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DESIGN, DEVELOPMENT, FORMULATION AND EVALUATION OF POSACONAZOLE AND ALOIN CONTAINING NOVEL VESICLE SYSTEM FOR ANTI-FUNGAL ACTIVITY

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Keywords:

Liposomal gel, Posaconazole, Aloin, Entrapment efficiency, Antifungal activity, Higuchi model

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ABSTRACT: Background: Posaconazole is a potent triazole antifungal with poor aqueous solubility, while Aloin from *Aloe vera* exhibits complementary antifungal and wound-healing properties. Co-delivery in a liposomal gel may enhance solubility, stability, and skin penetration. **Objective:** To design and evaluate a novel liposomal vesicle system co-encapsulating Posaconazole and Aloin for topical antifungal therapy. **Methods:** Liposomes were prepared by thin-film hydration using varying ratios of soya lecithin and cholesterol, followed by incorporation into a carbopol-based gel. Formulations were characterized for particle size, zeta potential, entrapment efficiency, viscosity, pH, spreadability, *in-vitro* drug release, and antifungal efficacy against Candida albicans. **Results:** The optimized formulation (LDDS3) showed the smallest particle size (68.07 nm), highest zeta potential (−15.8 mV), and entrapment efficiency (93.22%). The gel exhibited suitable viscosity (4836 ± 0.26 cps), pH (5.6) and good spreadability. The *in-vitro* release followed Higuchi kinetics (R^2 = 0.9701), indicating diffusion-controlled release. The liposomal gel displayed a concentration-dependent inhibition zone (up to 15 mm) against *Candida albicans*. **Conclusion:** Co-encapsulation of Posaconazole and Aloin in liposomal gel significantly enhanced solubility, stability, and antifungal efficacy, suggesting its potential as a novel topical delivery system for cutaneous fungal infections.

INTRODUCTION: Conventional antifungal therapies often face limitations such as poor solubility, low skin permeability, and systemic toxicity. Liposomes phospholipid-based vesicles capable of encapsulating both hydrophilic and lipophilic drugs offer improved dermal penetration and sustained release profiles [1]. Posaconazole, a triazole antifungal, inhibits 14-α-demethylase, blocking ergosterol synthesis and disrupting fungal membrane integrity [2]. However, its poor solubility limits topical use [3].

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Aloin, a bioactive compound from Aloe vera, exhibits antifungal, anti-inflammatory, and wound-healing effects [4]. Its combination with Posaconazole may yield synergistic antifungal activity and improved therapeutic performance. This study aims to develop and optimize a novel liposomal gel system co-encapsulating Posaconazole and Aloin for topical delivery, targeting enhanced antifungal efficacy, stability, and patient compliance.

MATERIALS AND METHODS:

Study Design and Period: The present research work entitled "Design, Development, Formulation and Evaluation of Posaconazole and Aloin Containing Novel Vesicle System for Antifungal Activity" was carried out at Sagar Institute of Pharmacy and Technology (SIPT), Bhopal, Madhya Pradesh, India, during the period

December 2023 to May 2025. The study involved formulation optimization, characterization, and antifungal evaluation of Posaconazole and Aloin-loaded liposomal gel.

Chemicals: Posaconazole was obtained as a gift sample from Pfizer India Pvt. Ltd. Aloin and potassium bromide (KBr) were purchased from Labogens, India. Methanol, dimethyl sulfoxide (DMSO), and chloroform were procured from Rankem. All other solvents and reagents were of analytical (AR) grade, purchased from Oxford, Recombigen, Analytical, and Himedia Laboratories.

Pre-formulation Studies: Preformulation studies were conducted to determine the fundamental physical and chemical characteristics of Posaconazole and Aloin prior to formulation development. These included solubility, melting point, pH, compatibility, and stability studies. Analytical techniques such as UV–Visible spectroscopy and Fourier Transform Infrared (FTIR) spectroscopy were used to assess purity and identify potential drug excipient interactions [5].

Organoleptic Properties: The color, odor, taste, and appearance of both drugs were evaluated visually [6].

Solubility Study: Solubility was assessed by adding 1 mg of each drug to 1 mL of various polar and non-polar solvents. Samples were shaken thoroughly and allowed to stand at room temperature. The presence of turbidity or undissolved particles indicated poor solubility, while clear solutions indicated good solubility [7].

Melting Point: Melting points were determined using a digital melting point apparatus [8].

pH Determination: The pH of both drugs was measured using a digital pH meter to evaluate their acidic or basic nature [9].

