DESIGN AND DEVELOPMENT OF NANOPARTICULATE BASED TOPICAL DRUG DELIVERY SYSTEM FOR THE EFFECTIVE TREATMENT OF PSORIASIS

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Abstract:

Psoriasis, a chronic autoimmune inflammatory condition, manifests as erythematous, indurated, scaly plaques. Tacrolimus (TAC), though effective for psoriasis, faces challenges like low solubility. Encapsulating TAC in solid lipid nanoparticles (SLNs) improves its skin penetration due to the nanoparticles' small size. TAC-loaded SLNs were prepared using glyceryl monostearate (GMS) and Tween-80 via the hot homogenization method and optimized using a 3^2 factorial design. Drug-to-lipid ratio (X_1) and surfactant concentration (X_2) were independent variables, while particle size (Y_1), PDI (Y_2), and entrapment efficiency (Y_3) were dependent variables. The optimized formulation (F9) exhibited a particle size of 111.1 nm and 82.37±1.12% entrapment efficiency.

Incorporating SLNs into dermal carriers like gels enhances targeting of viable epidermis and dermis. Among the tested formulations, CF5 demonstrated the highest cumulative drug release (83.78%) over 24 hours in ex-vivo studies, surpassing conventional formulations (65.12% cumulative release). The TAC-SLN-loaded Carbopol gel exhibited superior dermal penetration, especially for thick, hyperkeratotic psoriatic lesions. This system enhances drug delivery, minimizes administration frequency, and improves patient compliance, presenting a promising, safe alternative to conventional treatments for psoriasis.

Keywords: Psoriasis, Tacrolimus (TAC), Solid Lipid Nanoparticles (SLNs), Entrapment Efficiency, Dermal Penetration.

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1. Introduction

Psoriasis is a long-lasting inflammatory skin condition that impacts 0.5% to 1% of children worldwide. The hallmark of this long-term inflammatory disease is abnormal skin patches, which are frequently red, itchy, and scaly. Its intensity ranges from minor, localized areas to full body covering. T cell activation and migration to the dermis, which causes the release of cytokines that cause inflammation and the quick formation of skin cells, are the primary pathophysiological components of the disease. Emotional stress, physical trauma, systemic infections, some drugs, and digestive disturbances can all cause psoriasis. Clinical data, such as skin biopsies, can be used to diagnosis the various forms of psoriasis that have been documented. It is recommended that psoriasis be treated with therapeutic medicines that either normalize the differentiation program of psoriatic keratinocytes or modify the immune system. Numerous treatment plans, including topical medications, phototherapy, and systemic approaches, are available depending on the kind, location, severity, and degree of psoriasis, aid with symptom management. Since around 80% of persons who acquire psoriasis also have plaque psoriasis, this study attempts to cover every facet of the disorder. [1, 2, 3]

Types of psoriasis [4]

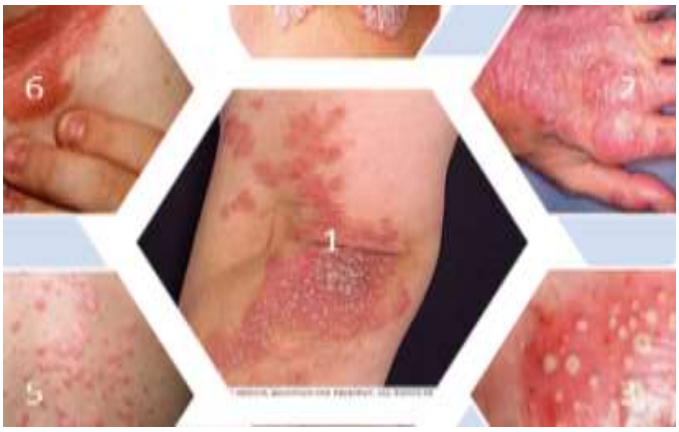


Figure 1. Types of psoriasis

A chronic autoimmune disease, psoriasis comes in a variety of forms:

- Plaque Psoriasis: The most common type, appearing as raised, inflamed, silvery-white scaly plaques on areas like elbows, knees, scalp, and back, often causing severe itching, swelling, and pain. Severe cases can impair the body's barrier functions.
- Psoriatic Arthritis: A chronic inflammatory arthritis associated with skin and nail psoriasis, affecting joints (commonly fingers and toes) and often preceded by skin symptoms.

- Pustular Psoriasis: Characterized by non-infectious pus-filled pustules, localized (hands/feet) or generalized across the body.
- Nail Psoriasis: Involves nail pitting, discoloration, thickening, crumbling, and detachment, often seen in those with psoriatic arthritis.
- Guttate Psoriasis: Small, droplet-like red lesions, primarily on the trunk, limbs, and scalp, often triggered by streptococcal infections.
- Flexural Psoriasis: Red, shiny lesions in skin folds like armpits or groin, exacerbated by sweat and friction, commonly misdiagnosed as infections.
- Scalp Psoriasis: Manifests as painful, itchy patches on the scalp, sometimes causing dandruff, hair loss, and social stress.

Each type varies in symptoms, triggers, and impact on quality of life.

