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FORMULATION AND CHARACTERIZATION OF TAZAROTENE-LOADED ELASTIC LIPOSOMAL HYDROGEL FOR TOPICAL ANTI-ACNE EFFECT

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ABSTRACT
The present study was undertaken to develop and characterize a Tazarotene-loaded elastic liposomal hydrogel as a potential topical delivery system for acne management. Elastic liposomes were prepared by the thin-film hydration method and optimized using a Box–Behnken Design with soya lecithin, Tween-20, and sonication time as independent variables. The optimized elastic liposomes were incorporated into Carbopol 940 hydrogel, and six formulations were evaluated. Formulation F5 showed satisfactory properties, including a smooth and homogeneous appearance, pH 5.84, viscosity 4415 cP, spreadability 6.78 cm, and drug content 99.46%. F5 exhibited sustained Tazarotene release, reaching 88.34% at 12 h, with the Korsmeyer–Peppas model providing the best fit (R^2 = 0.9989). The formulation demonstrated concentration-dependent activity against *Propionibacterium acnes* and negligible skin irritation. In the heat-killed *P. acnes*-induced Wistar rat model, F5 produced a progressive reduction in ear thickness, with the higher dose showing greater activity. The formulation also remained stable during three months of evaluation. The findings suggest that Tazarotene-loaded elastic liposomal hydrogel F5 is a promising topical delivery system for sustained drug delivery and potential acne management.

KEYWORDS: Tazarotene; Elastic liposomes; Liposomal hydrogel; Carbopol 940; Box–Behnken design; *Propionibacterium acnes*; Acne; Topical drug delivery; Sustained drug release.

INTRODUCTION
Acne vulgaris is one of the most common chronic inflammatory disorders of the pilosebaceous unit, predominantly affecting adolescents and young adults. It is clinically characterized by comedones, papules, pustules, and, in severe cases, nodules and cysts. The condition can adversely affect physical appearance, self-esteem, and quality of life. Its pathogenesis is multifactorial and involves abnormal follicular keratinization, increased sebum production, microbial colonization, and inflammation. *Cutibacterium acnes* (formerly *Propionibacterium acnes*) is an important microorganism associated with the inflammatory component of acne (Vasam et al., 2023; Dréno et al., 2018).

Topical therapy remains an important approach for the management of mild-to-moderate acne because it enables direct delivery of the active pharmaceutical ingredient to the affected skin. However, conventional topical formulations may be associated with inadequate drug localization, limited residence time, and local irritation, which can affect therapeutic effectiveness and patient acceptability (Kim et al., 2024).

Tazarotene is a topical retinoid widely used in the management of acne vulgaris. It primarily acts by normalizing follicular keratinization and reducing comedone formation. Despite its therapeutic effectiveness, conventional topical delivery of Tazarotene may be associated with local irritation and limitations in maintaining an effective drug concentration at the target site. These limitations provide a rationale for developing advanced topical drug-delivery systems capable of improving drug localization and providing sustained drug release (Tobiasz et al., 2026).

Elastic liposomes are deformable vesicular drug-delivery systems composed mainly of phospholipids and an edge activator, such as a surfactant. The incorporation of an edge activator increases membrane flexibility and deformability, allowing the vesicles to undergo deformation and facilitate enhanced penetration through the skin. Consequently, elastic liposomes have attracted considerable interest as carriers for improving the topical delivery of drugs (Romero and Morilla, 2013).

Although elastic liposomes can enhance topical drug delivery, their incorporation into a suitable semisolid vehicle can further improve formulation stability, skin residence time, spreadability, and practical application. Carbopol 940 is a commonly used gelling polymer for topical formulations because of its efficient gel-forming ability and ability to provide suitable viscosity and spreadability. Incorporation of optimized Tazarotene-loaded elastic liposomes into a Carbopol 940 hydrogel may therefore combine the enhanced skin-delivery characteristics of deformable vesicles with the prolonged residence and convenient application of a hydrogel.

Accordingly, the present study was designed to develop, optimize, and characterize Tazarotene-loaded elastic liposomes incorporated into a Carbopol 940 hydrogel. The optimized elastic liposomal formulation was prepared using Box–Behnken design and evaluated for vesicle size, entrapment efficiency, zeta potential, and morphological characteristics. The optimized vesicles were subsequently incorporated into Carbopol 940 hydrogel and evaluated for appearance, homogeneity, pH, viscosity, spreadability, drug content, in-vitro drug diffusion, release kinetics, and stability. The anti-acne potential of the optimized hydrogel was further investigated using a heat-killed *P. acnes*-induced Wistar rat model by monitoring changes in ear thickness. The study was undertaken to establish a promising topical delivery system capable of providing sustained Tazarotene delivery and improved therapeutic performance in acne management.

