. For the oil phase, Span 80 was dissolved in olive oil and gently heated to 70 °C to achieve complete mixing. The aqueous and oil phases were each heated separately to 70 ± 2 °C, and the oil phase was added slowly to the aqueous phase with continuous stirring using a mechanical homogenizer at 3000 rpm for 10 minutes. The resulting microemulsion was cooled to room temperature.The preformed microemulsion was incorporated into the Carbopol gel base in a 1:1 ratio with moderate stirring to form the final microemulgel. The formulations were prepared as per given in table.2 and stored in tightly closed containers until further evaluation.(6,7,14)

Table no. 2 – Formulation of Emulgel for following four batches A-2, B-9, C-9, D-1 (6,7)

Sr. No	Ingredients	Quantity A-2	Quantity B-9	Quantity C-9	Quantity D-1	Uses
1	T.C. extract	150 mg	150 mg	150 mg	150 mg	Active pharmaceutical ingredient
2	Carbopol 934	1gm	1gm	1gm	1gm	Polymer as gelling agent
3	Tween 80	1ml	3 ml	3 ml	0.65 ml	Emulsifier
4	Span 80	1ml	6 ml	9 ml	0.35 ml	Emulsifier
5	Olive oil	8 ml	1 ml	1 ml	9 ml	Moisturizer
6	Methyl paraben	0.02ml	0.02ml	0.02ml	0.02ml	Preservative
7	Propylene glycol	2ml	2ml	2ml	2ml	Solvent
8	Ethanol	2ml	2ml	2ml	2ml	Permeation Enhancer
9	Triethanolamine	Few drops	Few drops	Few drops	Few drops	Ph modifier
10	Distilled water	q.s. 50gm	q.s. 50gm	q.s. 50gm	q.s. 50gm	To adjust the final volume

***In-vitro* Drug Release and Kinetics**

The *in-vitro* diffusion study using Franz diffusion cells demonstrated a sustained release pattern for the *Tinospora cordifolia* microemulgel over eight hours. Fill donor compartment with 1gm of prepared *Tinospora cordifolia* leaf extract emulgel having diffusion area of 1.5 cm^2. Fill recipient compartment with phosphate buffer (pH 6.0) Maintain system temperature at 37 ± 0.5 °C using water circulation and Magnetic bar was put in recipient chamber and rotated at 75 rpm. Samples (1 ml) were withdrawn at regular time interval and replaced with fresh buffer solution to maintain sink condition. Withdraw samples at 0, 1, 2, 3, 4, 5, 6, 7, 8 hrs. After each withdrawal, replace the sample solution with fresh buffer solution. Measure the absorbance at 250 nm using UV-Visible spectrophotometer and Collect drug release data. Among all batches (A-2, B-9, C-9, D-1) *Tinospora cordifolia* emulgel A-2 containing Tween 1ml, Span 1ml, Olive oil 8 ml has shown highest drug release (85.76% in 8hrs) than all other emulgel formulations. So, it was selected as a optimized formula and suggesting that this composition provided the most efficient diffusion profile.

The drug release kinetics were estimated by fitting the release data into various kinetic models, namely Zero-order, First-order, Higuchi, Korsmeyer–Peppas, and Hixson–Crowell models. The resulting regression plots are shown in Figures 6-10. Among all models, the Korsmeyer–Peppas (power-law) model provided the best fit, with a coefficient of determination (r^2 = 0.999) as shown in fig-8, indicating that the drug release from the *Tinospora cordifolia* microemulgel followed a diffusion-controlled mechanism as per given dat in table no.3. The linearity of the plots further confirmed that the release was primarily governed by Fickian diffusion, consistent with the sustained-release characteristics of microemulsion-based gels. (6)

Table 3. Drug release kinetic models of optimized *Tinospora cordifolia* microemulgel formulation(12)

Model	Equation	r^2 value	Mechanism
Zero-order	Qt = 5.83t + 7.61	0.978	Constant-rate release
First-order	log Qt = 1.35 – 0.128t	0.962	Concentration-dependent
Higuchi	Qt = 12.14√t + 4.87	0.985	Diffusion-controlled
Korsmeyer–Peppas	Qt/Q∞ = 0.44t^0.67	0.999	Fickian diffusion
Hixson–Crowell	$(100 – Qt)^{1/3}$ = 0.121t + 4.59	0.971	Erosion mechanism

