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FORMULATION AND IN-VITRO EVALUTION OF PACLITAXEL LOADED SOLID LIPID NANOPARTICLES FOR TARGETED ANTICANCER THERAPY

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Abstract: Paclitaxel is a potent anticancer drug widely used in the treatment of various malignancies. However, its clinical application is limited by poor aqueous solubility and low bioavailability. The present study was aimed at the formulation and evaluation of Paclitaxel-loaded solid lipid nanoparticles (SLNs) to enhance drug encapsulation, stability, and controlled release characteristics. Paclitaxel-loaded SLNs were prepared by the hot homogenization method using Glyceryl monostearate as the lipid carrier and Tween 40 and Span 80 as surfactants. Preformulation studies including organoleptic evaluation, melting point determination, solubility studies, and FTIR analysis were carried out. FTIR studies confirmed the compatibility of Paclitaxel with the selected excipients, indicating the absence of significant drug–excipient interactions. The prepared formulations were evaluated for particle size, zeta potential, entrapment efficiency, surface morphology, in vitro drug release, and stability. The particle size of the formulations ranged from 102 to 210 nm, while zeta potential values ranged from −18.4 mV to −25.8 mV, indicating good stability of the nanoparticle system. Entrapment efficiency was found to be between 72.5% and 85.6%. SEM analysis revealed that the nanoparticles were spherical in shape with smooth surface morphology and minimal aggregation. Among all formulations, F4 was identified as the optimized formulation, exhibiting a particle size of 102 nm, zeta potential of −25.8 mV, and entrapment efficiency of 85.6%. In vitro drug release studies demonstrated a sustained release profile over 8 hours, with formulation F4 showing the highest cumulative drug release of 97.55%. Stability studies conducted for 3 months under different storage conditions confirmed the stability of the optimized formulation, with all parameters remaining within acceptable limits. The results of the present study demonstrated that Paclitaxel-loaded solid lipid nanoparticles can be successfully developed as a stable and efficient drug delivery system with improved encapsulation efficiency and controlled drug release characteristics. The optimized formulation may provide enhanced therapeutic efficacy and holds promise for future anticancer drug delivery applications.

Keywords: Paclitaxel, Solid Lipid Nanoparticles, Entrapment Efficiency, Controlled Release, Zeta Potential, Drug Delivery System.

INTRODUCTION

Solid lipid nanoparticles (SLNs) are advanced colloidal drug delivery systems that have gained significant attention in pharmaceutical research due to their ability to improve drug stability, bioavailability, and therapeutic efficacy. SLNs were first introduced in the early 1990s as an alternative to traditional carrier systems such as liposomes, emulsions, and polymeric nanoparticles. They are composed of physiologically compatible lipids that remain solid at both room and body temperatures, stabilized by suitable surfactants .SLNs typically range in size from 50 to 1000 nm and consist of a solid lipid core matrix in which the drug is either dissolved or dispersed.

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This solid matrix enables controlled and sustained drug release while protecting the incorporated drug from chemical degradation. Due to their unique properties, SLNs are particularly suitable for delivering poorly water-soluble drugs, such as Paclitaxel, enhancing their solubility and bioavailability. One of the major advantages of SLNs is their biocompatibility and biodegradability, as they are prepared using physiological lipids such as triglycerides, fatty acids, and waxes. Additionally, SLNs avoid the use of toxic organic solvents in many preparation methods, making them safer for clinical applications. Their ability to provide targeted drug delivery, reduce systemic toxicity, and improve therapeutic outcomes has made them a promising approach in modern drug delivery systems. Furthermore, SLNs have shown great potential in various routes of administration, including oral, topical, parenteral, and pulmonary delivery. Their versatility, ease of large-scale production, and stability during storage contribute to their growing importance in pharmaceutical development. As a result, SLNs are widely explored for applications in anticancer therapy, gene delivery, and controlled drug release systems .

MATERIALS

Paclitaxel was procured from Synpharma Research Labs, Hyd, Glyceryl monostearate, Tween 80, Span 20 were obtained from Synpharma Research Labs, Hyderabad. Other chemicals and the reagents used were of analytical grade.

METHODOLOGY

Method of preparation of Paclitaxel loaded solid lipid nanoparticles:

Preparation of solid lipid nanoparticle formulations of Paclitaxel by hot homogenization method

The solid lipid (Glyceryl monostearate) was melted above its melting point. The drug (Paclitaxel) was dissolved or dispersed in the molten lipid. An aqueous surfactant solution (Tween 40 and Span 80) was heated to the same temperature. The aqueous phase was added to lipid phase with stirring. The emulsion was subjected to sonicated for a specified time to reduce particle size. The nano emulsion was cooled to room temperature to allow lipid solidification and formation of SLNs.