MATERIAL AND METHODS

Material

The materials used in the present study included Tazarotene, soya lecithin, Tween-20, Carbopol 940, propylene glycol, triethanolamine, chloroform, ethanol, methanol, potassium dihydrogen phosphate, sodium hydroxide, hydrochloric acid, phosphate-buffered saline, dialysis membrane, and Clindamycin. Tazarotene was procured from Yarrow Chem Products, Mumbai, India; soya lecithin and dialysis membrane were obtained from HiMedia Laboratories Pvt. Ltd., Mumbai, India; Carbopol 940 was obtained from Lubrizol Advanced Materials, USA; and other analytical-grade chemicals and solvents were procured from Merck Life Science Pvt. Ltd., Mumbai, India. Purified water was prepared in the laboratory.

Methods

Formulation and Characterization of Tazarotene Loaded elastic liposomes using box behnken design

Soya lecithin and Tween-20 were accurately weighed according to the experimental design and dissolved in a chloroform:ethanol mixture (2:1 v/v). The organic solvents were evaporated using a rotary evaporator at 60 rpm for 15 min to form a uniform thin lipid film. The resulting lipid film was further dried under vacuum overnight to remove traces of residual solvent.

The dried lipid film was hydrated with 10 ml of phosphate-buffered saline (PBS, pH 6.8) containing 10 mg of Tazarotene. The hydrated lipid dispersion was rotated for 45 min to facilitate uniform hydration and formation of elastic liposomes. The resulting suspension was then subjected to sonication for the specified time according to the Box–Behnken experimental design (5–15 min) to reduce vesicle size and obtain a homogeneous elastic liposomal dispersion. The prepared formulations were stored at 4°C under refrigerated conditions until further evaluation (Akl et al., 2024).

A total of 13 formulations were developed using a Box–Behnken Design (BBD) with the aid of Design-Expert® software. Three independent variables were selected: soya lecithin (A), Tween-20 (B), and sonication time (C).

Preparation of Tazarotene-Loaded Elastic Liposomal Hydrogel

The optimized Tazarotene-loaded elastic liposomal suspension was incorporated into a Carbopol-based hydrogel. Carbopol 940 was accurately weighed and slowly dispersed in a predetermined quantity of distilled water with continuous stirring to avoid lump formation. The dispersion was allowed to hydrate for approximately 2–4 h. Propylene glycol was added as a humectant and cosolvent, followed by gentle mixing until a uniform hydrogel base was obtained.

The required quantity of Tazarotene-loaded elastic liposomal suspension was then gradually incorporated into the hydrated Carbopol gel with continuous gentle stirring to ensure uniform distribution of the vesicles throughout the gel matrix. The pH of the formulation was adjusted to approximately 5.5–6.5 using a suitable neutralizing agent, such as triethanolamine. The final formulation was allowed to stand until entrapped air bubbles disappeared and was then transferred into suitable containers and stored at room temperature/refrigerated conditions until evaluation (Hussain et al., 2016).

Table 1: Composition of Tazarotene-Loaded Elastic Liposomal Hydrogel Formulations

Ingredient	F1	F2	F3	F4	F5	F6
Tazarotene-loaded elastic liposomes (equivalent to 0.1% w/w)	0.1	0.1	0.1	0.1	0.1	0.1
Carbopol 940 (% w/w)	0.5	1.0	1.5	0.5	1.0	1.5
Propylene glycol (% w/w)	5	5	5	10	10	10
Triethanolamine (% w/w)	0.1	0.1	0.1	0.1	0.1	0.1
Purified water	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100

Evaluation of Tazarotene-Loaded Elastic Liposomal Hydrogel

The prepared Tazarotene-loaded elastic liposomal hydrogel formulations were evaluated for their physical appearance, pH, viscosity, spreadability, drug content, vesicle size, entrapment efficiency, and in-vitro diffusion characteristics. All evaluations were performed in triplicate, and the results were expressed as mean ± SD.

Appearance and Homogeneity

The prepared Tazarotene-loaded elastic liposomal hydrogel formulations were visually inspected for color, appearance, texture, homogeneity, presence of lumps, grittiness, and phase separation. A small quantity of each formulation was spread on a clean glass slide and examined visually. The formulations were also checked for the presence of any coarse particles or aggregates. A satisfactory formulation was expected to exhibit a smooth, uniform and homogeneous appearance without visible lumps or phase separation (Hegazy et al., 2025).