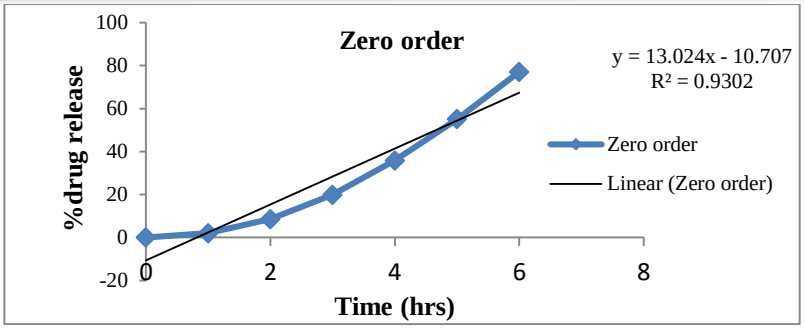

Figure .6: Drug release profiles of *TC* emulgel formulation by zero order model (12)

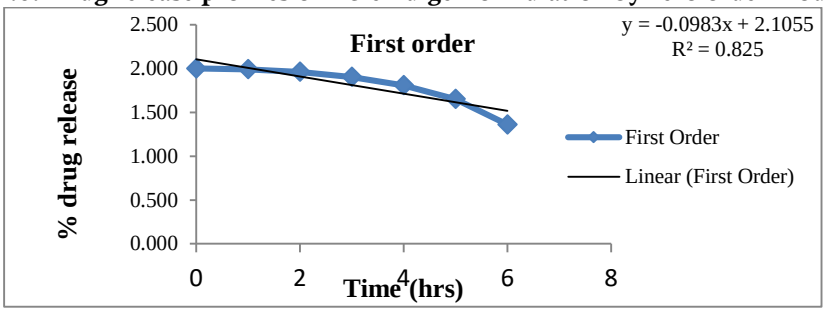

Figure .7: Drug release profiles of *TC* emulgel formulation *by First order* model (12)

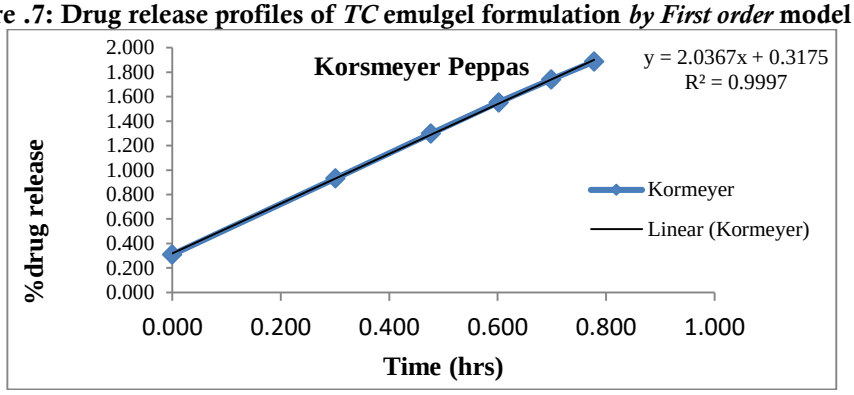

Figure .8: Drug release profiles of *TC* emulgel formulation by Korsmeyer Peppas model (12)

