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Review

Development & Characterization of Solid Lipid Nanoparticles of Lasmiditan

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Abstract

The present study focuses on the development and characterization of solid lipid nanoparticles (SLNs) of Lasmiditan with the aim of enhancing drug encapsulation, stability, and controlled drug release. Solid lipid nanoparticles were formulated using lipid-based excipients due to their biocompatibility, biodegradability, and ability to improve the bioavailability of poorly soluble drugs. Lasmiditan-loaded SLNs were prepared by the solvent evaporation method, employing stearic acid as the solid lipid, Tween 20 as the surfactant, and propylene glycol as the co-surfactant. Preformulation studies confirmed the suitability of Lasmiditan for incorporation into lipid matrices, and UV spectrophotometric analysis established its maximum absorbance at 255 nm in phosphate buffer pH 7.4 for analytical evaluation. Among all formulations, LSLN7 exhibited the smallest particle size, highest entrapment efficiency, and satisfactory zeta potential, indicating good colloidal stability. Surface morphological studies using scanning electron microscopy revealed nanosized particles with some aggregation attributed to the freeze-drying process. In vitro drug release studies demonstrated sustained release behavior, with the optimized formulation LSLN7 showing 99.01% drug release over 12 hours. Release kinetics analysis suggested diffusion-controlled drug release. Stability studies indicated no significant changes in physical appearance, particle size, or entrapment efficiency under different storage conditions. Overall, the results demonstrate that Lasmiditan-loaded solid lipid nanoparticles, particularly formulation LSLN7, represent a promising and stable drug delivery system suitable for further in vivo evaluation.

Keywords: Lasmiditan, Solid Lipid Nanoparticles, Solvent Evaporation Method, Entrapment Efficiency, Nanotechnology Based Drug Delivery

1. INTRODUCTION

The emergence of nanotechnology in pharmaceutical sciences has revolutionized drug delivery systems, particularly for drugs with poor solubility, limited bioavailability, and suboptimal pharmacokinetic profiles.[1] Among various nanocarriers, Solid Lipid Nanoparticles (SLNs) have garnered significant interest due to their unique ability to encapsulate lipophilic and hydrophilic drugs within a biocompatible lipid matrix, offering controlled drug release, enhanced stability, and improved drug bioavailability. Nanotechnology, defined as the manipulation and application of materials at the nanometer scale (1–100 nm), has emerged as a transformative field across multiple scientific disciplines.[2] In pharmaceutical sciences, nanotechnology has not merely introduced incremental improvements; it has initiated a paradigm shift in how drugs are designed, formulated, and delivered. The ability to engineer materials at the molecular and supramolecular levels allows for precise control over the physicochemical properties of drug carriers, including particle size, surface charge, hydrophobicity, and drug loading capacity.[3] This precision enables the design of drug delivery systems that can address limitations of conventional dosage forms, such as poor solubility, low stability, short circulation half-life, and non-specific distribution. Over the past three decades, nanotechnology in pharmaceuticals has evolved from experimental curiosity to clinical reality. Early approaches focused on polymeric nanoparticles and liposomes, which demonstrated the feasibility of nanoscale drug encapsulation.[4] Liposomal formulations such as liposomal amphotericin B and doxorubicin marked the first wave of clinically approved nanomedicines. Subsequently, the development of nanostructured lipid carriers (NLCs), dendrimers, nanoemulsions, and SLNs represented further refinements. Each generation of nanocarriers addressed specific drawbacks of previous systems—improving drug loading, stability, biocompatibility, or scalability.[5] Solid Lipid Nanoparticles (SLNs) are submicron colloidal carriers, typically in the range of 50–1000 nm, composed of physiologically compatible lipids that remain solid at both room and body temperatures. Unlike oil-in-water emulsions, where the core remains liquid, SLNs maintain a solid lipid core matrix capable of incorporating both hydrophobic and hydrophilic drug molecules.[6] The solid matrix provides controlled drug release, protection of labile drugs from degradation, and improved bioavailability. SLNs are stabilized by surfactants, which prevent particle aggregation and ensure a stable dispersion. The unique combination of solid lipid core and nanoscale dimensions imparts SLNs with several advantages. Firstly, they enhance the stability of drugs sensitive to hydrolysis or oxidation by protecting them within the lipid matrix. Secondly, SLNs can modulate drug release profiles, allowing for sustained or targeted delivery.[7] Thirdly, they offer excellent biocompatibility and biodegradability, as the lipids used are generally recognized as safe (GRAS). Moreover, SLNs can be produced without the use of toxic organic solvents, reducing environmental and safety concerns. Compared to polymeric nanoparticles, they avoid issues of polymer toxicity and cost. The formulation of SLNs generally includes solid lipids, surfactants, and aqueous phase. Solid lipids may include triglycerides (e.g., tristearin), partial glycerides (e.g., glyceryl monostearate), fatty acids (e.g., stearic acid), or waxes.[8] Surfactants such as polysorbates, poloxamers, or lecithin stabilize the dispersion by reducing surface tension and preventing aggregation. The choice of lipid and surfactant influences not only particle size but also drug loading, release kinetics, and physical stability. Several techniques have been developed for the preparation of SLNs, each with distinct advantages. High-pressure homogenization (HPH) is the most commonly employed method, involving the application of high shear forces to a hot lipid-drug-surfactant mixture.[9] Other methods include solvent evaporation, solvent emulsification–diffusion, microemulsion-based techniques, and ultrasonication. Process parameters such as homogenization pressure, temperature, and number of cycles must be optimized to produce SLNs with desired size, polydispersity, and drug loading efficiency. Drugs can be incorporated into SLNs through three main models: the homogeneous matrix model (drug evenly distributed in the lipid matrix), the drug-enriched shell model (drug concentrated near the particle surface), and the drug-enriched core model (drug concentrated in the central lipid core).[10] The release profile is influenced by drug solubility in the lipid, lipid crystallinity, and particle size. Release mechanisms may involve diffusion through the lipid matrix, erosion of the matrix, or a combination of both.