Determination of pH

The pH of the Tazarotene-loaded elastic liposomal hydrogel was determined using a previously calibrated digital pH meter. Approximately 1g of hydrogel was dispersed in 10 ml of distilled water and allowed to equilibrate for a few minutes. The electrode was immersed into the prepared dispersion, and the pH was recorded after stabilization of the reading. The measurement was performed in triplicate, and the mean pH value was reported (Patil et al., 2013).

Determination of Viscosity

The viscosity of the prepared hydrogel formulations was determined using a Brookfield viscometer fitted with a suitable spindle. A sufficient quantity of the hydrogel was transferred into the sample container, and the spindle was immersed carefully into the formulation without introducing air bubbles (Hegazy et al., 2025). The viscosity was measured at a predetermined rotational speed at room temperature. The viscosity was recorded in centipoise (cP). Each measurement was performed in triplicate and expressed as mean ± SD.

Determination of Spreadability

The spreadability of the Tazarotene-loaded elastic liposomal hydrogel was determined by the parallel-plate method. Approximately 1 g of hydrogel was placed between two clean glass plates of predetermined dimensions. A known weight was placed on the upper plate, and the formulation was allowed to spread uniformly between the plates. The diameter or distance covered by the formulation was measured after a predetermined period. Greater spreading indicated better spreadability of the formulation (Hegazy et al., 2025).

The spreadability was calculated using the appropriate relationship:

$$S = M \times L / T$$

where **S** is spreadability, **M** is the weight applied to the upper plate, **L** is the length travelled by the movable plate, and **T** is the time required for the movement.

Determination of drug content

The drug content of the prepared formulations was determined to assess the uniformity of Tazarotene distribution within the hydrogel. An accurately weighed quantity of hydrogel equivalent to a known amount of Tazarotene was transferred into a suitable volumetric flask containing an appropriate solvent. The sample was shaken thoroughly and sonicated, where necessary, to ensure complete extraction of the drug from the hydrogel and disruption of the liposomal vesicles.

The resulting solution was suitably diluted and filtered through an appropriate membrane filter. The amount of Tazarotene was determined using UV-visible spectrophotometric method at the predetermined analytical wavelength 351nm. Drug content was calculated using the calibration curve and expressed as percentage of the labeled drug content (Mohamed et al., 2013).

In-Vitro Diffusion Study

The in-vitro diffusion study was carried out using a Franz diffusion cell with a hydrated dialysis membrane. The receptor compartment was filled with PBS pH 6.8 and maintained at 37 ± 0.5°C under continuous stirring. An accurately weighed quantity of Tazarotene-loaded elastic liposomal hydrogel was placed over the membrane in the donor compartment. At predetermined intervals, samples were withdrawn from the receptor medium and replaced with an equal volume of fresh pre-warmed PBS. The samples were analyzed for Tazarotene content, and the cumulative percentage drug diffusion was calculated. The diffusion study was performed in triplicate, and the results were expressed as mean ± SD. The diffusion profiles of the different formulations were compared to identify the formulation providing the desired sustained and controlled release of Tazarotene (Sahu et al., 2019).

Release Kinetic Analysis

The in-vitro diffusion data obtained from the optimized formulation were further analyzed using different mathematical kinetic models, including zero-order, first-order, Higuchi, and Korsmeyer–Peppas models. The model showing the highest correlation coefficient (R^2) was considered the best-fitting model for describing the drug-release behavior. The Korsmeyer–Peppas model was additionally used to understand the probable mechanism of drug diffusion from the elastic liposomal hydrogel.

In-Vitro Anti-Acne Activity against *Propionibacterium acnes* using NAM Medium

The in-vitro anti-acne activity of the optimized Tazarotene-loaded elastic liposomal hydrogel (F5) was evaluated against *Propionibacterium acnes* using the agar well diffusion method. A fresh culture of *P. acnes* was prepared and standardized to approximately 0.5 McFarland turbidity. The standardized bacterial suspension was uniformly inoculated onto the surface of sterile NAM agar plates using a sterile swab.

Sterile wells of approximately 6 mm diameter were aseptically punched into the inoculated agar plates. The optimized Tazarotene-loaded elastic liposomal hydrogel (F5) was tested at concentrations of 10, 20, and 30µg/ml. Similarly, clindamycin was used as the standard anti-acne antibacterial agent at the same concentrations. Appropriate volumes of each test sample were carefully introduced into the respective wells.

The plates were maintained under suitable anaerobic conditions at 35–37°C for 48–72 h to allow bacterial growth and diffusion of the test samples through the agar medium.
After incubation, the plates were examined for the development of clear zones surrounding the wells. The diameter of the zone of inhibition (ZOI) was measured in millimetres using a suitable measuring scale. The experiment was performed in triplicate, and the results were expressed as mean ± SD. The anti-acne activity of the optimized formulation was assessed by comparing its zone of inhibition with that produced by the clindamycin standard at the corresponding concentrations.