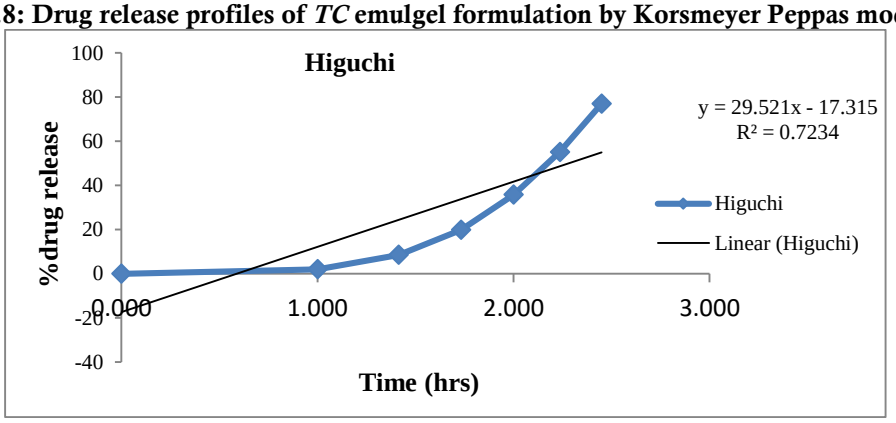

Figure .9: Drug release profiles of *TC* emulgel formulation by Higuchi model (12)

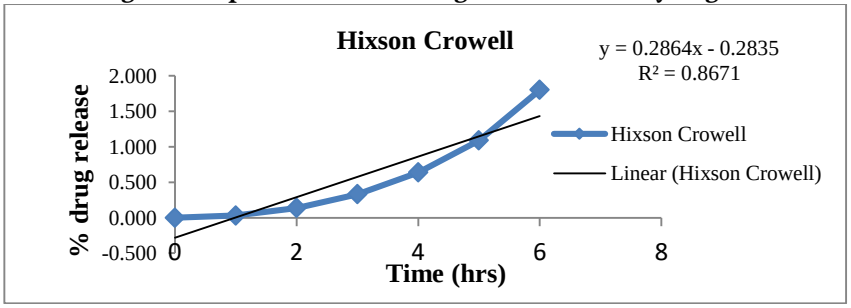

Figure .10: Drug release profiles of *TC* emulgel formulation by Hixson crowell model (12)

Evaluation of Prepared Microemulgel Formulation (For optimized batch -A2)

The prepared final formulation was subjected to a series of evaluations to determine their physical, physicochemical, and functional characteristics. Visual inspection was performed to assess colour, odour, homogeneity, and phase separation. The pH was measured using a digital pH meter, and viscosity was determined using a Brookfield viscometer (spindle 63 at 50 rpm). Spreadability was assessed by the glass-slide method, while extrudability was evaluated by measuring the force required to extrude the formulation through a collapsible aluminum tube. Drug content was determined by dissolving a known weight of the emulgel in phosphate buffer (pH 6.8), followed by spectrophotometric analysis at 570 nm. The optimized batch (A-2) was selected for further characterization based on its ideal pH, viscosity, spreadability and drug content. (6,7,14,15)

Physical Appearance- The physical properties of the emulgel were observed, including the appearance, Colour, Odour, Homogeneity, phase separation, and ease of application and removal.

Ph - 1gm of gel was dissolved in 100 ml of distilled water and it was placed for 2 hr and then dip the glass electrode into an emulgel. The measurement of pH of was done using digital Ph meter and the value was noted.

Spreadability - Spreadability refers to the ease and extent to which an emulgel spreads on the skin or affected area upon application. It is a key parameter influencing the bioavailability of the formulation. To determine spreadability, two glass slides of standard size were used. A fixed amount of the herbal emulgel was placed on one slide, and the second slide was placed on top forming a sandwich over a 6 cm area. A 50 g weight was placed on the top slide to evenly spread the emulgel into a thin layer. After removing the weight, excess emulgel adhering to the slides was scrapped off. The two slides in position were fixed to a stand without slightest disturbance and in such a way that only the upper slide to slip off freely by the force of weight tied to it. A 50 gm weight was tied to the upper slide carefully. The time taken for the upper slide to travel the distance of 6 cm and separated away from the lower slide under the influence of the weight was noted. The experiment was done and the time taken to separate the slides was noted for calculation. Spreadability was calculated using formula:

$S = M. L / T$

Where M= weight tied to upper slide (50g)

L = length of glass slide (6cm)

T = Time taken to separate the slides

Determination of viscosity:

viscosity of emulgel were determined by Brookfield viscometer (cone and plate). It was done using viscometer (Spindle no.6) at 6 and 12 rpm. Small amount of the emulgel was taken in the cup and the spindle was dipped in it for about 5 minutes and then the reading was taken.