Pathogenesis of psoriasis:

Psoriasis is a multifactorial disease involving genetic and environmental triggers like trauma, drugs, infections, alcohol, and stress. Its progression is driven by immune cell activation, cytokines (e.g., TNF-α, IL-23, IL-17), NF-κB-mediated inflammation, angiogenesis, VEGF overexpression, altered TNF levels, and increased natural killer (NKT) cells. [5]

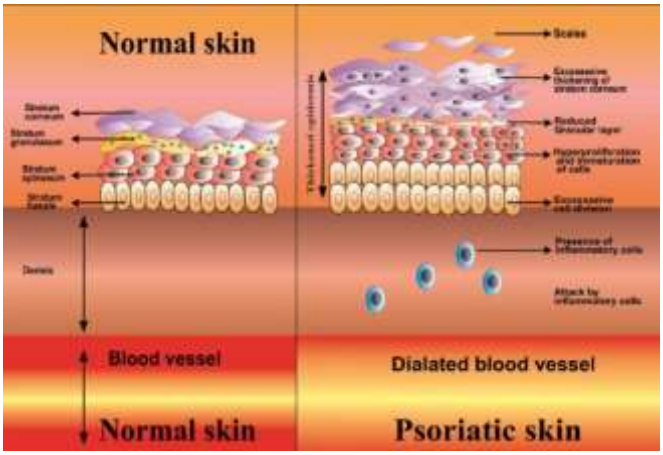


Figure 2. Difference in Normal skin and Psoriatic skin

Topical treatments for psoriasis include corticosteroids for inflammation and itching, vitamin D analogues (e.g., Calcipotriene) to slow skin cell growth, anthralin for smoother skin, retinoids for reducing inflammation, and calcineurin inhibitors (e.g., Tacrolimus) for sensitive areas. Additional options include salicylic acid for scaling, coal tar for itching, and moisturizers to relieve dryness. [6,7]

Tacrolimus, a BCS Class 2 drug, effectively treats psoriasis by reducing skin cell production and inflammation. Its oral bioavailability is limited by low solubility and first-pass metabolism, causing systemic side effects. Topical solid lipid nanoparticles (SLNs) enhance skin penetration, minimize systemic toxicity, and enable targeted, sustained drug release for effective treatment.

2. Materials and methods

2.1 List of chemicals

Tacrolimus (Concord Biotech limited), Glyceryl monostearate(GMS) (Loba Chemie Pvt Ltd),Compritol 888 ATO(Gattefosse Pvt Ltd), Precirol ATO 5 (Gattefosse Pvt Ltd), Tween 80 (SD fine chemicals), Sodium Hydroxide (Hi-media Ltd., Mumbai), Potassium dihydrogen Phosphate(Qualigens fine chemicals), Acetonitrile (SD Fine Chemicals Ltd., Mumbai),Carbopol 934P (Hi-Media laboratory Pvt Ltd. ,Mumbai), Glycerine (Hi-Media laboratory Pvt Ltd., Mumbai), De-ionized water (Millipore -Ellix3 India), Methanol (SD Fine Chemicals Ltd., Mumbai), Dialysis Membrane (Hi-Media Ltd., India).

2.2 List of equipments

Weighing balance (Shimadzu ELB 300), UV1700 Spectrophometer (Shimadzu, Japan),FTIR (Shimadzu 8700 Shimadzu, Japan), Scanning Electron Microscope (IISC Bangalore), DSC Q2000 (Microlabs limited), Malvern Nano S-90 Zetasizer (Malvern Instruments, UK), Water Bath Shaker (Remi equipment's Ltd), Ultra Turrax T 25 Homogenizer (IKA), pH meter (Micropro Gradmate), XRPD (IISc, Bangalore), Magnetic stirrer (Remi equipment Ltd), Tissue Homogenizer Remi Instruments, Remi Centrifuge (Remi Instruments Ltd), Eppendroffs Tube Tarson, Brookfield viscometer (Brookfield Engineering Laboratories).

2.3 Formulation of Drug loaded solid lipid nanoparticles [8]

Hot Homogenization method:

The medication (10 mg) was added to melting lipid (GMS) at 60 to 70 degrees Celsius. melt. At 70°C, the melt was transferred into 20 milliliters of 1% aqueous Tween 80 solution. After five minutes of stirring with a magnetic stirrer, the resulting hot dispersion was homogenized for thirty minutes at 24,000 rpm using a high shear homogenizer (Ultra-Turrax). To create the solid lipid nanoparticles, the resultant nano emulsion was allowed to cool to ambient temperature.

3. Experimental methodology [9,10,11]

3.1 Preformulation studies

3.1.1 Solubility Studies:

Solubility of Tacrolimus (10 mg/10 ml) was tested in various solvents including buffers (pH 5.2, 6.8), ethanol, methanol, acetonitrile, DMF, and DMSO to determine suitable media.

3.1.2 uv-spectrophotometric estimation:

λmax was determined at 291 nm using methanol as blank. A calibration curve (10–60 µg/ml) was prepared, and intra- and inter-day variability was studied to validate linearity and reproducibility.

3.1.3 partition coefficient:

Partitioning of drug was studied in n-octanol/water system by flask shake method. After equilibrium, concentrations in both phases were estimated spectrophotometrically to calculate log P.

3.1.4 compatibility studies:

FTIR spectra were obtained by KBr disc method and DSC analysis was performed to study thermal transitions and confirm drug–excipient compatibility.

4 Formulation development

4.1 Screening of Lipids:

Based on literature, lipids suitable for SLN preparation were screened and glyceryl monostearate (GMS) was selected.