Functionalization of SLNs with targeting ligands such as antibodies, peptides, or folic acid can direct drug-loaded nanoparticles to specific tissues or cells. This active targeting approach is particularly valuable in cancer therapy, where selective delivery to tumor cells can reduce systemic toxicity.[11] Passive targeting can also be achieved via the enhanced permeability and retention (EPR) effect in tumor vasculature.

The regulatory approval pathway for SLN-based products involves rigorous evaluation of their safety, efficacy, and quality attributes. Parameters such as particle size distribution, zeta potential, encapsulation efficiency, and in vitro release profile must be thoroughly characterized.[12] Several SLN-based cosmetic products are already on the market, and pharmaceutical products are progressing through clinical trials, indicating growing commercial interest.

The future of SLNs lies in hybrid systems that combine their solid lipid core with other nanostructures, such as polymer coatings or stimuli-responsive materials, to achieve on-demand drug release. Advances in lipid chemistry and nanofabrication techniques will enable more precise control over drug loading and release kinetics.[13] Moreover, integrating SLNs with diagnostic agents could pave the way for theranostic applications—simultaneous therapy and diagnosis.

The emergence of nanotechnology in pharmaceutical sciences has revolutionized drug delivery, offering novel solutions for drugs with poor solubility, low bioavailability, and challenging pharmacokinetics. Among various nanocarriers, SLNs stand out due to their biocompatibility, versatility, and ability to provide controlled release.[14] Continued research and technological advancements hold promise for translating SLNs from laboratory prototypes to widely available therapeutic products, ultimately enhancing patient outcomes.

2. Materials and Methods

Materials

Lasmiditan was procured from Spark Analytical, Hyderabad, a supplier recognized for providing high-purity analytical-grade pharmaceutical compounds. All other excipients and formulation components were obtained from S.D. Fine Chemicals. The solid lipid selected for the preparation of solid lipid nanoparticles included Glyceryl Monostearate (GMS), which served as the lipid matrix for drug encapsulation. Surfactants such as Poloxamer 188 and Tween 80 were employed to stabilize the nanoparticulate dispersion and prevent particle aggregation during formulation.[15] Soy lecithin was used as a co-surfactant to enhance emulsification efficiency and improve nanoparticle stability. Organic solvents such as Iso Propyl Alcohol were utilized for dissolving the lipid phase during the preparation process. Purified water was used as the aqueous phase throughout the formulation.[16] The use of pharmaceutical-grade lipids, surfactants, and solvents from trusted suppliers contributed to the successful development of stable, reproducible, and efficient solid lipid nanoparticles of Lasmiditan suitable for enhanced drug delivery.

Methods

Preformulation Studies- The drug substance selected for the development of solid lipid nanoparticles was characterized for its essential physicochemical properties prior to formulation. Lasmiditan is a white, odourless crystalline powder with an extremely bitter taste; however, taste masking is not a primary concern in lipid-based nanoparticulate systems intended to enhance solubility and bioavailability.[17] The solubility profile of Lasmiditan revealed good solubility in 5.5 pH phosphate buffer, which is advantageous for dissolution studies and in vitro release evaluation of lipid-based formulations. The drug exhibited high solubility in Dimethyl Sulfoxide (DMSO), making it suitable for analytical estimations and drug loading studies, while it was only slightly soluble in ethanol, indicating limited compatibility with alcohol-based solvents.[18] The lipophilic nature of Lasmiditan supports its incorporation into lipid matrices used in solid lipid nanoparticles. The maximum absorbance (λmax) of Lasmiditan was found to be 296 nm, which was utilized for spectrophotometric analysis during drug content determination and in vitro release studies.[19]