Excrudability- It is a test to measure the force required to extrude the material from tube. The emulgel was packed in a collapsible aluminum tube, measuring the length of ribbon extruded from the container in 10 seconds and calculating the extrudability using the formula:

Extrudability = Weight of load (in grams)/Area of ribbon extruded (in cm square)

Centrifugation -Selected formulations A2 was centrifuged at 1500 rpm for 15 min. The formulation was observed for any phase separations.

Drug content-

1 g of the emulgel formulation (contain 500mg of *Tinospora cordifolia* extract) transferred to a beaker. 80 ml of methanol was added to the beaker. The mixture was heated at 50 °C for 30 minutes. After heating, the mixture was filtered, volume was made up to the mark 100mlwith methanol. The resulting solution was sonicated in an ultrasonic bath for 5 minutes to ensure complete dissolution of the drug. The absorbance of the final solution was measured at 250 nm using a UV–visible spectrophotometer.

Stability Studies –

Stability studies were carried out for the optimized formulation according to International Conference on Harmonization (ICH) guidelines. The resulting microemulgel was placed in collapsible tube and tested for three-month stability tests at 5 C ±2°C, 25 C ±2°C with 60% RH, and 30 C ±2°C with 65% RH, and 40 C ±2°C with 75% RH. After every 15 days, samples were taken out and observed for colour, phase separation, homogeneity, consistency and liquefaction and Ph.

Characterization Studies

FTIR –

Fourier Transform Infrared (FTIR) spectroscopy was performed for both the pure extract and the optimized formulation (A2) to evaluate drug–excipient compatibility. The spectra were recorded within the 4000–400 cm^{-1} range using the KBr pellet method. The characteristic peaks corresponding to O–H, C–H, and C=O groups were

retained without significant shifts, indicating no chemical interaction between the extract and excipients.

Particle Size –

FESEM is used to visualize and analyze surface structures at very high resolution, particularly useful for understanding the micro scale morphology of materials. FESEM analysis reveals that samples with 1–2 µm to 20 µm particle size, especially those analyzed at 500X to 25.00KX magnification.

The micrographs revealed uniformly distributed spherical particles with smooth surfaces, and particle sizes ranged between 1 and 2 µm. The absence of aggregation confirmed proper dispersion and emulsification of the *T. cordifolia* extract within the gel matrix.

RESULTS

The formulated *Tinospora cordifolia* microemulgel exhibited excellent physical characteristics, appearing greenish-white, glossy, and homogeneous with a pleasant herbal odour. The formulation was smooth, easily spreadable, and non-greasy, indicating good patient acceptability as data provided in table no.4. The pH of the optimized batch (A2) was found to be 5.48 ± 0.02, which falls within the normal physiological pH range of the skin, ensuring its compatibility and minimizing irritation potential. The measured viscosity of 67.8 cps confirmed adequate consistency and stability, while the spreadability value of 42.58 g·cm/s indicated that the gel could be applied effortlessly with minimal shear. The extrudability value of 111 g/cm reflected smooth expulsion of the formulation from collapsible tubes, demonstrating its suitability for practical use.

Table . 4. Physicochemical characteristics of the optimized *Tinospora cordifolia* microemulgel (6,7)

Parameter	Observation / Value (Mean ± SD)
Appearance	Greenish-white, glossy, homogeneous
Odour	Characteristic herbal
pH	5.48 ± 0.02
Viscosity (cps)	67.8 ± 0.5
Spreadability (g·cm/s)	42.58 ± 0.8
Extrudability (g/cm)	111 ± 1.2

The FESEM analysis revealed uniformly distributed spherical particles with sizes ranging from 1–2 µm, as per the data of table no.5, confirming proper emulsification and dispersion of the extract within the gel matrix.