4.2 sln preparation:

Drug was dispersed in melted GMS (60–70°C), homogenized in 1% Tween 80 solution at varying rpm/time and cooled to obtain SLNs.

4.3 & 4.4 standardization:

Process parameters (rpm, time) and formulation variables (drug:lipid ratio, surfactant %) were optimized for desired particle size, PDI, and entrapment efficiency.

4.5 Factorial Design:

A 3^2 full factorial design was applied to study the effect of drug:lipid ratio (X1) and surfactant concentration (X2) on particle size, PDI and EE.

4.6 Statistical Analysis:

Data was analyzed using Design-Expert® software. ANOVA and desirability functions were applied to identify optimized formulations.

5 Evaluations of nanoparticles

5.1 Particle Size & PDI:

Measured using Malvern Zetasizer Nano S90 in distilled water medium.

5.2 Entrapment Efficiency & Drug Content:

SLNs were centrifuged, supernatant analyzed by UV and %EE and %DC calculated from free vs. total drug.

5.3 In vitro Drug Release:

Franz diffusion cell with dialysis membrane in pH 5.2 buffer was used; aliquots withdrawn at intervals were analyzed at 291 nm.

5.4 Stability Studies:

Optimized SLNs were stored at room temperature for 3 months and tested for particle size, PDI, and drug content.

5.5 sln-loaded gel formulation

5.5.1 gel preparation:

Optimized SLNs (equivalent to 1% Tacrolimus) were incorporated into carbopol 934 gel (0.5–1.5%) and neutralized with triethanolamine.

5.5.2 gel evaluation:

Gels were evaluated for homogeneity, pH, viscosity, spreadability, drug content, and ex-vivo permeability using goat skin in Franz diffusion cell.

Stability Studies:

Optimized SLN gel was stored at room temperature for 3 months and analyzed for viscosity, pH and % drug content.

6. Results and discussion

Drug overview:

Tacrolimus, a 23-membered macrolide lactone, features an alpha, beta-diacetamide hemiacetal structure.

Uses: Prevention of organ transplant rejection and treatment of skin conditions (e.g., vitiligo, psoriasis, atopic dermatitis).

BCS Class 2 is characterized by high permeability but low solubility**.**

Study Objective:

Formulation of Tacrolimus-loaded solid lipid nanoparticles (SLNs) as a topical gel to enhance therapeutic effectiveness, prolong drug release and improve dermal targeting.

Preformulation Studies:

Solubility: Tacrolimus is practically soluble in acetonitrile, ethanol and pH 5.2 buffer.

Partition Coefficient: Log P = 2.81, indicating high lipid solubility.

Compatibility: FTIR and DSC studies confirmed no interaction between drug and excipients.

Formulation Methodology:

SLNs prepared using glyceryl monostearate (GMS) as lipid and Tween 80 as surfactant via hot homogenization at 24,000 RPM for 30 minutes. With a 1.5% surfactant concentration, the ideal drug-to-lipid ratio was 1:5.

Evaluation of SLNs:

Particle Size & PDI:

Range: 111.1–260.6 nm; optimal batch (T9) had 111.1 nm size and 0.340 PDI.

Drug Entrapment:

Efficiency ranged from 54.28% to 82.37%; high entrapment due to lipophilicity.

Drug Release:

SLN formulations showed 64.21% release in 24 hours, outperforming pure Tacrolimus (29.58%).

SLN Gel Incorporation:

SLNs added to a carbopol 934 P gel basis (optimized concentration of 1%).

pH compatibility: 5.3–5.6, ensuring minimal skin irritation.

Ex-Vivo Permeability:

SLN gel showed 85.78% drug release in 24 hours, superior to marketed formulations (65.12%).

Stability Studies:

SLN (F9) and SLN gel (CF5) were stable in terms of particle size, PDI, viscosity and drug content for 3 months at room temperature.

Conclusion

Tacrolimus-loaded glyceryl monostearate-based solid lipid nanoparticles (SLNs) were successfully prepared using the hot homogenization method, achieving low particle size and high entrapment efficiency (%EE). The concentrations of lipid and surfactant had a considerable impact on the particle size and drug entrapment efficiency. FTIR studies confirmed drug-excipient compatibility, while SEM and DSC studies validated the spherical nanometer-sized particles and decreased drug crystallinity, ensuring successful incorporation into SLNs.

In-vitro release studies showed optimized formulation F9 had the best % cumulative drug release (CPR) and was incorporated into a gel for further studies. The TAC-SLN gel (CF5) showed enhanced skin deposition, efficient occlusion, and superior anti-psoriatic activity compared to conventional formulations, with improved permeation (85.78% CPR) versus marketed tacrolimus ointment (65.12% CPR). Because the gel's pH range of 5.5 to 6.5 is in line with the skin's natural pH, there is less chance of irritation.

These findings suggest that TAC-SLN gels are a promising, scalable, and effective alternative for psoriasis treatment, enabling better dermal penetration and targeted drug delivery.