Preparation of Standard Stock Solution: Ten milligrams of each drug were accurately weighed and dissolved in 5 mL methanol in a 10 mL volumetric flask. The volume was made up to 10 mL with methanol to obtain a 1000 µg/mL stock solution. A 100 µg/mL working solution was prepared by diluting 1 mL of the stock to 10 mL with methanol [10].

Determination of λmax: A 20 µg/mL solution of each drug was scanned between 200–400nm using a UV–Visspectrophotometer, with methanol as the blank, to determine the absorption maxima [11].

Linearity and Calibration Curve: The standard solutions were diluted to obtain concentrations of 5–25 µg/mL (Posaconazole) and 40–80 µg/mL (Aloin)**.** Absorbance was measured at 260 nm and 298 nm, respectively. Calibration curves were plotted to confirm linearity [12].

Functional Group Identification by FTIR: FTIR analysis was conducted using the KBr pellet method to identify characteristic functional groups and confirm compatibility. One milligram of each drug was mixed with 100 mg KBr, compressed into a disc, and scanned between 400–4000 cm^{-1} [13].

Preparation of Liposomal Formulations:

Rationale for Concentration Selection: Posaconazole and Aloin were incorporated in a 1:1 drug ratio (200 mg each) to achieve synergistic antifungal activity. Lipid compositions were optimized by varying soya lecithin (100–300 mg) and cholesterol (50–250 mg) concentrations to evaluate their effects on vesicle size, stability, and entrapment efficiency, following previously reported methods [14].

Method of Preparation: Liposomes were prepared by the thin-film hydration technique using a rotary evaporator. The drug, soya lecithin, and cholesterol were dissolved in chloroform: ethanol (8:2 v/v) and transferred to a 250 mL round-bottom flask. The solvent was evaporated under vacuum at 40°C and 900 mm Hg, rotating at 80 rpm for 30 minutes, to form a thin lipid film. The dry film was hydrated with 15 mL phosphate buffer (pH 6.8) and agitated for 2 hours to obtain a milky dispersion. The liposomal suspension was centrifuged at 3000 rpm for 30 minutes, and the resulting liposomes were collected and stored in airtight containers [15].

TABLE 1: COMPOSITION OF LIPOSOMES:

Ingredients	LDDS1	LDDS2	LDDS3	LDDS4	LDDS5
Drug (Posaconazole: Aloin, 1:1)	200:200	200:200	200:200	200:200	200:200

Soya Lecithin (mg)	100	150	200	250	300
Cholesterol (mg)	50	100	150	200	250
Phosphate Buffer (pH 6.8, mL)	15	15	15	15	15
Chloroform (mL)	8	8	8	8	8
Ethanol (mL)	2	2	2	2	2
Methyl Paraben (%)	0.02	0.02	0.02	0.02	0.02
Propyl Paraben (%)	0.02	0.02	0.02	0.02	0.02

Evaluation of Liposome Formulations:

Physical Properties: Formulations were visually inspected for color, clarity, and homogeneity.

Particle Size Distribution: Particle size was determined using a Malvern Zetasizer (Malvern Instruments, UK).

Zeta Potential: The surface charge of diluted liposomal dispersions was analyzed using a Zetasizer to evaluate stability.

Scanning Electron Microscopy (SEM): Morphology and surface characteristics were studied using SEM after sputter coating with gold under vacuum [16].

Entrapment Efficiency (EE%): EE% was determined indirectly by centrifuging the liposomal suspension at 15,000 rpm for 30 min. The unentrapped drug in the supernatant was quantified spectrophotometrically, and EE% was calculated as:

%EE = (Total amount of drug - Amount of free/unentrapped drug) / Total amount of drug × 100

Formulation of Liposomal Gel: Carbopol-940 (0.5 g) was dispersed in 50 mL warm water and hydrated for 2 hours (Solution A). Separately, carboxymethyl cellulose (0.5 g) and methyl paraben were dissolved in another 50 mL warm water (Solution B). Both solutions were mixed with continuous stirring, and propylene glycol (0.25 mL) was added as a permeation enhancer. The optimized liposomal dispersion (10 mL) was incorporated, and triethanolamine was added dropwise to adjust pH and form a smooth, homogenous gel.

TABLE 2:

Ingredient	Quantity
Carbopol 940	0.5 g
Carboxymethyl Cellulose	0.5 g
Propylene Glycol	0.25 mL
Methyl Paraben	0.25 mL
Liposome Formulation	10 mL
Triethanolamine	q.s.
Water	50 mL

Evaluation of Liposomal Gel:

Physical Appearance: Color, consistency, homogeneity, and phase separation were examined visually [17].

pH Measurement: pH was measured using a digital pH meter.

Viscosity: Viscosity was determined using a Brookfield viscometer [18].

