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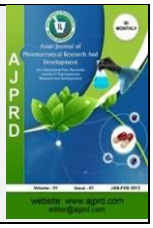

Open Access Research Article

Formulation and Evaluation of Phytosomal Anti Acne Herbal Gel

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ABSTRACT

The present study aimed to formulate and evaluate a phytosomal anti-acne herbal gel containing turmeric for enhanced topical drug delivery. Turmeric-loaded phytosomes were prepared using varying drug-to-phospholipid ratios and evaluated for physicochemical characteristics including entrapment efficiency, drug content, particle size, zeta potential, and in-vitro diffusion. Among all formulations, batch F3 was selected as the optimized formulation based on its superior entrapment efficiency and drug diffusion profile. The optimized phytosomal formulation exhibited an entrapment efficiency of 98.87%, indicating effective incorporation of the herbal constituent within the phospholipid matrix.

The optimized phytosome was incorporated into a gel base and further evaluated for pH, viscosity, spreadability, washability, drug content, and in-vitro diffusion. The phytosomal gel demonstrated enhanced drug diffusion with cumulative drug release of 72.16% after 6 hours, indicating improved permeability and sustained release behaviour. Drug release kinetic studies revealed that the formulation followed the Korsmeyer–Peppas model (R^2 = 0.9975), suggesting a controlled and diffusion-mediated release mechanism.

The results suggest that turmeric-loaded phytosomal gel is a promising carrier for topical anti-acne therapy, offering improved drug permeation, controlled drug release.

Keywords: Phytosome, Phyto-phospholipid complex, Topical drug delivery, Lipid-based nanocarriers, Skin penetration enhancement, Bioavailability

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INTRODUCTION

Topical drug delivery has gained considerable attention in recent years because it allows drugs to be applied directly to the affected area. This route is non-invasive, easy to use, and helps avoid first-pass metabolism and gastrointestinal side effects associated with oral administration. It is widely used for the treatment of various skin disorders, especially when systemic routes such as oral or injectable administration are not suitable. Many herbal extracts have shown beneficial effects in skin diseases due to their antimicrobial, anti-inflammatory, antioxidant, and wound-healing properties. Skin conditions such as acne, eczema, psoriasis, and microbial infections are commonly treated using topical formulations. The major advantages of topical drug delivery include site-specific action, improved patient compliance, reduced systemic side effects, and enhanced therapeutic effectiveness.[1,2]

The use of herbal medicines has increased worldwide due to their therapeutic benefits and lower risk of adverse effects. Herbal drugs contain several bioactive constituents that work together to produce therapeutic activity. However, many plant-derived compounds show poor solubility and low permeability, which limit their absorption and bioavailability. Therefore, there is a need to develop suitable drug delivery systems to improve the effectiveness of herbal medicines.[3–5]

Recent advances in Novel Drug Delivery Systems (NDDS) have provided effective approaches for improving the delivery of herbal drugs. Various carrier systems such as liposomes, phytosomes, niosomes, transferosomes, ethosomes, nanoparticles, and microspheres have been developed to enhance drug solubility, stability, permeability, and bioavailability. These systems also help in achieving controlled and targeted drug delivery.[6–8]

Among these systems, phytosomes have emerged as a promising carrier for herbal drugs. The term “phyto” means plant, while “some” refers to a vesicular structure. Phytosomes are phospholipid-based complexes that improve the absorption and bioavailability of poorly soluble phytoconstituents. In phytosomes, the active herbal constituent forms a complex with phospholipids through hydrogen bonding, which enhances membrane permeation and drug absorption. Phytosomes also improve drug stability, skin penetration, and therapeutic efficacy compared to conventional herbal formulations. Commonly used phospholipids include phosphatidylcholine, phosphatidylserine, and phosphatidylethanolamine. Due to these advantages, phytosomes have become an important approach for the delivery of herbal drugs.[9–13]

Acne vulgaris is one of the most common chronic inflammatory skin disorders affecting adolescents and young adults worldwide. It is characterized by the formation of comedones, papules, pustules, and nodules. Acne mainly occurs due to excessive sebum production, blockage of hair follicles, proliferation of Cutibacterium acnes, and inflammation. The condition commonly affects the face, chest, shoulders, and back and can negatively affect a person's appearance, confidence, and quality of life.[14]

Turmeric (Curcuma longa) is a well-known medicinal herb widely used in traditional medicine. Curcumin, the major active constituent of turmeric, possesses anti-inflammatory, antioxidant, antimicrobial, and wound-healing properties. It has been reported to reduce acne-causing bacteria and inflammatory responses associated with acne. However, curcumin has poor water solubility, low permeability, and poor bioavailability, which limit its therapeutic effectiveness. Incorporation of curcumin into a phytosomal delivery system can improve its solubility, skin penetration, and therapeutic activity.[15]

Therefore, the present study was undertaken to formulate and evaluate a turmeric-loaded phytosomal anti-acne herbal gel for enhanced topical drug delivery. The developed formulation was evaluated for its physicochemical properties, drug release behaviour, and suitability for the topical treatment of acne vulgaris.