Conflicts of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

Figure and Table legends

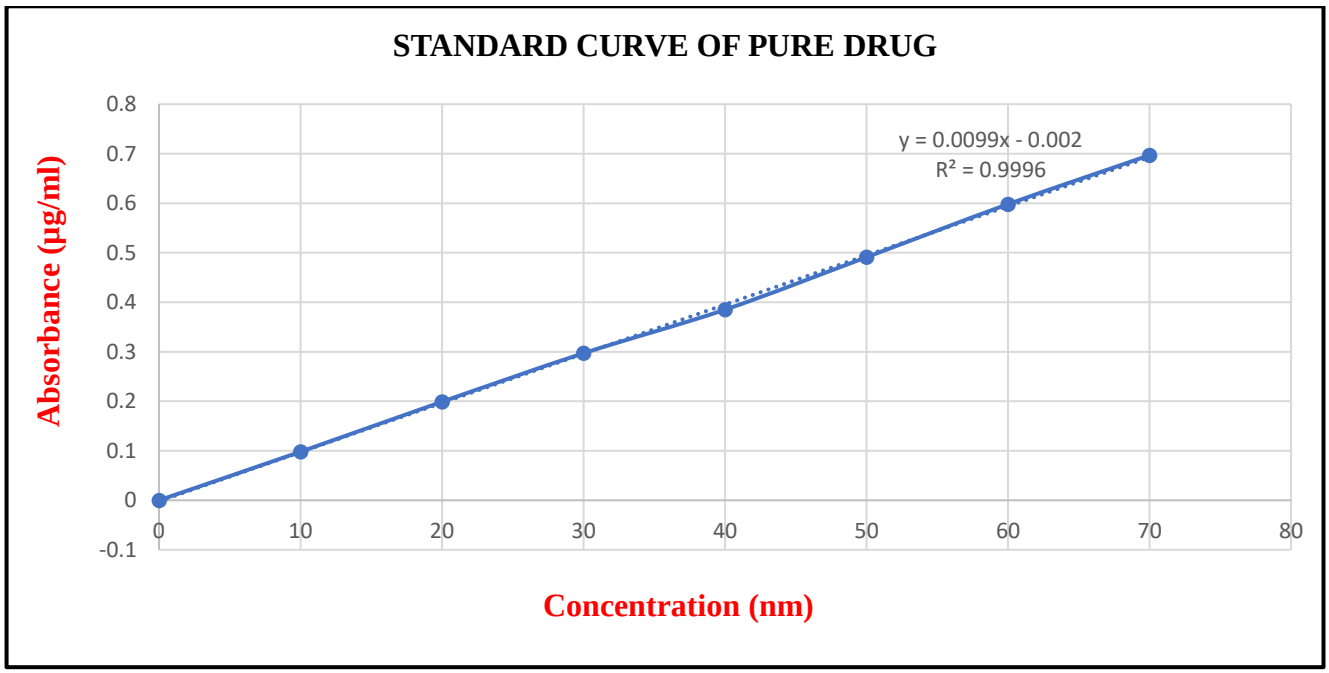
6. Results and discussion

6.1 Preformulation studies:

The results of pre-formulation studies carried out and the absorption spectrum showed highest absorbance of the drug at 291nm

6.2 Solubility studies

The solubility profile of the selected immunosuppressant drug in various media were carried out for solubility profile of pure drug and standard calibration curve data of pure drug.

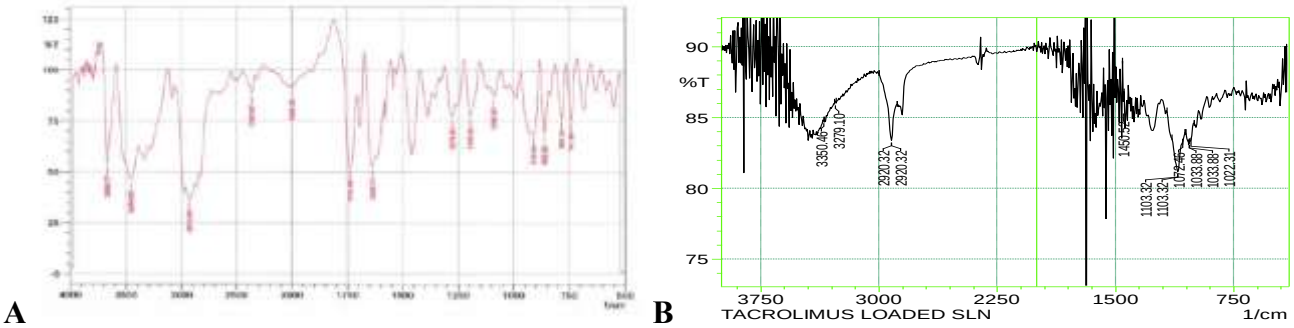


(Fig. 3) Standard calibration curve of pure drug

6.3 Partition coefficient of pure drug in n-octanol and water

Partition coefficient of Tacrolimus was found to be 2.81.

6.3 Compatibility studies



(Fig. 4) Fourier transform infrared spectroscopy studies (FTIR): (A) pure drug; (B) Spectra of optimized SLN formulation.

(Table 1) Characteristic peaks of FTIR spectrum of pure drug

Functional Group	Wave number(cm^{-1})
C-O stretching	1020 and 1035
C=C stretching	1451
-OH stretching	2903, 2977 and 3281
N-H stretching	3350 and 3451

(Table 2) Comparison of FTIR of pure drug and optimized SLN formulation

Functional Group	Wave number in cm^{-1}	
	Pure Drug	Optimized SLN formulation
C-O stretching	1020 and 1035	1022.31 and 1033.88
C=C stretching	1451	1450.52
-OH stretching	2903, 2977 and 3281	2900.32
N-H stretching	3350 and 3451	3279.10 and 3360.46

Differential scanning calorimetry (DSC):

DSC of pure drug shows the endothermic peak of drug at 131.98℃, suggesting that the drug is crystalline in nature.