Table .5. Particle size and surface morphology analysis (FESEM results) (3,4)

Magnification	Average Particle Size (µm)	Observation
500X	20 µm	Coarse particles
2.5KX	5 µm	Uniform distribution
25.00KX	1–2 µm	Spherical, smooth surface

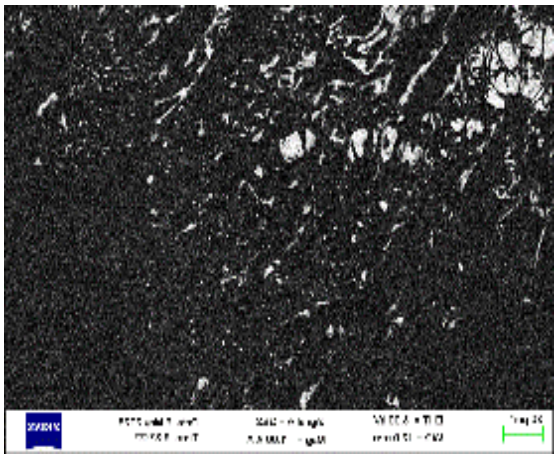

Figure. 11. –Image of microemulgel having 20 µm particlesize and magnification at 500X**(3,4)**

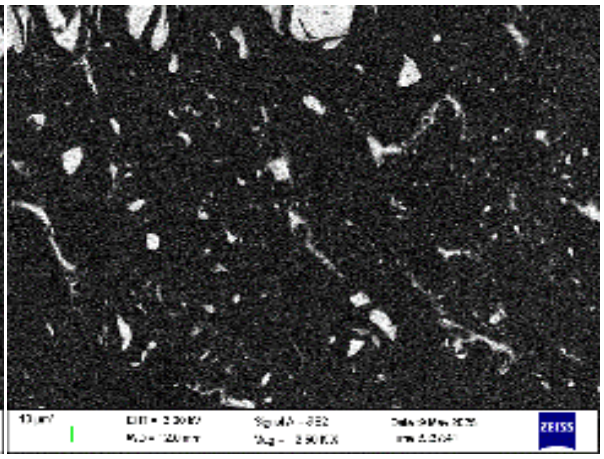

Figure.12.–Image of microemulgel having 1 µm particle sizeand magnification at 25.00KX**(3,4)**

The recorded data of table no.6, showed particle sizes ranging from 1 to 20 µm across different magnifications (100X to 25.00KX), with smaller and more uniform particles observed at higher magnifications. The working distance (WD) varied between 11.7–12.1 mm, and the electron high tension (EHT) was maintained at 3.00 kV, ensuring high-resolution imaging without surface distortion. The micrographs Fig.11 and Fig.12, clearly depicted smooth, spherical particles with no signs of aggregation, indicating proper dispersion of the *Tinospora cordifolia* extract within the gel matrix. Overall, the FESEM findings confirmed that the optimized formulation possessed desirable morphological characteristics essential for achieving uniformity, stability, and effective topical drug delivery.

Table 6. FESEM imaging parameters and particle size analysis of the *Tinospora cordifolia* microemulgel (3,4)

Sr. No.	Particle Size (µm)	EHT (kV)	Detector (SE)	WD (mm)	Magnification	Sample ID
1	20	3	SE2	11.7	500X	101
2	100	3	SE2	11.7	100X	102
3	20	3	SE2	11.9	500X	103
4	20	3	SE2	12	1KX	104
5	10	3	SE2	12	2.50KX	105
6	2	3	SE2	12	5.00KX	106
7	2	3	SE2	12.1	10.00KX	107
8	1	3	SE2	12	25.00KX	108
9	2	3	SE2	12	5.00KX	109
10	2	3	SE2	12	10.00KX	110
11	1	3	SE2	12	25.00KX	111
12	2	3	SE2	12	5.00KX	112
13	20	3	SE2	12	1KX	113
14	10	3	SE2	12	2.50KX	114
15	2	3	SE2	12.1	5.00KX	115
16	2	3	SE2	12.1	10.00KX	116
17	1	3	SE2	12.1	25.00KX	117

The small particle size contributes to enhanced drug diffusion and stability of the emulgel. The FTIR spectra of the pure extract and the final formulation displayed all major characteristic peaks of functional groups, such as O–H, C–H, and C=O stretching vibrations, without any significant shifts, confirming that there was no chemical interaction between the extract and excipients as given in table no. 7, ensuring formulation compatibility as shown in fig.13 and fig.14.