MATERIALS AND METHOD

Materials

Turmeric (Curcuma longa) was obtained from Everest Food Products Pvt. Ltd., Mumbai, Maharashtra, India. Soya lecithin, dichloromethane, n-hexane, disodium hydrogen phosphate, potassium dihydrogen phosphate, Carbopol 940, methyl paraben, propylene glycol and triethanolamine were procured from S.D. Fine Chemicals, Mumbai, India. All chemicals and reagents used in the study were of analytical grade.

UV Spectroscopy Study (Determination of λmax)

In order to ascertain the wavelength of maximum absorption of turmeric, 10 mg of turmeric was accurately weighed and transferred into a 10 ml volumetric flask. The drug was dissolved in a mixture of phosphate buffer (pH 6.8) and methanol (50:50 v/v), and the volume was made up to 10 ml to obtain a concentration of 1000 µg/ml. From the above solution, 1 ml was withdrawn and diluted up to 10 ml to obtain a working stock solution of 100 µg/ml. The resulting solution was scanned between 200–600 nm against the solvent system as a blank.

From the solution having a concentration of 100 µg/ml, aliquots of 1, 2, 3, 4 and 5 ml were pipetted out into separate 10 ml volumetric flasks. The volume was made up to the mark with phosphate buffer (pH 6.8) and methanol (50:50 v/v) to obtain final concentrations of 10, 20, 30, 40 and 50 µg/ml, respectively. A graph of absorbance versus concentration was plotted. It showed a straight line indicating that the calibration curve obeyed Beer-Lambert’s law.[16]

Method of Preparation for Turmeric Phytosome

The turmeric phytosomes were prepared by using solvent evaporation method. The turmeric phytosomes were prepared by combining turmeric and soya lecithin in different drug:phospholipid weight ratios of 1:1, 1:2, 1:3, 1:4 and 1:5 respectively. The quantity of drug was kept constant while the amount of soya lecithin was varied accordingly. The drug and phospholipid were dissolved in dichloromethane and subjected to mechanical stirring at 500 rpm. The temperature was maintained at 35–40°C until the formation of a thin film was observed. After the formation of the thin film, n-hexane was added slowly with continuous stirring while maintaining the same temperature. Subsequently, phosphate buffer (pH 6.8) was added dropwise under continuous stirring. The resulting mixture was further stirred for 20–30 min to ensure complete formation of the phytosomal complex. The obtained mixture was filtered and the residue was collected, dried properly and stored in an airtight container for further evaluation.[17].

Table 1: Formulation table of turmeric phytosome

Sr.No	Composition	F1	F2	F3	F4	F5
1	Drug	100mg	100mg	100mg	100mg	100mg
2	Soya-Lecithin	100mg	200mg	300mg	400mg	500mg
3	Dichloromethane	20ml	20ml	20ml	20ml	20ml
4	n-hexane	15ml	15ml	15ml	15ml	15ml
5	Phosphate Buffer	5ml	5ml	5ml	5ml	5ml

Characterization of the Prepared Turmeric Phytosome

Entrapment Efficiency

The phytosomal formulation (1 mg) was centrifuged at 2000 rpm for a duration of 30 min. The purpose of this process was to separate the entrapped drug from the unentrapped drug. The supernatant was collected carefully and 1 ml of the supernatant was diluted up to 10 ml with buffer solution. The concentration of the free drug present in the supernatant was determined using a UV-Visible spectrophotometer by measuring the absorbance at a wavelength of 428 nm. The amount of free drug was calculated from the calibration curve.[18]

The entrapment efficiency was calculated using the following formula:

$$\%EE = \left(\frac{Total\ amount\ of\ drug - Amount\ of\ free\ drug}{Total\ amount\ of\ drug}\right) \times 100$$

Drug Content

A precise amount of turmeric phytosomes (10mg) was weighed and transferred into a volumetric flask with a capacity of 10 ml. The flask's contents were dissolved in a small quantity of a mixture of phosphate buffer and methanol (50:50 v/v) and subjected to sonication for a duration of 30 minutes. The drug content was quantified through spectrophotometric analysis utilizing a UV Visible spectrophotometer, measuring the absorbance at a wavelength of 428 nm following suitable dilution.[19]

The drug content was calculated using following formula:

$$Drug\ Content\ (\%) = \left(\frac{Practical\ Value}{Theoretical\ Value}\right) \times 100$$

Particle Size

The particle size of optimized batch were estimated by using Malvernzetasizer.