Spreadability: Spreadability was determined using the glass slide method and calculated using the formula:

$$S = TM \times L$$

Where, S = spreadability (g·cm/s), M = weight on upper slide, L = length of glass slide, and T = time in seconds [19].

***In-vitro* Drug Release:** The drug release was studied using a Franz diffusion cell with phosphate buffer (pH 7.4) maintained at 37 ± 0.5 °C. Samples were withdrawn at fixed intervals and analyzed using a UV–Vis spectrophotometer.

Antifungal Activity of Liposomal Gel:

Preparation of Sabouraud Dextrose Agar (SDA): 6.5 g of SDA powder was dissolved in 100 mL distilled water, heated, and sterilized by autoclaving at 121°C for 15 min (15 psi). The medium was cooled to 45–50°C and poured into sterile Petri plates [21].

Well Diffusion Assay: The antifungal activity against *Candida albicans* was determined using the well diffusion method. Wells were filled with 50–100 µL of the liposomal gel. A control well containing blank gel was included for comparison. Plates were incubated at 28–30°C for 24–48 hours, and zones of inhibition (mm) were measured to assess antifungal efficacy [22].

Statistical Analysis: All experiments were performed in triplicate (n = 3), and the results were expressed as mean ± standard deviation (SD).

The data were statistically analyzed using one-way Analysis of Variance (ANOVA) followed by the Bonferroni t-test for multiple comparisons to determine significant differences between formulations. A p-value less than 0.05 ($p < 0.05$) was considered statistically significant. Statistical analysis was carried out using GraphPad Prism (version 9.0) software.

RESULT AND DISCUSSION:

Pre-formulation Studies:

Organoleptic Properties:

TABLE 3: ORGANOLEPTIC PROPERTIES OF POSACONAZOLE AND ALOIN

Drug	Organoleptic properties	Posaconazole	Aloin
Posaconazole and Aloin	Color	White to off-white	Yellow-brown
	Odor	Fruit-like breath odor	Similar to a body odor
	Appearance	Powder or as crystals.	Yellow crystals
	State	Solid	Crystalline solid

The organoleptic characteristics of Posaconazole and Aloin were evaluated to confirm their physical identity and purity **Table 3.** Posaconazole appeared as a white to off-white crystalline powder with a fruit-like odor, while Aloin was observed as yellowish-brown crystals with a faint body-like odor. These findings were consistent with reported characteristics of both drugs [6], confirming the authenticity and suitability of the materials for formulation.

Solubility Study: Solubility assessment revealed that Posaconazole was freely soluble in methanol, soluble in chloroform and DMSO, and practically insoluble in water, whereas Aloin was freely soluble in methanol and ethanol, soluble in water, and very slightly soluble in chloroform **Table 4**. These results align with earlier studies [7], suggesting that methanol is a suitable solvent for analytical and formulation purposes.

TABLE 4: SOLUBILITY STUDY OF POSACONAZOLE AND ALOIN

Drug	Solvents	Observation (Posaconazole)	Observation (Aloin)
Posaconazole and Aloin	Water	Practically insoluble	Soluble
	Ethanol	Slightly soluble	Freely soluble
	Methanol	Freely Soluble	Freely soluble
	Chloroform	Soluble	Very slightly soluble
	DMSO	Soluble	Soluble

pH Determination: The measured pH and melting points **Table 5** of both drugs were consistent with literature values [23]. The slightly acidic pH values of Posaconazole (5.7) and Aloin (4.3) suggest good stability for topical formulations.

TABLE 5: PH AND MELTING POINT OF BOTH DRUGS

Drugs	Observed (pH)	Observed (Melting Point)	Reference
Posaconazole	5.7	169 °C	165°C to 172°C
aloin	4.3	148 °C	148°C to 149°C

Determination of λmax by UV Spectroscopy:

Lambda max Posaconazole and Aloin: The UV absorption spectra of Posaconazole and Aloin displayed maxima at 264 nm and 357 nm, respectively, with a combined center point at 271 nm **Table 6, Fig. 1–2**. These wavelengths were used for subsequent analytical quantification.