Table -1: Composition of Paclitaxel for preparation of solid lipid nanoparticles

F.no	Drug(mg)	Glyceryl monostearate (mg)	Tween 40 (mg)	Span 80 (mg)
F1	100	100	10	-
F2	100	200	20	-
F3	100	300	-	10
F4	100	400	-	20

Evaluation of Paclitaxel loaded SLNs:

Particle size:

The mean particle size of the prepared SLNs were determined using dynamic light scattering (DLS) to evaluate particle size distribution and stability.

SEM analysis:

The surface morphology and shape of Paclitaxel -loaded solid lipid nanoparticles were examined using scanning electron microscopy (SEM). A small amount of lyophilized SLN powder was mounted on metallic stubs using double-sided conductive adhesive tape and coated with a thin layer of gold to enhance conductivity and prevent charging. The samples were then observed under the SEM at appropriate accelerating voltages, and images were captured at various magnifications. The samples were observed under SEM at appropriate magnifications to determine their surface morphology and particle characteristics. These morphological observations were correlated with particle size measurements obtained from dynamic light scattering, providing a comprehensive understanding of the nanoparticle characteristics.

Drug Entrapment efficiency:

The entrapment efficiency of Paclitaxel in solid lipid nanoparticles was determined using the indirect method. Briefly, a known volume of SLN dispersion was centrifuged at high speed (e.g., 15,000–20,000 rpm) for 30–60 minutes to separate the free (unentrapped) drug in the supernatant from the nanoparticle pellet. The supernatant was carefully collected, and the concentration of unencapsulated Paclitaxel was quantified using a validated UV-Visible spectrophotometric method.

$$\text{Entrapment Efficiency (\%)} = \frac{\text{Amount entrapped}}{\text{Total drug loaded}} \times 100$$

In-vitro drug release studies

The in-vitro release of Paclitaxel from solid lipid nanoparticles was evaluated using the dialysis bag diffusion method. Briefly, a known quantity of SLN dispersion containing a predetermined amount of Paclitaxel was placed into a pre-soaked dialysis membrane with an appropriate molecular weight cut-off (e.g., 12–14 kDa). The sealed dialysis bag was immersed in a dissolution medium, such as phosphate-buffered saline (PBS, pH 7.4) or simulated body fluid, maintained at 37 ± 0.5°C with continuous stirring at 100 rpm to mimic physiological conditions. At predetermined time intervals (e.g., 1, 2, 4, 6, 8 hours), aliquots of the dissolution medium were withdrawn and replaced with an equal volume of fresh medium to maintain sink conditions. The amount of Paclitaxel released was quantified using a validated UV-Visible spectrophotometric method.

Percentage of drug release was determined using the following formula.

$$\text{Perentage drug release} = \frac{Da}{Dt} \times 100$$

Where, Dt = Total amount of the drug

Da = The amount of drug released

Stability studies:

The stability of Paclitaxel-loaded solid lipid nanoparticles was evaluated to assess the formulation's physical and chemical integrity over time under different storage conditions. SLN samples were stored in tightly sealed containers at refrigerated (2–8°C), room temperature (25°C ± 2°C, 60% ± 5% RH), and accelerated conditions (40°C ± 2°C, 75% ± 5% RH) for a period of 3 months.

RESULTS AND DISCUSSION

Drug Excipient Compatibility Studies

FT-IR Spectra of Paclitaxel and excipients were recorded. The characteristic peaks of Paclitaxel were retained in the optimized formulation with minor shifts, indicating the absence of significant drug–excipient interactions and confirming compatibility between the drug and formulation components.