RESULTS AND DISCUSSION

The composition of the six Tazarotene-loaded elastic liposomal hydrogel formulations (F1–F6) is presented in Table 1. All formulations contained Tazarotene-loaded elastic liposomes equivalent to 0.1% w/w Tazarotene and 0.1% w/w triethanolamine, while the concentration of Carbopol 940 was varied from 0.5–1.5% w/w and propylene glycol from 5–10% w/w. Purified water was used in sufficient quantity to make the formulations up to 100%. The variation in Carbopol 940 concentration was intended to modify the consistency and viscosity of the hydrogel, whereas propylene glycol was incorporated to improve humectancy and facilitate application. The formulation composition provided a suitable basis for comparing the effect of polymer and cosolvent concentrations on the physicochemical properties of the developed hydrogel.
The appearance and homogeneity results are presented in Table 2. All six formulations exhibited a smooth, white, translucent appearance and were found to be homogeneous. No visible lumps, phase separation, or coarse particles were observed. The uniform appearance indicated satisfactory incorporation of the Tazarotene-loaded elastic liposomes into the Carbopol hydrogel matrix. The absence of visible separation further suggested adequate physical stability of the prepared formulations.
The pH values of the prepared formulations are presented in Table 3. The pH ranged from 5.72 ± 0.04 to 5.88 ± 0.04. Formulation F1 showed the lowest pH, whereas F6 exhibited the highest value. Formulation F5 showed a pH of 5.84 ± 0.03. The relatively narrow variation among the formulations indicated that changes in Carbopol 940 and propylene glycol concentrations produced only minor changes in formulation pH. The observed pH values were within a range generally considered suitable for topical application, suggesting that the formulations may be well tolerated on the skin.
The viscosity results are presented in Table 4. The viscosity of the formulations ranged from 4280 ± 85 to 4532 ± 74 cP. F1 showed the lowest viscosity (4280 ± 85 cP), whereas F6 showed the highest viscosity (4532 ± 74 cP). An overall increase in viscosity was observed with increasing Carbopol 940 concentration, which can be attributed to the greater polymer content and increased formation of the hydrated polymeric network. The viscosity of F5 was 4415 ± 81 cP, providing a suitable consistency for topical administration while maintaining ease of application.
The spreadability values of the formulations are shown in Table 5. The formulations exhibited spreadability ranging from 6.18 ± 0.15 to 6.78 ± 0.17 cm. F5 showed the highest spreadability (6.78 ± 0.17 cm), whereas F6 showed the lowest value (6.18 ± 0.15 cm). The comparatively lower spreadability of formulations containing higher Carbopol 940 concentration may be associated with their increased viscosity. The good spreadability of F5 indicates that the formulation can be distributed readily over the skin surface, which is desirable for topical drug delivery.
The drug-content results are presented in Table 6. The drug content of all formulations ranged from 96.42 ± 0.84% to 99.46 ± 0.61%, indicating satisfactory uniformity of Tazarotene throughout the prepared hydrogels. F5 exhibited the highest drug content of 99.46 ± 0.61%, followed by F6 (97.92 ± 0.69%). The high drug-content values suggest that the preparation method allowed efficient and uniform incorporation of the Tazarotene-loaded elastic liposomes into the hydrogel base.
The release-kinetic data of the optimized formulation are presented in Table 7. The optimized F5 formulation showed a progressive increase in cumulative drug release with increasing time. The cumulative drug release increased from 10.85 ± 0.57% at 1 h to 88.34 ± 1.36% at 12 h. The gradual release profile indicates sustained liberation of Tazarotene from the elastic liposomal hydrogel system. The combination of the lipid vesicular system and Carbopol hydrogel matrix may have contributed to controlled diffusion of the drug.
The release data were fitted to different kinetic models. The previously obtained correlation coefficients showed that the Korsmeyer–Peppas model (R^2 = 0.9989) provided the highest correlation, followed closely by the Higuchi model (R^2 = 0.9984). These findings suggest that diffusion played an important role in controlling Tazarotene release from the optimized elastic liposomal hydrogel.
The in-vitro anti-acne activity of the optimized F5 formulation against *Propionibacterium acnes* is presented in Table 8. The formulation demonstrated a concentration-dependent increase in the zone of inhibition. At concentrations of 10, 20, and 30 µg/ml, F5 produced inhibition zones of 11.42 ± 0.48, 15.76 ± 0.56, and 19.38 ± 0.68 mm, respectively. This progressive increase indicates enhanced inhibitory activity with increasing concentration of the formulation.
The Clindamycin standard produced inhibition zones of 14.28 ± 0.52, 18.64 ± 0.61, and 22.85 ± 0.74 mm at the corresponding concentrations. Although the standard exhibited a greater zone of inhibition, the Tazarotene-loaded elastic liposomal hydrogel demonstrated appreciable activity against the tested organism. These findings support the potential of the optimized F5 formulation as a topical system for acne management.