TABLE 6: LAMBDA MAX OF POSACONAZOLE AND ALOIN

Drugs	Lambda max of Posaconazole	Lambda max of Aloin	Center point (Both Drug)
Posaconazole and Aloin	264.0 nm	357.0nm	271.0 nm

Calibration Curve of both Drugs:

Calibration Curve of Posaconazole:

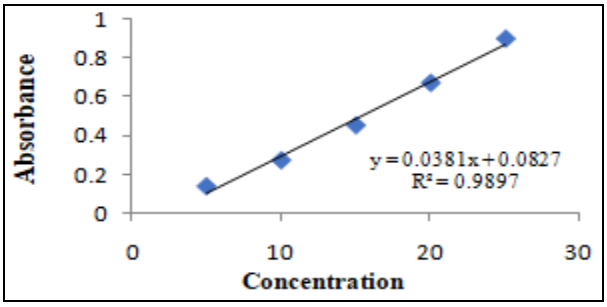

FIG. 1: CALIBRATION CURVE OF POSACONAZOLE

Calibration Curve of Aloin:

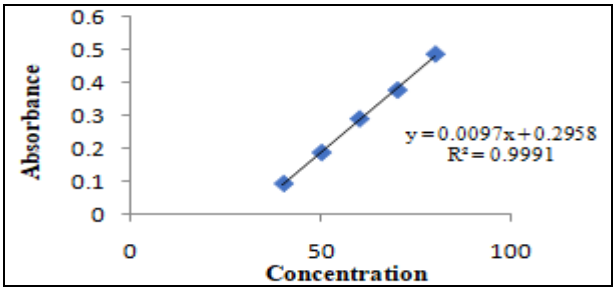

FIG. 2: CALIBRATION CURVE OF ALOIN

Functional Group Identified by Fourier Transform Infrared (FTIR) Study:

FTIR of Posaconazole: The FTIR spectrum of Posaconazole confirmed characteristic peaks corresponding to primary amine (N–H stretch), alkane (C–H stretch), and imine (C=N stretch) groups, confirming the structural integrity of the drug **Fig. 3, Table 7.**

TABLE 7: INTERPRETATION OF IR SPECTRUM OF POSACONAZOLE

Peak obtained	Reference peak	Functional group	Name of functional group
3440.97	3500- 3400	N-H Stretch	Primary amine
2966.46	3000-2840	C-H Stretch	Alkane
1685.01	1690-1640	C=N Stretch	Imine / oxime
1233.68	1275-1200	C-O Stretch	Alkyl aryl ether
1134.97	1160-1120	S=O Stretch	Sulfone
823.76	840-790	C=C bending	Alkene

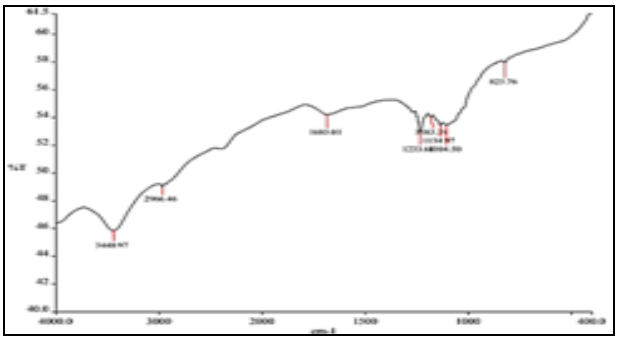

FIG. 3: FTIR OF POSACONAZOLE

FTIR of Aloin: Similarly, Aloin exhibited characteristic absorption bands for O–H, C–H, and C–N stretching vibrations **Fig. 4, Table 8.**

These spectra indicated no major structural changes, confirming that both drugs retained their chemical stability and compatibility with excipients.

TABLE 8: INTERPRETATION OF IR SPECTRUM OF ALOIN

Peak obtained	Reference peak	Functional group	Name of functional group
3407.46	3500–3200	O–H stretch	Alcohols
2921.03	3000–2850	C–H stretch	Alkane
1622.91	1650–1580	N–H bend	Primary amines
1167.63	1250–1020	C–N stretch	Aliphatic amines
745.46	850–550	C–Cl stretch	Alkyl halides

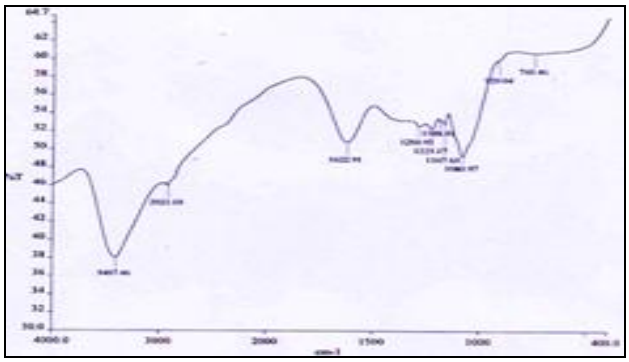

FIG. 4: FTIR OF ALOIN

Evaluation Parameter of Posaconazole and Aloin Loaded Liposomes Formulation:

Physical Appearance of Liposomes: All liposomal formulations appeared as whitish milky liquids with a characteristic odor and homogeneous texture **Table 9**, confirming successful lipid vesicle formation.