Zeta Potential

Charge drug loaded vesicles surface of phytosome was determined using Malvern.[20]

In-Vitro Diffusion Study

A diffusion study of turmeric phytosome powder was carried out using Franz diffusion cell through dialysis membrane. Dialysis membrane was soaked in distilled water for 24 hours. The receptor compartment was filled with phosphate buffer (pH 6.8) and donor compartment contain 44mg of phytosome powder (equivalent to 10mg drug) on dialysis membrane and whole assembly was kept on magnetic stirrer at 600 rpm for a period of 10 hours and samples were withdrawn at specified time interval of 1 hr and replaced with equal volume of buffer. Samples were appropriately diluted with buffer and analyzed using UV spectrophotometer at 428 nm.Work Steady state Flux (Jss) was calculated from the slope of the linear part of the cumulative amount of drug permeated per unit area (µg/cm²) against a time (h) plot. Permeability coefficient (Kp) = Jss / Co, (Co = initial drug concentration.)[21]

Formulation of Phytosomal Gel of Turmeric

The preparation of gel was achieved by gradual addition of gelling agent 1% Carbopol 940 by mechanical mixing at 600 rpm for 30 min. A 133mg phytosome powder equivalent to 30mg drug was subsequently introduced gradually into the polymer gel. The ultimate amount was adjust to 100g utilizing distilled water. The gel that were produced were subsequently stored at ambient temperature in order to facilitate subsequent investigation.[22]

Table 2: Formulation plan of Phytosomal Gel

Sr.no.	Ingredients	Quantity
1	Carbopol 940 1g	1g
2	Propylene glycol	0.5ml
3	Methyl paraben	0.2g
4	Triethanolamine	q.s.
5	Turmeric Phytosome Powder	133mg (equivalent 30mg drug)
6	Distilled water	100ml

Evaluation of Prepared Phytosomal Gel

Determination of pH

1 g of gel was dispersed in 20 ml of distilled water, and a digital pH meter was used to determine the pH value. The measurement was perform three times and mean ± SD was calculated.[23]

Spreadability

Two glass slides measuring 20 cm × 20 cm were used for the spreadability study. A small quantity of gel was placed between the two slides and a weight of 50 g was carefully positioned on the upper slide to obtain a uniform thin film of the gel. After uniform spreading, the weight was removed and the upper slide was attached to a stand in such a manner that it could move freely under the influence of the applied weight. The time required for the upper slide to separate completely from the lower slide was recorded using a stopwatch.[24]

The following equation was used to determine the spreadability:

$S = m \times L/T$

Drug Content

The drug content was determined by dissolving 1 g of gel in 10 ml of phosphate buffer. The resulting solution was

filtered through Whatman filter paper and the filtrate was analyzed using a UV-Visible spectrophotometer.[25]

Viscosity

The measurement of viscosity of the sample was done using Brookfield Viscometer (DV-E Model). The required quantity of gel was placed in small volume holder and the spindle used was LV4-64 at room temperature and at 10, 20, 50, 100 Rpm. The corresponding viscosity value in Cp (centipoises) was noted.[26]

Washability

Washability was determined by applying the gel on the hand and washing it under running water for 1 min.

In-Vitro Drug Diffused

The in-vitro diffusion study of the phytosomal gel was performed using a Franz diffusion cell fitted with a dialysis membrane. Prior to the study, the dialysis membrane was soaked in distilled water for 24 h. The receptor compartment was filled with phosphate buffer (pH 6.8), while 1 g of phytosomal gel (equivalent to 0.3 mg drug) was placed in the donor compartment over the dialysis membrane. The entire assembly was maintained on a magnetic stirrer at 600 rpm for 10 h. Samples were withdrawn at predetermined intervals of 1 h and replaced with an equal volume of fresh buffer solution. The collected samples were suitably diluted and analyzed using a UV-Visible spectrophotometer at 428 nm.