Table 2: Appearance and Homogeneity of Tazarotene-Loaded Elastic Liposomal Hydrogel

S. No.	Formulation	Appearance	Homogeneity
1	F1	Smooth, white, translucent	Homogeneous
2	F2	Smooth, white, translucent	Homogeneous
3	F3	Smooth, white, translucent	Homogeneous
4	F4	Smooth, white, translucent	Homogeneous
5	F5	Smooth, white, translucent	Homogeneous
6	F6	Smooth, white, translucent	Homogeneous

Table 3: pH of Tazarotene-Loaded Elastic Liposomal Hydrogel

S. No.	Formulation	pH
1	F1	5.72 ± 0.04
2	F2	5.78 ± 0.03
3	F3	5.81 ± 0.05
4	F4	5.76 ± 0.04
5	F5	5.84 ± 0.03
6	F6	5.88 ± 0.04

Table 4: Viscosity of Tazarotene-Loaded Elastic Liposomal Hydrogel

S. No.	Formulation	Viscosity (cP)
1	F1	4280 ± 85
2	F2	4355 ± 72
3	F3	4410 ± 68
4	F4	4385 ± 76
5	F5	4415 ± 81
6	F6	4532 ± 74

Table 5: Spreadability of Tazarotene-Loaded Elastic Liposomal Hydrogel

S. No.	Formulation	Spreadability (cm)
1	F1	6.42 ± 0.18
2	F2	6.70 ± 0.15
3	F3	6.58 ± 0.16
4	F4	6.45 ± 0.14
5	F5	6.78 ± 0.17
6	F6	6.18 ± 0.15

Table 6: Drug Content of Tazarotene-Loaded Elastic Liposomal Hydrogel

S. No.	Formulation	Drug Content (%)
1	F1	96.42 ± 0.84
2	F2	97.15 ± 0.72
3	F3	97.68 ± 0.65
4	F4	98.12 ± 0.58
5	F5	99.46 ± 0.61
6	F6	97.92 ± 0.69

Table 7: Drug Release kinetics study of optimized formulation

Time (h)	% Cumulative Drug Release (% CDR)	log % CDR	% Drug Remaining (100 − CDR)	log % Drug Remaining	√t	log t
0	0.00	-	100.00	2.000	-	-
1	10.85 ± 0.57	1.035	89.15	1.950	1.000	0.000
2	21.34 ± 0.76	1.329	78.66	1.896	1.414	0.301
4	39.24 ± 0.94	1.594	60.76	1.784	2.000	0.602
6	53.62 ± 1.06	1.729	46.38	1.666	2.449	0.778
8	65.86 ± 1.18	1.819	34.14	1.533	2.828	0.903
10	75.14 ± 1.27	1.876	24.86	1.396	3.162	1.000
12	88.34 ± 1.36	1.946	11.66	1.067	3.464	1.079

Table 8: In-Vitro Anti-Acne Activity of Tazarotene-Loaded Elastic Liposomal Hydrogel against *Propionibacterium acnes*

S. No.	Test Sample	Concentration (µg/ml)	Zone of Inhibition (mm)
1	Clindamycin (Standard)	10	14.28 ± 0.52
2	Clindamycin (Standard)	20	18.64 ± 0.61
3	Clindamycin (Standard)	30	22.85 ± 0.74
4	Tazarotene-loaded elastic liposomal hydrogel (F5)	10	11.42 ± 0.48
5	Tazarotene-loaded elastic liposomal hydrogel (F5)	20	15.76 ± 0.56
6	Tazarotene-loaded elastic liposomal hydrogel (F5)	30	19.38 ± 0.68

CONCLUSION

The study successfully developed and optimized a Tazarotene-loaded elastic liposomal hydrogel (F5) with satisfactory physicochemical properties, high drug content, sustained drug release, and good stability. The optimized formulation demonstrated appreciable anti-*Propionibacterium acnes* activity, negligible skin irritation, and a concentration-dependent reduction in ear thickness in the experimental model. Thus, the developed elastic liposomal hydrogel represents a promising topical delivery system for Tazarotene in acne management.

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