DSC of drug loaded SLN formulation exhibited an endothermic peak at 55.21℃, but the drug peak was not found which suggests that the drug got entrapped in SLNs and existed in amorphous form.

6.2 Formulation studies

6.2.1 Screening of Lipids

Lipid for the preparation of solid lipid nanoparticles was screened through literature survey.

6.2.2 Formulation of drug loaded slns by hot homogenization method

(Table 3) Standardization of process parameters Particle size and PDI based on process parameters

Batch no.	Homogenization Rpm	Duration of homogenization	Particle size (nm)	PDI
T_1	18000	10	186.5	0.435
T_2	21000	10	169	0.485
T_3	24000	10	123.4	0.549
T_4	18000	20	257.9	0.338
T_5	21000	20	157.1	0.517
T_6	24000	20	125.1	0.539
T_7	18000	30	260.6	0.251
T_8	21000	30	118.3	0.362
T_9	24000	30	111.1	0.340

Particle size and PDI for T_9 batch was found to be better than other batches. Hence, homogenization at 24,000 rpm for 30 minutes was selected for further studies.

6.2.3 Standardization of formulation parameters

(Table 4) Selection of Drug: lipid ratio and surfactant concentration

Batch No	Drug: lipid ratio	Surfactant conc.	Particle size (nm)	Polydispersity index (PDI)
T_{10}	1:1	1	186.5	0.435
T_{11}	1:3	1	257.9	0.338
T_{12}	1:5	1	260.6	0.251
T_{13}	1:5	1	260.6	0.251

T_{14}	1:5	1.5%	111.1	0.340
T_{15}	1:5	2%	118.3	0.362

T_{12} batch shows a PDI value of 0.251, which was better than the other two batches (i.e. T_{10} and T_{11}). Hence, T_{12} was selected for further studies.

T_{14} batch shows a lesser particle size 111.1 nm as desired and hence, was selected for further studies.

6.2.4 Statistical analysis of standardized drug loaded sln formulation by 3^2full factorial design:

(Table 5) 3^2full factorial design with actual values of drug: lipid ratio and surfactant concentration

Formulation code	Factor 1 Drug : lipid ratio (mg)	Factor 2 Surfactant concentration (%)	Response 1 Particle size (nm)	Response 2 PDI	Response 3 Entrapment Efficiency (%)
F_1	1:5	2	118.3	0.362	80.28 ± 2.52
F_2	1:3	2	125.1	0.539	69.41 ± 1.63
F_3	1:1	1.5	169	0.485	56.29 ± 2.03
F_4	1:1	1	186.5	0.435	54.28 ± 1.87
F_5	1:5	1.5	111.1	0.340	82.37 ± 1.12
F_6	1:1	2	123.4	0.549	57.26 ± 1.33
F_7	1:5	1	260.6	0.251	80.17 ± 1.45
F_8	1:3	1	257.9	0.338	64.28 ± 1.65
F_9	1:3	1.5	157.1	0.517	65.17 ± 1.69

Anova of dependent variables from 3^2 full factorial design

(Table 6) ANOVA for response surface quadratic model of Particle size (A); PDI (C); Entrapment Efficiency (E)Squared values for particle size (B); PDI (D); Entrapment Efficiency (F).

A Response 1: Particle size

Source	Sum of Squares	Df	Mean Square	F-value	p-value
Model	19083.74	2	9541.87	7.56	0.0229
A-Lipid concentration	20.53	1	20.53	0.0163	0.9027
B-Surfactant concentration	19063.21	1	19063.21	15.11	0.0081
Residual	7571.36	6	1261.89		
Cor Total	26655.10	8			

Std. Dev.	**35.52**	**R^2**	**0.7160**
Mean	167.67	Adjusted R^2	0.6213
C.V. %	21.19	Predicted R^2	0.3242
		Adeq Precision	5.6771

The Model F-value of 7.56 implies the model is significant. (B)

C Response 2: PDI

Source	Sum of Squares	df	Mean Square	F-value	p-value
Model	0.0746	2	0.0373	14.98	0.0046
A-Lipid concentration	0.0444	1	0.0444	17.82	0.0056
B-Surfactant concentration	0.0302	1	0.0302	12.14	0.0131
Residual	0.0149	6	0.0025		
Cor Total	0.0896	8			

Std. Dev.	**0.0499**	**R^2**	**0.8332**
Mean	0.4240	Adjusted R^2	0.7775
C.V. %	11.77	Predicted R^2	0.6913
		Adeq Precision	10.8976

The Model F-value of 14.98 implies the model is significant. (D)