TABLE 9: PHYSICAL APPEARANCE OF POSACONAZOLE AND ALOIN LOADEDLIPOSOMES

Formulation	Parameters	Observation
Liposomes	Colour	Whitish milky
	Odour	Characteristic
	Appearance	liquid

Particle Size: The particle size of formulations ranged from 68.07 nm (LDDS3) to 102.18 nm (LDDS5) **Table 10, Fig. 10**. LDDS3 demonstrated the smallest mean particle size and optimal homogeneity (PI = 31.7%), which is favorable for skin penetration and stability. Similar nanoscale sizes were reported by [14] for effective dermal liposomal systems.

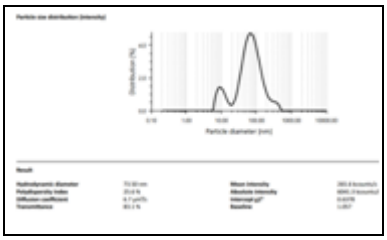

FIG. 5: PARTICLE SIZE (LDDS1)

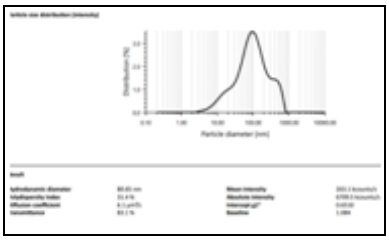

FIG. 6: PARTICLE SIZE (LDDS2)

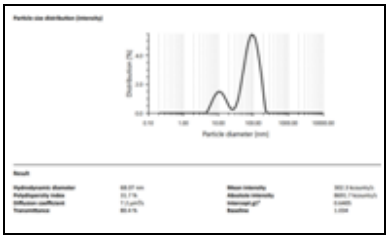

FIG. 7: PARTICLE SIZE (LDDS3)

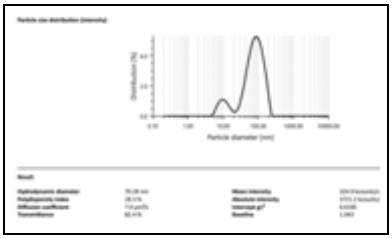

FIG. 8: PARTICLE SIZE (LDDS4)

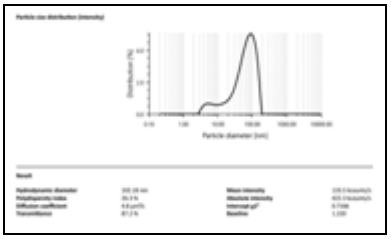

FIG. 9: PARTICLE SIZE (LDDS5)

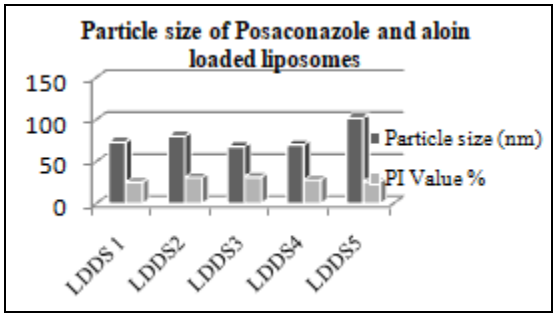

FIG. 10: GRAPHICAL REPRESENTATION OF PARTICLE SIZE OF LIPOSOMES

TABLE 10: PARTICLE SIZE OF POSACONAZOLE AND ALOIN LOADED LIPOSOMES

Formulation code	Particle size (nm)	PI Value %
LDDS 1	73.50 nm	25.6 %
LDDS2	80.65 nm	31.4 %
LDDS3	**68.07** nm	**31.7** %
LDDS4	70.28 nm	28.3 %
LDDS5	102.18 nm	26.3 %

Zeta Potential: All formulations exhibited negative surface charges (–9.7 mV to –15.8 mV), indicating moderate electrostatic stability **Table 11**, **Fig. 16.** LDDS3 (–15.8 mV) showed the highest zeta potential magnitude, signifying the most stable vesicle dispersion.