In-vitro diffusion studies play an important role in evaluating the drug release behavior of a formulation. To understand the mechanism of drug release and release kinetics of the prepared phytosomal formulation, the diffusion data obtained from the study were fitted into various kinetic models, including Zero-order, First-order, Higuchi, and Korsmeyer–Peppas models. The regression coefficient (R^2) values obtained from each model were compared, and the model showing the highest correlation was considered as the best-fit model for describing the drug release pattern.[27]

RESULT AND DISCUSSION

Determination of wavelength maxima (ƛ max) and Calibration Curve of drug

The UV absorption spectrum of turmeric was obtained by scanning a drug solution in the wavelength range of 200–600 nm using phosphate buffer (pH 6.8) and methanol (50:50 v/v) as the solvent system. The maximum absorbance (λmax) was observed at 428 nm. A calibration curve was prepared at 428 nm using concentrations ranging from 10–50 µg/ml. The absorbance values obtained were subjected to linear regression analysis. The calibration curve exhibited good linearity, indicating compliance with Beer-Lambert's law within the selected concentration range. The results are presented in Table No. 3 and Fig. No. 1.

Table 3: Standard calibration curve of turmeric in phosphate buffer

Sr. no	Concentration ug/ml	Absorbance
1	0	0
2	10	0.06
3	20	0.09
4	30	0.13
5	40	0.17
6	50	0.23

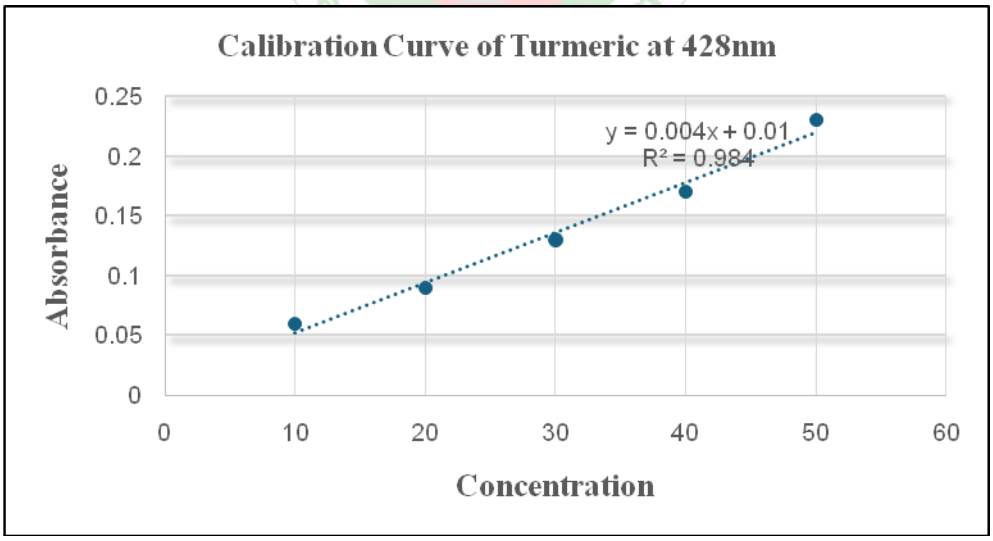

Figure1: Standard calibration curve of turmeric

Evaluation of Prepared Phytosome

Turmeric-loaded phytosomes were successfully prepared by the solvent evaporation method. The entrapment efficiency of the prepared formulations was found to be in the range of 98.24–98.87%, indicating efficient incorporation of turmeric into the phytosomal vesicles. Among all the batches, F3 exhibited the highest entrapment efficiency (98.87%). This may be attributed to the optimum drug-to-phospholipid ratio, which facilitated effective complex formation between turmeric and soya lecithin.

The drug content of the prepared phytosomal formulations was observed in the range of 18.95–22.62%, indicating satisfactory drug loading in all formulations. Among all the batches, F3 showed the highest drug content (22.62%),

which may be due to the strong interaction between turmeric and soya lecithin. Based on the highest entrapment efficiency and drug content, F3 was selected as the optimized batch for further evaluation studies.

Table 4: Result of various evaluation parameters of phytosome

Batches	% Entrapment Efficiency	% Drug Content
F1	98.24%	18.95%
F2	98.86%	19.43%
F3	98.87%	22.62%
F4	98.61%	20.93%
F5	98.48%	20.12%

Particle Size and Zeta Potential

The particle size and zeta potential of the optimized phytosomal formulation (F3) were analyzed using a Malvern Zetasizer. The particle size distribution graph illustrates the distribution of particles within different size ranges, where the x-axis indicates particle size and the y-axis represents particle intensity. The optimized formulation F3 exhibited an average particle size of 243.2 nm with a polydispersity index (PDI) of 0.185, indicating a narrow and uniform particle size distribution. The zeta potential value of F3 was found to be −11.8 mV, suggesting acceptable stability of the phytosomal formulation. The obtained results confirmed the successful formation of nanosized phytosomal vesicles (Fig. No. 2 & 3).