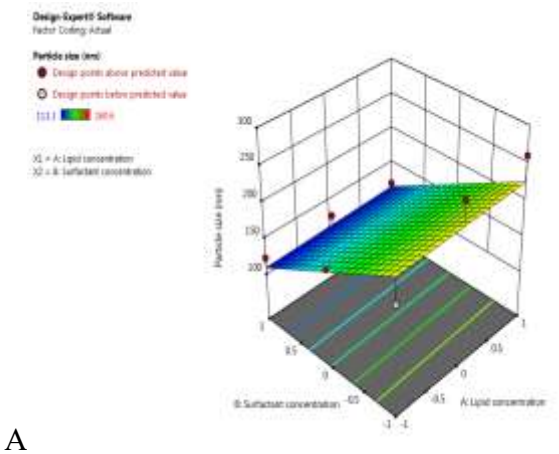
E Response 3: Entrapment efficiency

Source	Sum of Squares	Df	Mean Square	F-value	p-value
Model	948.51	2	474.26	137.14	< 0.0001
A-Lipid concentration	937.25	1	937.25	271.02	< 0.0001
B-Surfactant concentration	11.26	1	11.26	3.26	0.1212
Residual	20.75	6	3.46		
Cor Total	969.26	8			

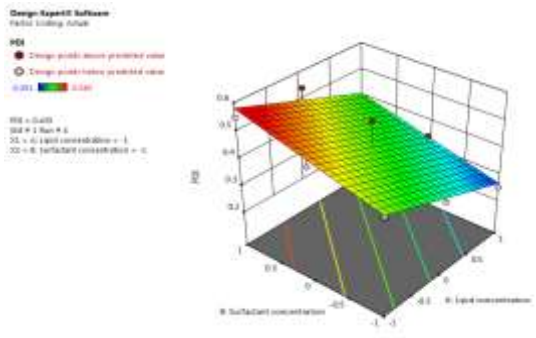
Std. Dev.	**1.86**	**R^2**	**0.9786**
Mean	67.72	Adjusted R^2	0.9715
C.V. %	2.75	Predicted R^2	0.9578
		Adeq Precision	25.8338

(F)

The Model F-value of 137.14 implies the model is significant.



A



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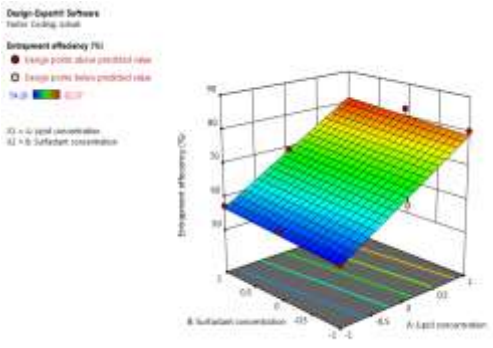

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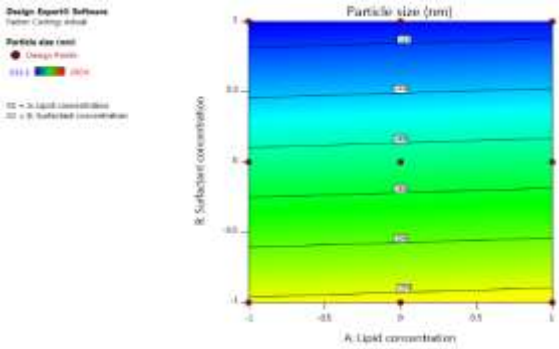

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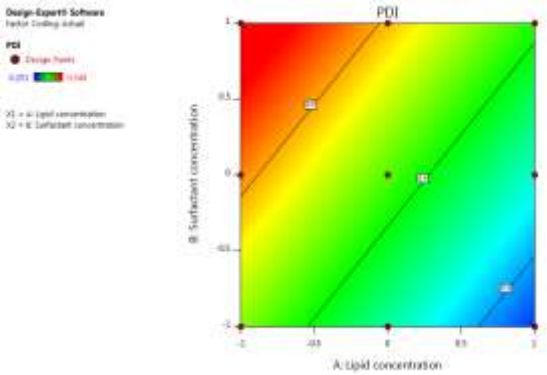

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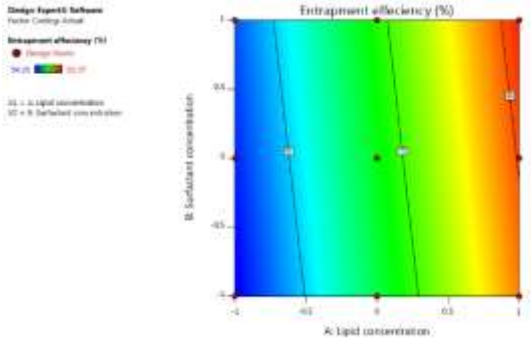


F

(Fig. 5) Response surface (3D) plot showing effect of factorial variables on (A) Particle size; (B) PDI; (C) Entrapment Efficiency.

Contour plot (2D) showing the effect on (D)particle size; (E) PDI; (F) Entrapment Efficiency.