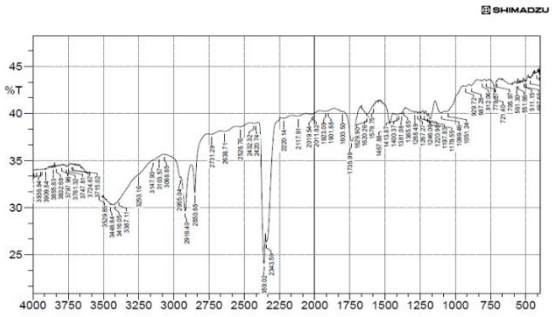


Fig-1: FTIR Spectra of Paclitaxel

Table 2: Characteristic Peaks and frequency of Paclitaxel

S. No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	4000-3500	3902.75
2	OH Bending	1500-1000	1204.65
3	C-H stretching	3000-2500	2839.31
4	C=O stretching	2000-1500	1599.93

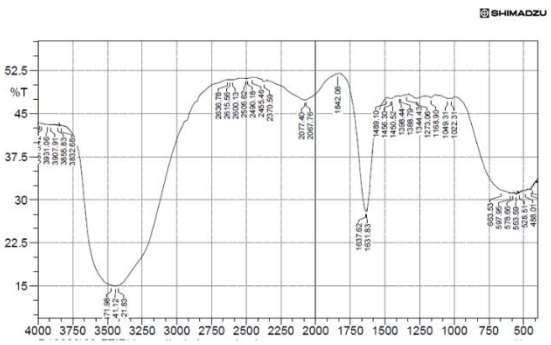


Fig-2: FTIR Spectra of Optimized formulation

Table-3: Characteristic Peaks of Optimized formulation

S. No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	4000-3750	3907.65
2	OH Bending	1500-1000	1481.39
3	C-H stretching	3000-2500	2633.85
4	C=O stretching	2000-1500	1635.73

EVALUATION PARAMETERS

Particle size:

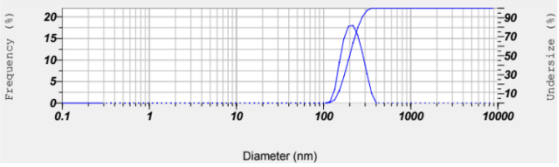


Fig-3: Particle size analysis of Optimized formulation

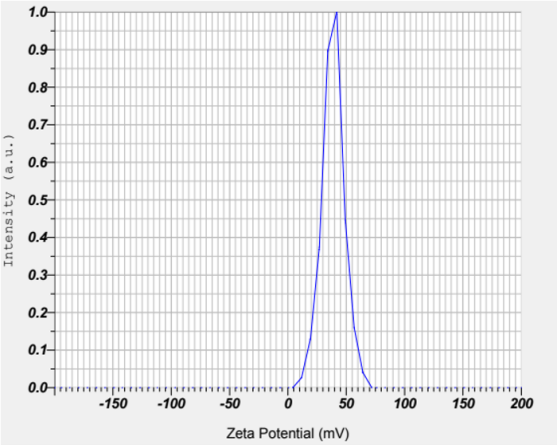


Fig-4: Zeta potential of Optimized formulation

Surface morphology:

The SEM images revealed that the SLNs were predominantly spherical in shape with a smooth surface and minimal aggregation.

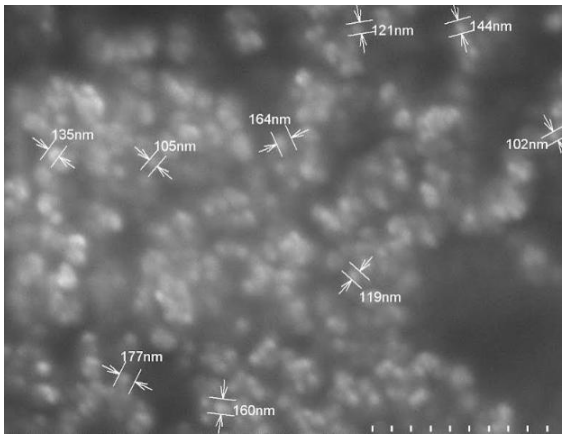


Fig-5: SEM analysis of Optimized Solid lipid nanoparticle

Particle Size:

The particle size of the prepared solid lipid nanoparticles ranged from 102 nm to 210 nm. It was observed that particle size decreased from F1 to F4, which indicates better homogenization and stabilization of nanoparticles. Smaller particle size improves drug absorption, stability, and targeting efficiency. Among all formulations, F4 showed the smallest particle size (102 nm) indicating better nanoparticle formation.

Zeta Potential:

The zeta potential values of the prepared formulations ranged from -18.4 mV to -25.8 mV. Negative zeta potential values indicate good stability of nanoparticles due to electrostatic repulsion between particles, which prevents aggregation. F4 exhibited the highest absolute zeta potential value (−25.8 mV), indicating improved stability of the nanoparticle system.