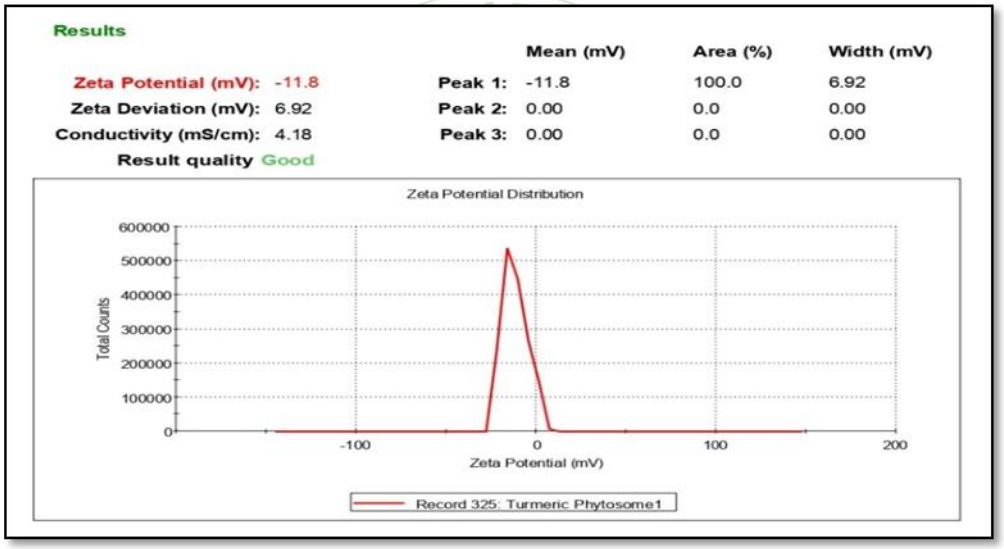

Figure 2: Particle size of phytosome

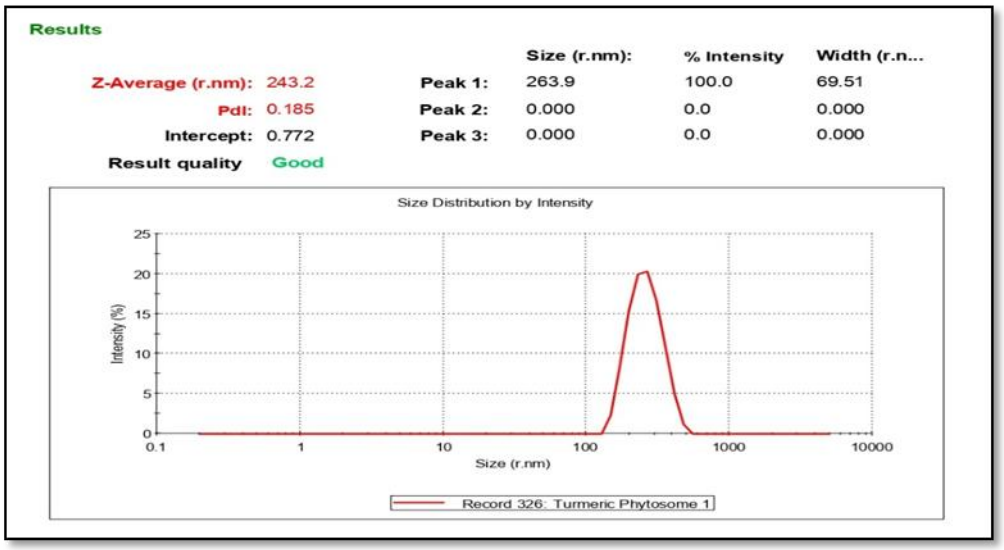

Figure 3: Zeta-potential of phytosome

In-vitro Drug Diffusion Study

The in-vitro diffusion study of turmeric demonstrated that the cumulative drug diffusion ranged from 3.42–19.03% over a period of 6 h (Fig. No.4). The permeability of turmeric through the diffusion membrane was found to be 0.014 mg/cm². In contrast, the phytosomal formulations exhibited higher drug release, with cumulative diffusion ranging from 8–89%. The permeability coefficient of the prepared phytosomal batches was observed to be in the range of 0.021–0.028 mg/cm².