Table .7. FTIR spectral data of *Tinospora cordifolia* extract and formulation(5,6)

Wavenumber (cm^{-1})Crude extract	Wavenumber (cm^{-1}) Emulgel formulation	Assignment	Functional Group
3406	3401	Broad O–H or N–H stretch	Alcohol or amine (possible H-bonding)
3014	3010	=C–H stretch	Aromatic or alkene
2923, 2857	2926, 2855	C–H stretch (sp^3)	Alkanes
2070	2077	Sharp C≡C or C≡N stretch	Alkyne or nitrile
1749	1743	Strong C=O stretch	Ester or ketone (carbonyl group)
1641	1638	C=C or N–H bending	Alkene, amide, or aromatic ring
1463, 1363, 1360	1460, 1379, 1354	CH_2 and CH_3 bending	Alkyl groups
1249, 1146, 1099	1243, 1139, 1090	C–O or C–N stretches	Ethers, esters, or amines
998–726	990–720	Aromatic C–H out-of-plane bending	Substituted benzene ring likely

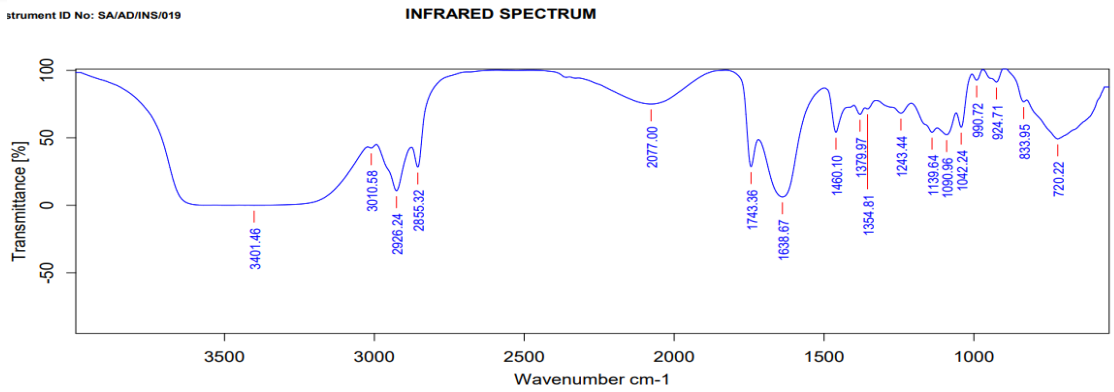

Fig.ure.13. FTIR spectrum of *Tinospora cordifolia* microemulgel formulation (5,6)

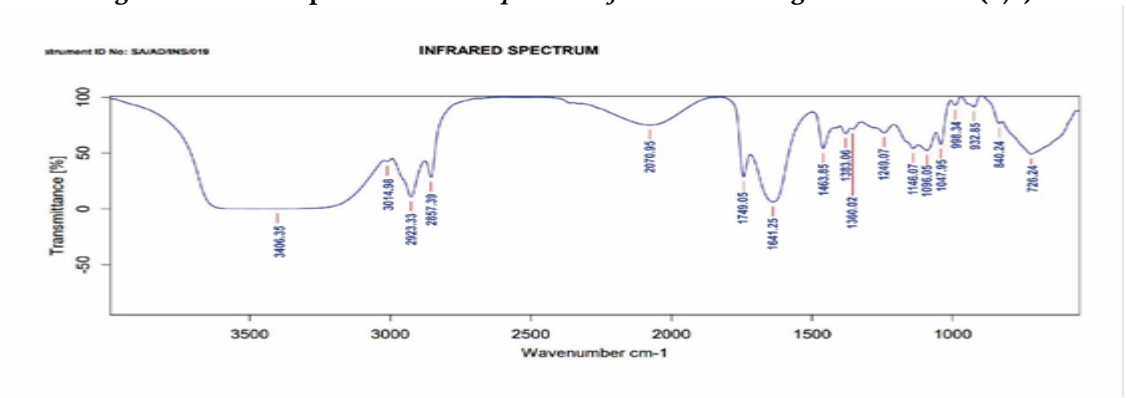

Figure.14. FTIR spectrum of pure *Tinospora cordifolia* extract (5,6)