Polynomial equations obtained by 3² full factorial design

The polynomial equation derived for Particle size= +167.67 +1.85*A - 56.37*B

The polynomial equation derived for PDI = +0.4240 - 0.0860*A +0.0710*B

The polynomial equation derived for entrapment efficiency= +67.72 +12.50*A +1.37*B

6.3 Evaluation of drug loaded solid lipid nanoparticles:

(Table 7) Particle size, entrapment efficiency and drug content for optimized formulation batches

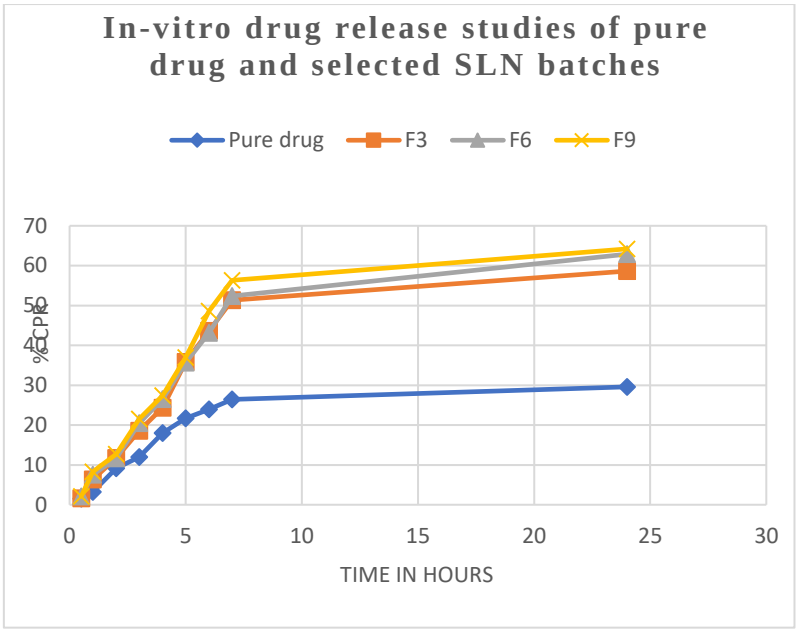
Formulation code	Drug : lipid ratio (mg)	Surfactant concentration(%)	Particle size (nm)	PDI	Entrapment Efficiency (%)	Drug content (%)
F_1	1:1	2	123.4	0.549	57.26±1.33	73.65±1.23
F_2	1:3	1	257.9	0.338	64.28±1.65	84.32±1.46
F_3	1:5	2	118.3	0.362	80.28±2.52	92.84±0.94
F_4	1:3	1.5	157.1	0.517	65.17±1.69	78.69±2.16
F_5	1:1	1	186.5	0.435	54.28±1.87	69.34±0.68
F_6	1:5	1	260.6	0.251	80.17±1.45	88.61±1.35
F_7	1:1	1.5	169	0.485	56.29±2.03	74.32±1.83
F_8	1:3	2	125.1	0.539	69.42±1.63	80.64±0.45
F_9	1:5	1.5	111.1	0.340	82.37±1.12	95.88±1.62

6.4 In-vitro drug release studies of pure drug and optimized formulations through dialysis membrane

(Table 8) Comparison of *in-vitro* release for pure drug and optimized formulations

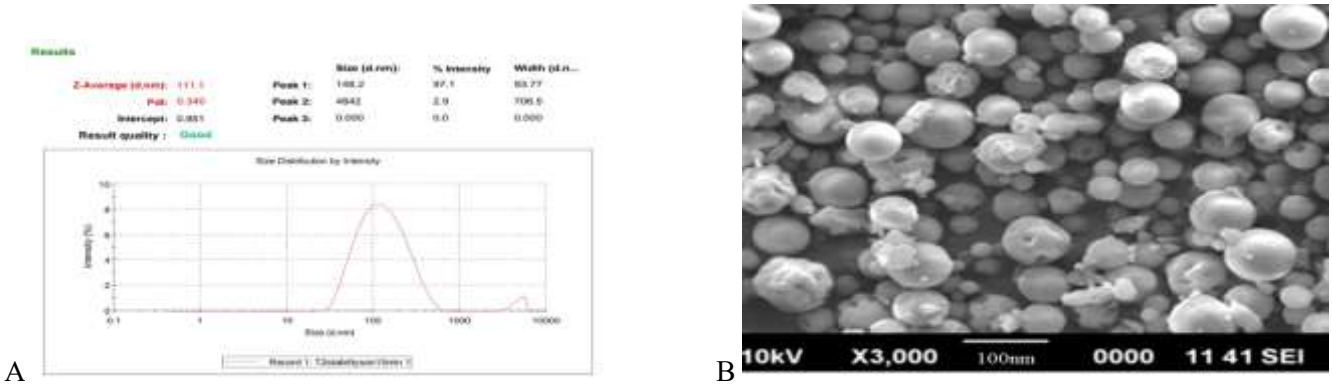
Time in hours	Pure drug	% CPR		
		F3	F6	F9
0.5	1.48±0.091	1.57±0.235	2.06±0.856	2.09±0.748
1	3.20±0.188	6.38±0.351	6.52±0.325	6.83±0.865
2	9.13±0.255	11.72±0.264	11.68±0.125	12.72±0.154
3	11.94±0.429	18.54±0.782	18.49±0.458	19.56±0.356
4	17.99±0.277	24.32±0.495	24.51±0.785	25.47±0.478
5	21.71±0.634	35.79±0.165	35.64±0.368	36.93±0.236
6	23.97±0.524	43.66±0.478	43.12±0.841	44.56±0.214
7	26.43±0.747	51.32±0.591	52.36±0.259	52.98±0.875
24	29.58±0.298	58.64±0.347	62.89±0.157	64.21±0.426

*Average of three determinations



(Fig. 6) In-vitro drug release profile of pure drug and selected SLN batches

From the *in-vitro* drug release profile it was found that the F_9 formulation had a higher %CPR when compared to the SLN batches F_3 and F_6 and hence, F_9 was selected as the optimized batch.