Compared with the pure drug, all phytosomal formulations showed improved drug diffusion and permeability characteristics. Among the different batches, F3 exhibited the maximum cumulative drug diffusion (89%) along with the highest permeability coefficient (0.028 mg/cm²). The enhanced performance of F3 may be attributed to the optimum drug-to-phospholipid ratio, which facilitated better drug release from the phytosomal system. Hence, F3 was selected as the optimized formulation for further evaluation studies (Table No. 5 and 6).

Table 5: In-vitro drug diffusion of turmeric and phytosomal formulations

	% Cumulative Amount of Drug Diffused						
Sr.no.	**Time (Hr.)**	**Pure Drug (Turmeric)**	**F1**	**F2**	**F3**	**F4**	**F5**
1	1	3.42	8	10	12	11	9
2	2	8.76	18	21	24	22	19
3	3	11.58	29	33	37	35	31
4	4	14.92	46	51	56	53	48
5	5	17.14	58	64	69	66	61
6	6	19.03	82	86	89	87	84

Table 6: Result of permeability coefficient of turmeric and phytosome formulation

Sr. No	Batches	pKa value (mg/cm²)
1	Pure Drug (Turmeric)	0.014 mg/cm²
2	F1 (Phytosome Formulation)	0.021 mg/cm²
3	F2	0.024 mg/cm²
4	F3	0.028 mg/cm²
5	F4	0.026 mg/cm²
6	F5	0.023 mg/cm²

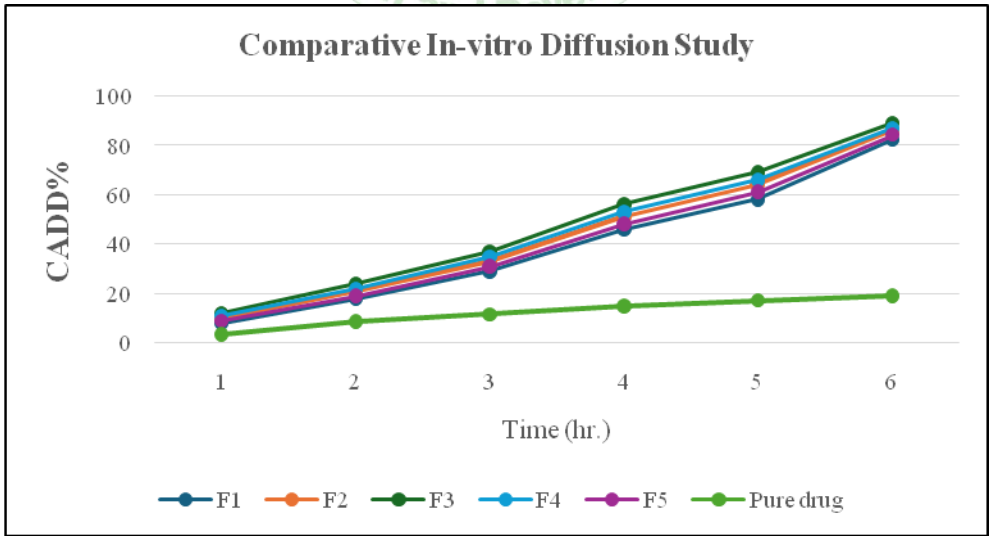

Figure4: % Comparative In-vitro Diffusion Study of Pure Drug and Phytosomal Formulations (F1–F5)

Evaluation of Prepared Phytosomal Gel

The phytosomal gel was formulated using Carbopol 940 as the gelling agent, and the optimized phytosomal formulation (F3) was incorporated into the gel base. The pH of the prepared gel was determined in triplicate, and the average pH was found to be 6.82, indicating its compatibility with the normal skin pH. The spreadability of the gel was recorded as 17.5 g.cm/s, suggesting that the formulation can be applied and spread easily over the skin surface. The drug content of the prepared phytosomal gel was found to be 40.95%, confirming satisfactory

incorporation and uniform distribution of turmeric within the gel. The viscosity study demonstrated that the viscosity decreased with an increase in spindle speed (rpm) and increased with a decrease in rpm, indicating shear-dependent flow behavior. The rheological evaluation further confirmed that the gel exhibited pseudoplastic (shear-thinning) characteristics, which are considered suitable for topical formulations. The washability of the prepared gel was found to be 82%, indicating good retention during application while allowing easy removal with water. Overall, the prepared phytosomal gel showed satisfactory physicochemical properties and was considered suitable for topical drug delivery.