The *in-vitro* drug release studies using Franz diffusion cells demonstrated a sustained release pattern for the *Tinospora cordifolia* microemulgel over eight hours. Among all batches, formulation A2 (Tween 1 ml, Span 1 ml, Olive oil 8 ml) showed the highest cumulative drug release of 85.76%, as shown in table no.8, suggesting that this composition provided the most efficient diffusion profile.

Table .8. Cumulative % drug release of *Tinospora cordifolia* emulgel formulations (12,13)

Time (h)	A2	B9	C9	D1
1	10.2	8.4	7.9	6.5
2	22.8	19.6	17.2	15.9
4	45.6	39.5	36.3	33.8
6	70.4	63.7	58.9	55.4
8	85.76	76.2	71.8	69.1

The release kinetics of the optimized formulation followed the Korsmeyer–Peppas model, with an r^2 value of 0.999 as per table no.9, indicating that the release mechanism was predominantly diffusion-controlled. This finding supports the microemulgel's potential to maintain prolonged therapeutic levels at the application site.

Table .9. Drug release kinetic models of optimized formulation (A2) (12,15)

Model	Regression equation	r^2 value	Interpretation
Zero order	Qt = 5.83t + 7.61	0.978	Nonlinear
First order	Log Qt = 1.35 – 0.128t	0.962	Nonlinear
Higuchi	Qt = 12.14√t + 4.87	0.985	Diffusion-controlled
Korsmeyer–Peppas	Qt/Q∞ = 0.44t^0.67	0.999	Fickian diffusion
Hixson–Crowell	$(100 – Qt)^{1/3}$ = 0.121t + 4.59	0.971	Erosion mechanism

The stability studies conducted under various temperature and humidity conditions (5°C, 25°C, and 40°C) for three months revealed that the optimized formulation remained physically and chemically stable with no signs of phase

separation, colour change, or significant alteration in pH. The consistent pH (5.48–5.50) and uniform appearance confirmed that the emulgel retained its integrity throughout the storage period as given values in table no.10.

Table 10. Stability study results of optimized microemulgel (A2) (15,16)

Condition	Duration (Days)	pH	Appearance	Phase Separation	Viscosity (cps)
5°C ± 2°C	90	5.48	Greenish-white	Nil	67.6
25°C ± 2°C / 60% RH	90	5.49	Greenish-white	Nil	67.3
40°C ± 2°C / 75% RH	90	5.5	Greenish-white	Nil	67.4

Overall, the optimized *Tinospora cordifolia* microemulgel demonstrated favorable physicochemical characteristics, excellent drug release, and long-term stability, establishing its suitability as a promising topical herbal delivery system.

DISCUSSION

The present study was designed and the formulation was optimized to develop, optimize, and evaluate a topical microemulgel containing Tinospora cordifolia leaf extract for enhanced dermal delivery. The overall formulation strategy involved systematic screening of oils, surfactants, and co-surfactants to ensure maximum solubility, stability, and skin compatibility. The formulation of Tinospora cordifolia microemulgel was developed using olive oil, Tween 80, and PEG 400, which together provided optimal emulsification and solubilization characteristics. Olive oil was chosen as the oil phase due to its excellent biocompatibility, emollient properties, and ability to enhance skin permeation (4). Tween 80, a non-ionic surfactant with low irritancy, effectively reduced interfacial tension and stabilized the emulsion, while PEG 400 acted as a co-surfactant to improve flexibility of the interfacial film, resulting in a clear and thermodynamically stable microemulsion (1). The combination of surfactant and co-surfactant (Smix) ensured a uniform droplet size distribution and enhanced solubilization of the hydrophobic constituents of Tinospora cordifolia, which is crucial for achieving sustained and controlled drug release (2).