(Fig. 7) Size distribution of optimized SLN batch (A); SEM of optimized SLN batch (B).

6.5 Incorporation of selected sln into gel

(Table 9) Optimization of carbopol 934 P concentration

Formulations	pH ± SD	Spreadability ± SD (gm cm/sec)	Homogeneity	Viscosity (cps) ± SD	Drug content (%) ± SD
CF4	5.36± 0.032	10.41± 0.003	+++	3615 ± 0.27	83.74 ± 0.52

CF5	5.24± 0.026	10.65± 0.001	+++	2463 ± 0.45	86.35 ± 0.36
CF6	5.61± 0.033	10.35± 0.002	+++	3487 ± 0.36	82.51 ± 0.41

(Table 10) *Ex-vivo* permeability study for topical SLN gel formulations using excised goat abdominal skin

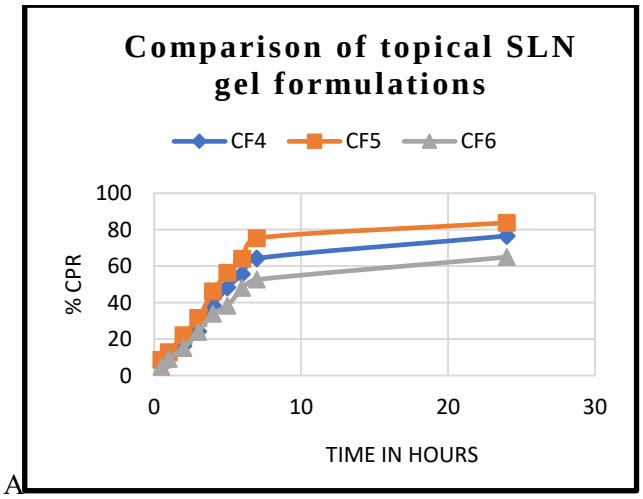
Time (hrs)	Cumulative percentage drug release from SLN gel (%)		
	CF4	CF5	CF6
0	0	0	0
0.5	5.43	8.65	4.66
1	10.96	12.73	9.21
2	16.38	22.18	15.02
3	24.15	31.52	23.91
4	38.23	46.12	33.54
5	48.29	56.35	38.25
6	55.74	64.03	48.11
7	64.25	75.36	52.63
24	76.54	83.78	64.93

*Average of three determinations

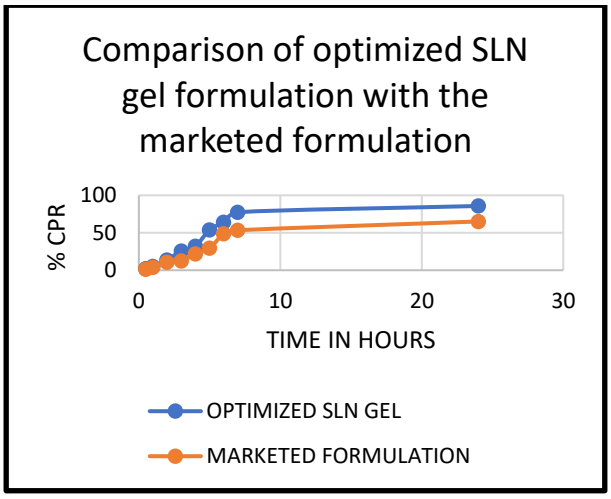
(Table 11) *Ex-vivo* permeability study for optimized SLN gel formulation and marketed formulation

	Time (hours)	Optimized gel formulation (% CPR)	Marketed formulation (%CPR)
1	0.5	2.15	1.34
2	1	5.37	4.06
3	2	13.52	10.85
4	3	25.84	12.53
5	4	32.26	21.62
6	5	53.94	29.34
7	6	64.16	48.73
8	7	77.45	53.43
9	24	85.78	65.12

A



B



(Fig. 8) Comparison of topical SLN gel formulations(A); Comparison of optimized SLN gel formulation with marketed formulation(B).

From the above graph the cumulative percentage drug release from the SLN gel formulation of CF5 batch showed the highest drug release and was selected as the best formulation for the effective treatment of psoriasis.

6.7 Stability studies:

Stability studies were carried out for the optimized SLN and SLN gel formulation for a period of three months under the storage conditions of 25± 2° C/RH 45± 10^0C**.**

(Table 12) Stability studies for optimized SLN formulation

Sl.no	Sampling interval	Particle size	PDI	Drug Content (%)
1	Initial	111.1 ± 0.24	0.340 ± 0.12	95.88 ± 0.36
2	30 days	113.6 ± 0.89	0.342 ± 0.97	83.09 ± 1.34
3	60 days	115.2 ± 0.36	0.398 ± 0.76	78.89 ± 1.46
4	90 days	117.4 ± 8.45	0.415 ± 0.12	77.09 ± 1.53

(Table 13) Stability studies for optimized SLN gel formulation

Sl.no	Sampling interval	Viscosity	pH	Drug Content (%)
1	Initial	2463 ± 0.45	5.54 ± 0.026	86.35 ± 0.36
2	30 days	2458 ± 0.45	5.12 ± 0.02	84.08 ± 1.25
3	60 days	2451 ± 0.36	5.09 ± 0.04	83.93± 1.35
4	90 days	2354 ± 0.27	5.05 ± 0.18	83.85 ± 1.48

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