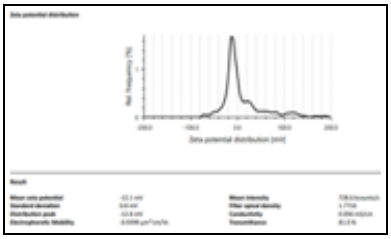

FIG. 11: ZETA POTENTIAL (LDDS 1)

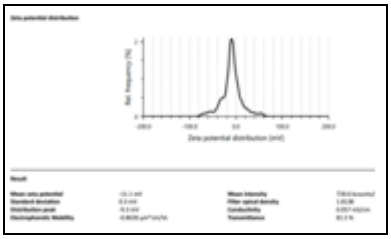

FIG. 12: ZETA POTENTIAL (LDDS2)

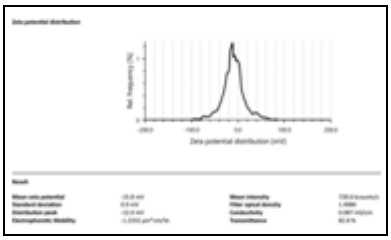

FIG. 13: ZETA POTENTIAL (LDDS3)

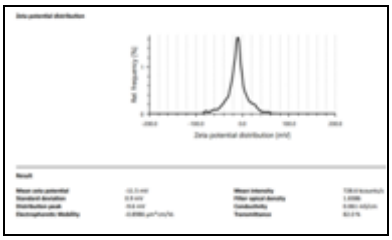

FIG. 14: ZETA POTENTIAL (LDDS4)

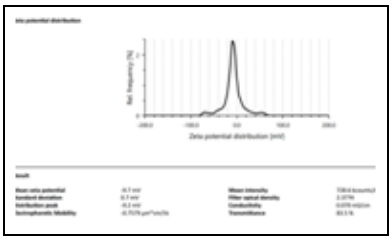

FIG. 15: ZETA POTENTIAL (LDDS5)

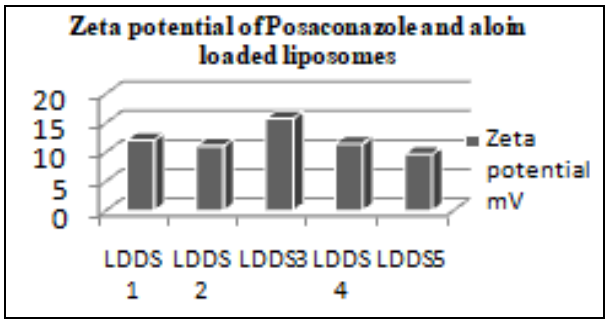

FIG. 16: GRAPHICAL REPRESENTATION OF ZETA POTENTIAL OF LIPOSOMES

TABLE 11: ZETA POTENTIAL OF POSACONAZOLE AND ALOIN LOADED LIPOSOMES

Formulation Code	Zeta potential mV
LDDS 1	-12.1 mV
LDDS 2	-11.1 mV
LDDS3	-15.8mV
LDDS 4	-11.5 mV
LDDS5	-9.7 mV

Entrapment Efficiency of Liposomes Formulation: Entrapment efficiency ranged between 74.08% (LDDS4) and 93.22% (LDDS3) **Table 12, Fig. 17**. The high efficiency in LDDS3 may be attributed to the optimal lecithin-to-cholesterol ratio enhancing bilayer rigidity and drug retention [24].

TABLE 12: - % EE

Formulation code	% Entrapment efficiency
LDDS 1	86.28
LDDS 2	80.86
LDDS 3	93.22
LDDS 4	74.08
LDDS 5	81.68

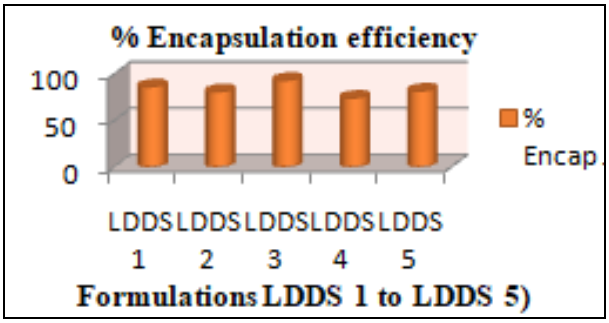

FIG. 17: GRAPHICAL REPRESENTATION OF ENCAPSULATION EFFICIENCY

Scanning Electron Microscope (SEM): SEM micrographs **Fig. 18** revealed spherical, smooth-surfaced vesicles with uniform distribution, further confirming successful liposome formation and nanoscale morphology.

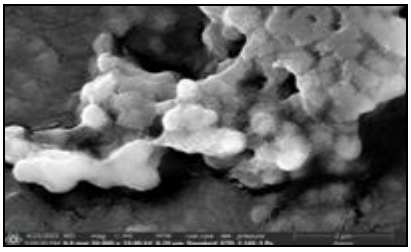

FIG. 18: SCANNING ELECTRON MICROSCOPE (SEM)

Evaluation of Prepared Posaconazole and Aloin Loaded Liposomes Gel:

Organoleptic Properties: The liposomal gel appeared as a smooth, slightly yellowish, homogeneous semisolid without aggregates **Table 13,** indicating uniform drug dispersion and acceptable aesthetic characteristics for topical application.