The thermodynamic stability of the optimized formulation can be attributed to the proper balance between oil, surfactant, and co-surfactant phases. The selected Smix ratio (1:1) provided sufficient interfacial coverage to minimize surface free energy and prevent coalescence or phase separation (7). Microemulsions are inherently more stable than conventional emulsions due to their spontaneous formation, ultralow interfacial tension, and dynamic nature of surfactant films (13). The stable, homogeneous appearance of the formulation and consistent viscosity during the stability study confirmed that the microemulsion system resisted temperature and humidity-induced changes. Similar findings were reported by Bhavani et al. (2022) (5), where microemulsion-based topical systems exhibited long-term stability and improved drug retention within the skin layers.

The in-vitro drug release profile of the optimized formulation followed the Korsmeyer–Peppas kinetic model ($r^2 = 0.999$), indicating that the drug release mechanism was primarily diffusion-controlled (6). The smaller droplet size and uniform dispersion of the extract within the gel matrix facilitated controlled and sustained release through Fickian diffusion. Comparable results were observed in the emulgel systems developed for Ocimum basilicum extract and and rographolide, which also exhibited diffusion-based release patterns and improved skin absorption (6,16). The sustained release behavior of the Tinospora cordifolia formulation suggests a prolonged therapeutic effect, reducing the need for frequent application and enhancing patient compliance.

The rheological properties of the emulgel played a key role in its performance. The optimized viscosity (67.8 cps) and spreadability (42.58 g•cm/s) indicated a balanced consistency suitable for topical use (8). Adequate viscosity ensures drug retention at the application site, while good spreadability facilitates uniform distribution over the skin, enhancing drug absorption and therapeutic efficacy (12). The results of this study are in agreement with the work of Ambhore et al. (2017) (3) and Khan et al. (2020) (6), who reported that the interplay between viscosity, particle size, and surfactant concentration significantly influences diffusion and release kinetics in emulgel formulations.

In summary, the developed Tinospora cordifolia microemulgel demonstrated stable physicochemical properties, controlled drug release, and compatibility among its components. Its herbal nature and sustained-release profile make it an attractive option for topical treatment of inflammation, wound healing, and other dermatological conditions. The study confirms that such microemulgel systems not only improve the bioavailability of plant-derived actives but also provide an effective, patient-friendly platform for localized drug delivery.

CONCLUSION

The present study successfully formulated and evaluated a stable topical microemulgel containing *Tinospora cordifolia* leaf extract, demonstrating optimum physicochemical characteristics, homogeneity, and sustained drug release. The FTIR analysis confirmed the compatibility between the extract and excipients, while the *in-vitro* diffusion studies using the Franz diffusion cell revealed a controlled and diffusion-driven release profile, following the Korsmeyer–Peppas kinetic model (r^2 = 0.999). The formulation exhibited desirable viscosity, spreadability, and stability, making it a suitable candidate for topical applications. Overall, the *Tinospora cordifolia* microemulgel shows great potential as a novel herbal drug delivery system for anti-inflammatory and wound-healing therapies. Future studies should focus on *in-vivo* evaluation, large-scale formulation development, and clinical validation to further establish its therapeutic efficacy and commercial applicability.

Limitations: The present study was limited to *in-vitro* evaluation of the *Tinospora cordifolia* microemulgel. The stability assessment was conducted for the six months, and the biological activity (skin irritation along with wound healing) studies will be performed for its findings to future clinical use.

Data Availability

All the analysed and generated information during this study are included in this published article

Abbreviations

TDDS- Topical Drug Delivery Systems
PEG- Polyethylene glycol
FTIR- Fourier Transform Infrared spectroscopy
FESEM –Field emission scanning electron microscopy
NDDS- Novel Drug Delivery Systems
TEA- Triethanolamine
S- Spreadability
V- Viscosity
E- Extrudability
ICH- International Conference on Harmonization
RH- Relative Humidity
TC- *Tinospora cordifolia*
WD- working distance
EHT- Electron high tension
Smix- Surfactant and co-surfactant

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Ethics Declaration

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Not applicable.

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Not applicable.

Competing interests
The authors declare no competing interests.

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