Table 7: Result of prepared phytosomal gel

Sr. no.	Batch	pH	Spread ability	Drug Content
1	F3 (1:3)	6.82	17.5g.cm/s	40.95%

Table 8: Result of Viscosity

Sr. no.	Temperature	RPM	Viscosity cps	RPM	Viscosity cps
1	37.4°C	10	65651	100	6577
2	37.4°C	20	32863	50	13157
3	37.4°C	50	13150	20	32892
4	37.4°C	100	6577	10	65777

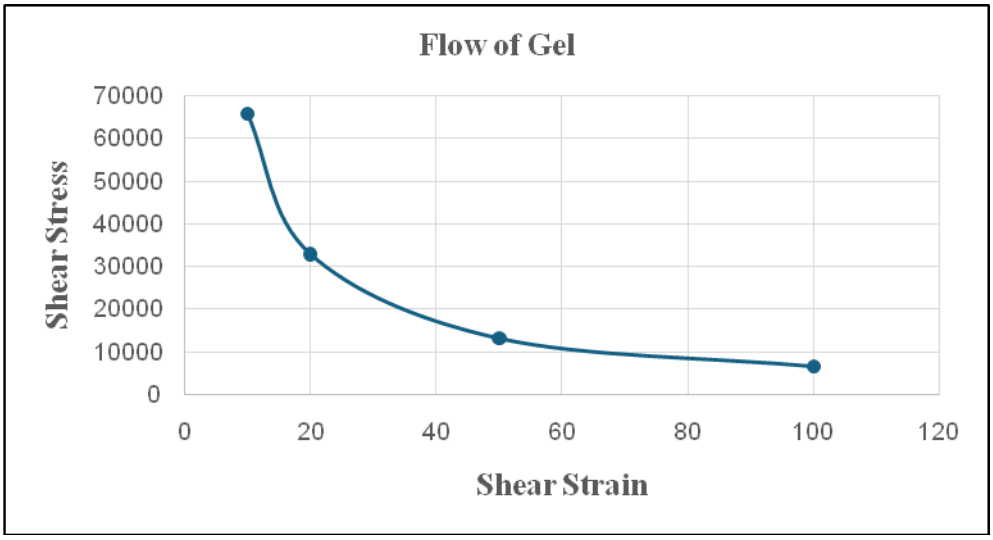

Figure 5: Flow of Gel

Table 9: Result of Washability

Sr. no.	Time (min.)	Wt. of gloves + gel	Wt. of gloves after washing and dry	Washability%
1	1	8.42g + 1g = 9.42g	8.60g	82%

In-Vitro Diffusion Study

The in-vitro diffusion study of the phytosomal gel showed that the cumulative drug release was 72.16% after 6 h. At 4 h, the phytosomal gel exhibited 39.64% drug diffusion, and the permeability coefficient of the gel through the diffusion membrane was found to be 0.07 mg/cm². The drug release kinetics study showed that the phytosomal gel followed the Korsmeyer–Peppas model, as it exhibited the highest R^2 value (Table No. 10).

Table 10: Regression coefficient of phytosomal gel

Sr. No.	Phytosomal gel	Zero order kinetic	First order kinetic	Higuchi model	Korsmeyer–Peppas
1	F3 (1:3)	0.9867	0.9253	0.944	0.9975

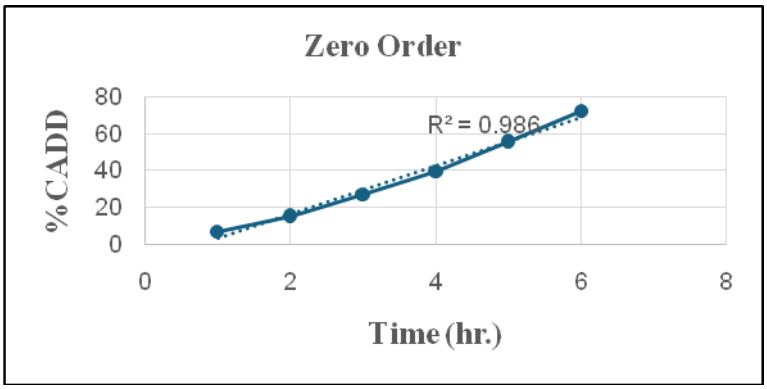

Figure 6: Plot of % Cum. Drug released Vs. Time (Zero order kinetic)