TABLE 13: ORGANOLEPTIC PROPERTIES OF POSACONAZOLE AND ALOIN LOADED LIPOSOMES GEL

Parameters	Results
Physical appearance	Semisolid gel
Colour	Slightly yellowish gel
Homogeneity	Absence of aggregates

Measurement of pH of Posaconazole and Aloin Loaded Liposomes Gel: The gel exhibited a pH of 5.6, which is within the normal skin pH range (4.5–6.5), ensuring minimal irritation potential.

The viscosity (4836 ± 0.26 cps) was adequate for easy application and adhesion, while spreadability (18.94 g·cm/s) confirmed good uniformity.

TABLE 14: VISCOSITY, PH, AND SPREADABILITY TEST OF GEL FORMULATION

Formulation	Results (pH)	Viscosity Results (cps)	Spreadability test (gm.cm/sec)
Drug-loaded liposomal gel	5.6	4836±0.26	18.94

***In-vitro* Drug Release Study of Liposomal Gel Formulation:**

TABLE 15: RELEASE KINETICS STUDY OF LIPOSOMAL GEL FORMULATION

Time (Hr)	cumulative %drug released	% drug remaining	Square root time	log Camu % drug remaining	Log time	Log Camu %drug released
0	0	100	0.000	2.000	0.000	0.000
2	29.17	70.83	1.414	1.850	0.301	1.465
4	38.08	61.92	2.000	1.792	0.602	1.581
6	47.22	52.78	2.449	1.722	0.778	1.674
8	60.01	39.99	2.828	1.602	0.903	1.778
10	76.91	23.09	3.162	1.363	1.000	1.886
12	88.11	11.89	3.464	1.075	1.079	1.945
14	93.46	6.54	3.742	0.816	1.146	1.971
16	97.01	2.99	4.000	0.476	1.204	1.987

TABLE 16: CORRELATION VALUE (R^2 VALUE)

Formulation	Model	Correlation value (R^2value)
Liposomal formulation	Zero Order	R^2= 0.9621
	First Order	R^2= 0.9314
	Higuchi	R^2= 0.9701
	Korsmeyer peppas	R^2= 0.7847