Entrapment Efficiency (EE):

Entrapment efficiency of the prepared SLNs ranged from 72.5% to 85.6%. The results showed that entrapment efficiency increased from F1 to F4, indicating better drug incorporation within the lipid matrix. Higher entrapment efficiency suggests effective drug loading and reduced drug loss during formulation. The highest entrapment efficiency was observed in F4 (85.6%), which indicates better drug encapsulation.

Table-4: Entrapment Efficiency, Zeta potential and Particle size

Batch No	Particle size (nm)	Zeta potential (mV)	Entrapment Efficiency (%)
F1	210	-18.4	72.5
F2	144	-21.6	78.2
F3	121	-23.2	81.4
F4	102	-25.8	85.6

In vitro drug release studies

Table-5: In vitro drug release profiles of SLN (F1-F4)

Time	F1	F2	F3	F4
0	0	0	0	0
1	14.63	15.93	16.83	17.35
2	23.28	25.50	24.58	23.60
3	34.57	35.76	33.21	34.51
4	45.30	44.97	46.58	47.75
5	59.86	66.58	63.28	65.35
6	68.43	74.12	72.15	73.28
7	79.82	81.20	83.25	82.35
8	89.56	91.25	95.57	97.55

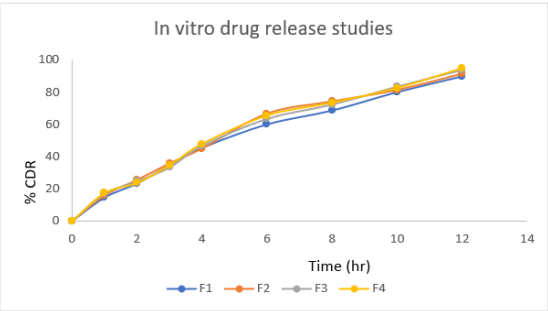


Fig-6: Drug release for (F1-F4) formulations

Observation:

The in-vitro drug release study of SLN formulations (F1–F4) showed a gradual and sustained release pattern over 8 hours. Drug release increased with time for all formulations. Among them, F4 showed the highest cumulative drug release (97.55%), followed by F3 (95.57%), F2 (91.25%), and F1 (89.56%) at 8 hours, indicating better drug release behavior and suggesting F4 as the optimized formulation.

Stability studies:

Table-6: Results of stability studies of optimized formulation F-4

Formulation Code	Parameters	Initial	1st Month	2nd Month	3rd Month	Limits as per Specifications
F-4	250C/60%RH	97.55	95.82	93.74	91.63	Not less than 90%
F-4	300C/75% RH	97.55	95.40	93.15	91.84	Not less than 90%
F-4	400C/75% RH	97.55	95.96	93.48	91.34	Not less than 90%

The stability study results showed that the optimized formulation F4 remained stable for 3 months under different storage conditions, with only a slight decrease in drug content. The values remained within the acceptable limit (NLT 90%), indicating good stability of the SLN formulation.

CONCLUSION

The present study was successfully carried out to formulate and evaluate Paclitaxel-loaded solid lipid nanoparticles (SLNs) with the aim of improving drug delivery and release characteristics. Paclitaxel-loaded SLNs were prepared by the hot homogenization method using Glyceryl monostearate as the lipid matrix and Tween 40 and Span 80 as surfactants. Reformulation studies confirmed the identity and purity of Paclitaxel. FTIR studies revealed the absence of significant drug–excipient interactions, indicating compatibility between Paclitaxel and the formulation components. The prepared SLNs were successfully evaluated for particle size, zeta potential, entrapment efficiency, surface morphology, and in vitro drug release. Among all formulations, F4 was identified as the optimized formulation, exhibiting the smallest particle size (102 nm), highest zeta potential (−25.8 mV), and maximum entrapment efficiency (85.6%). SEM analysis demonstrated that the nanoparticles were predominantly spherical in shape with smooth surface morphology and minimal aggregation. In vitro drug release studies showed a sustained release pattern, with formulation F4 exhibiting the highest cumulative drug release of 97.55% over 8 hours. Stability studies conducted for a period of 3 months under different storage conditions demonstrated that the optimized formulation remained stable, with drug content remaining within acceptable limits. Overall, the results indicate that Paclitaxel-loaded solid lipid nanoparticles are a promising drug delivery system capable of enhancing drug encapsulation, stability, and controlled release characteristics. The optimized formulation may offer improved therapeutic efficacy and can be considered a potential carrier system for Paclitaxel delivery.

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