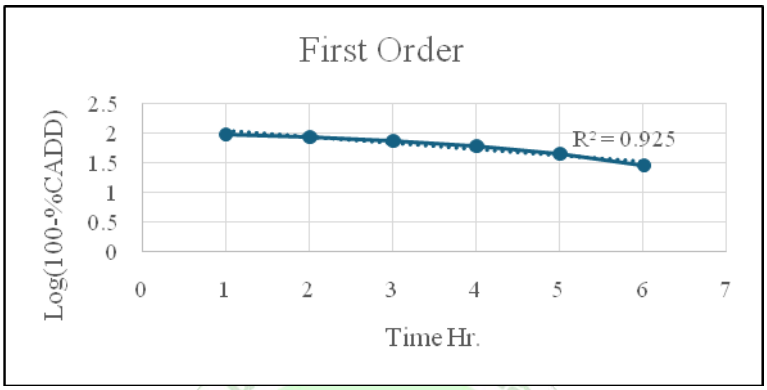

Figure 7: Plot of log % Cum. Drug retained Vs. Time (First order kinetic)

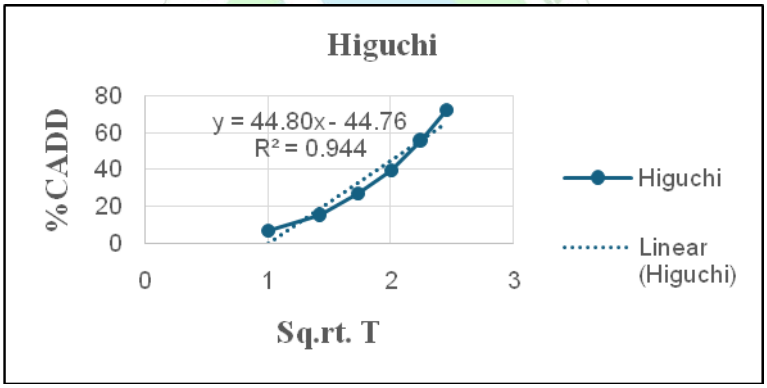

Figure 8: Plot of % Cum. Drug released Vs. square root of time (Higuchi model)

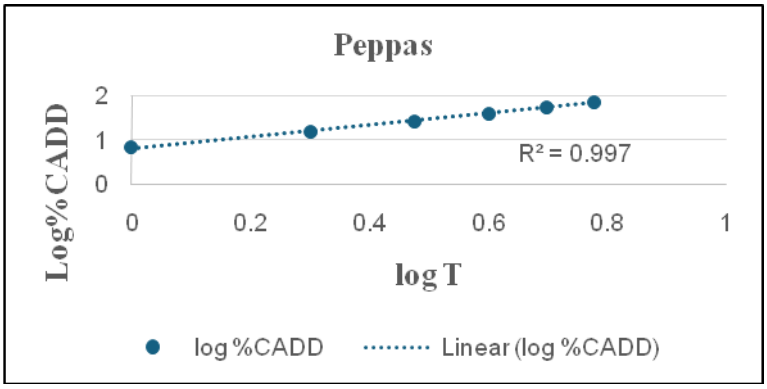

Figure 9: Plot of log % Cum. Drug released Vs. log of time (Korsmeyer-Peppas model)

CONCLUSION

Turmeric-loaded phytosomes were successfully prepared by the solvent evaporation method using different drug-to-phospholipid ratios. Among all the formulations, batch F3 was selected as the optimized formulation based on its highest entrapment efficiency (98.87%), drug content (22.62%), cumulative drug diffusion (89%) and permeability coefficient (0.028 mg/cm²). The optimized formulation exhibited a particle size of 243.2 nm and a zeta potential of −11.8 mV, indicating the successful formation of the phytosomal system. The optimized phytosomal formulation was incorporated into Carbopol 940 gel, which

exhibited satisfactory physicochemical properties, including a pH of 6.82, spreadability of 17.5 g.cm/s, and drug content of 40.95%. The prepared phytosomal gel showed cumulative drug diffusion of 72.16% after 6 h, with a permeability coefficient of 0.07 mg/cm². Drug release from the prepared gel followed the Korsmeyer–Peppas kinetic model (R^2 = 0.9975), indicating controlled and diffusion-mediated drug release. Overall, the developed turmeric phytosomal gel demonstrated enhanced drug diffusion and satisfactory physicochemical characteristics, suggesting its potential as an effective topical drug delivery system for the management of acne.

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