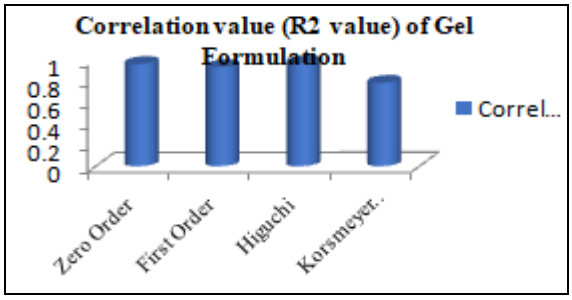

FIG. 19: GRAPHICAL REPRESENTATION OF RELEASE KINETICS STUDY

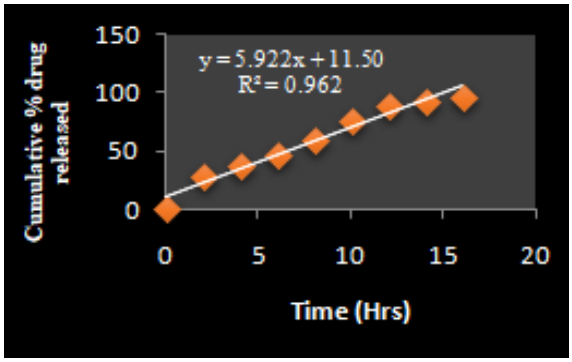

FIG. 20: ZERO ORDER KINETIC MODEL

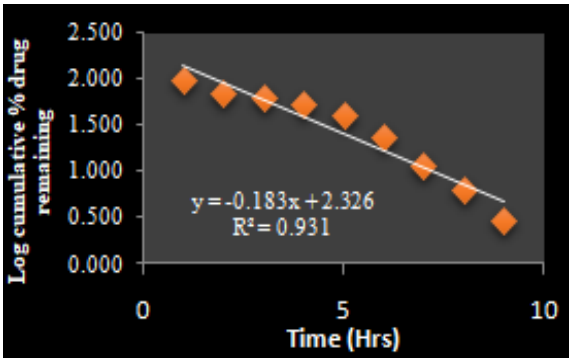

FIG. 21: FIRST ORDER KINETIC MODEL

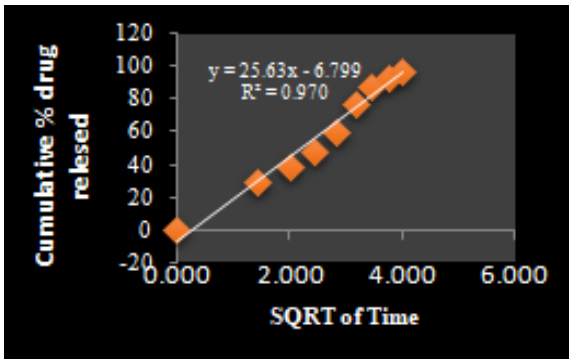

FIG. 22: HIGUCHI MODEL

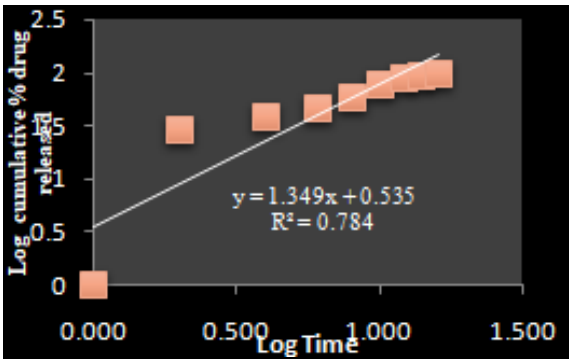

FIG. 23: KORSMEYER PEPPAS

The *in-vitro* release profile **Table 15, Graph 18** demonstrated a sustained release pattern over 16 hours, achieving 97.01% cumulative release. The release followed the Higuchi kinetic model (R^2 = 0.9701), indicating diffusion-controlled release **Table 16, Fig. 19–22**. Such controlled release behavior is advantageous for prolonged antifungal action at the site of infection.

Results of Anti-Fungal Activity of Liposomes Gel Formulation:

Anti-fungal Activity of Liposomes Gel: The liposomal gel exhibited dose-dependent antifungal activity against *Candida albicans* **Table 17, Fig. 24**. The highest inhibition zone (9 mm at 1.5 mg/mL) reflected effective antifungal potential due to enhanced drug penetration and synergistic action of Posaconazole and Aloin [22].

TABLE 17: ANTI-FUNGAL ACTIVITY OF LIPOSOMAL GEL AGAINST *CANDIDA ALBICANS* FUNGUS

Sample Name (mg/ml)	Zone of Inhibition (mm) of *Candida albicans*
Control (C)	0 mm
liposomal gel (placebo or blank gel) (C1)	3 mm
liposomal gel (1mg/ml) (C2)	5 mm
liposomal gel (1.5mg/ml) (C3)	9 mm

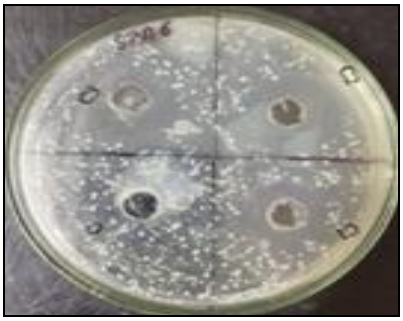

FIG. 24: ANTI-FUNGAL ACTIVITY OF LIPOSOMAL GEL AGAINST *CANDIDA ALBICANS* FUNGUS

DISCUSSION: Pre-formulation studies confirmed the physical identity, purity, and compatibility of Posaconazole and Aloin through organoleptic evaluation, solubility testing, pH, and melting point determination. The results indicated that Posaconazole possesses poor aqueous solubility but

high solubility in organic solvents, whereas Aloin demonstrated favorable solubility in both aqueous and alcohol-based media. The optimized liposomal gel formulation exhibited desirable physicochemical characteristics, including nanosized vesicles, high entrapment efficiency, suitable pH, and sustained drug release, along with significant antifungal activity against *Candida albicans*. Overall, the pre-formulation, characterization, and biological evaluation results confirm the successful development of a stable, biocompatible, and effective liposomal gel for topical antifungal delivery.

The optimized formulation (LDDS3) exhibited: Small particle size (~68 nm), High entrapment efficiency (93.22%), Sustained drug release up to 16 h significant antifungal activity. The findings are consistent with previously reported liposomal systems enhancing dermal drug delivery and antifungal efficacy [14, 22].

CONCLUSION: These findings highlight the formulation's novelty as a dual-drug, lipid-based topical delivery system offering enhanced permeability and prolonged therapeutic action. Therefore, the developed Posaconazole–Aloin liposomal gel shows strong potential for the effective management of superficial fungal infections, warranting further *in-vivo* and stability studies to confirm its clinical applicability.

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CONFLICTS OF INTEREST: Nil

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