FORMULATION OF SOLID LIPID NANOPARTICLES OF LASMIDITAN

The Solid Lipid Nanoparticles (SLNs) of Lasmiditan were prepared using the hot homogenization followed by ultrasonication technique, a widely used method for formulating lipid-based nanoparticles. A specific quantity of solid lipid (e.g., GMS or Compritol) was weighed and melted at 5–10°C above its melting point (typically 70–80°C). Lasmiditan was dispersed or dissolved in the molten lipid under continuous stirring to ensure uniform mixing.[20] Surfactants (e.g., Poloxamer 188 or Tween 80) and co-surfactants, if applicable, were dissolved in hot distilled water maintained at the same temperature as the lipid phase. The hot aqueous phase was slowly added to the molten lipid phase under high-speed magnetic or mechanical stirring (e.g., 8000–10000 rpm for 5–10 minutes) to form a coarse pre-emulsion. The pre-emulsion was then subjected to probe ultrasonication (e.g., 60% amplitude for 5–10 minutes) to reduce the particle size and obtain a fine nanoemulsion.[21] The hot nanoemulsion was rapidly cooled in an ice bath or kept at room temperature, leading to solidification of lipid droplets, forming Solid Lipid Nanoparticles. The

SLNs were stored in airtight amber glass vials at 4°C until further evaluation.[22]

Table No: 1 Formulation Table

Ingredients	LSLN1	LSLN2	LSLN3	LSLN4	LSLN5	LSLN6	LSLN7	LSLN8	LSLN9
Lasmiditan (mg)	20	20	20	20	20	20	20	20	20
Stearic Acid(mg)	20	30	40	20	30	40	20	30	40
Olive oil(ml)	5	5	5	10	10	10	15	15	15
Propylene Glycol(ml)	5	5	5	5	5	5	5	5	5
Methanol(ml)	20	20	20	20	20	20	20	20	20

EVALUATION OF SOLID LIPID NANOPARTICLES OF LASMIDITAN

1. Physical Appearance:

The SLNs were visually inspected for color, uniformity, opacity, phase separation, and any signs of precipitation or drug crystallization.

2. Particle Size, Polydispersity Index (PDI), and Zeta Potential:

Dynamic Light Scattering (DLS) technique was used to measure average particle size and PDI using a Zetasizer.

Zeta potential was analyzed to evaluate the surface charge and colloidal stability.

Ideal SLNs showed particle size in the range of 100–300 nm, PDI < 0.3, and zeta potential > ±30 mV.

3. Entrapment Efficiency (%EE):

The formulation was centrifuged at high speed (e.g., 15000 rpm for 30 min at 4°C) to separate free drug from SLNs. The supernatant was collected, and unentrapped Lasmiditan was analyzed by UV-Vis spectrophotometer at λ_{max} ~273 nm. %EE was calculated using the formula:

$$\%EE=(\text{Total drug}-\text{Free drug}\text{Total drug})\times 100\backslash\%EE = \backslash left(\backslash frac\{Total\backslash:drug - Free\backslash:drug\}\{Total\backslash:drug\} \backslash right) \backslash times\ 100\%EE=(\text{Totaldrug}\text{Totaldrug}-\text{Freedrug})\times 100$$

4. Drug Loading (%DL):

$$\%DL=(\text{Amount of drug in SLNs Total weight of SLNs})\times 100\backslash\%DL = \backslash left(\backslash frac\{Amount\backslash:of\backslash:drug\backslash:in\backslash:SLNs\}\{Total\backslash:weight\backslash:of\backslash:SLNs\}100\%DL=(\text{TotalweightofSLNsAmountofdruginSLNs})\times 100$$

5. Morphological Study:

Transmission Electron Microscopy (TEM) or Scanning Electron Microscopy (SEM) was used to visualize the shape and surface characteristics of SLNs.[23]

Well-formed SLNs showed spherical morphology with a smooth surface.

6. pH Determination:

The pH of the SLN dispersion was measured using a calibrated digital pH meter to ensure it is suitable for biological application (ideally between 5.5–7.5).

7. In Vitro Drug Release:

Drug release studies were carried out using a dialysis membrane method. The SLN dispersion was placed in a dialysis bag and suspended in phosphate buffer pH 7.4 at 37 ± 0.5°C with constant stirring.[24] Samples were withdrawn at regular intervals, filtered, and analyzed spectrophotometrically.

8. Drug Release Kinetics:

The cumulative drug release data were fitted to zero-order, first-order, Higuchi, and Korsmeyer–Peppas models. The correlation coefficient (R^2) values were compared, and the best-fit model was determined.

Lasmiditan SLNs typically showed Higuchi or Korsmeyer–Peppas kinetics, indicating diffusion-controlled or anomalous transport mechanisms.[25]

Results and Discussions-

Table No: 2 organoleptic properties of Lasmiditan

Properties	Results
Taste	Extremely bitter in taste
Odour	Odourless
Colour	White

Solubility study of Lasmiditan:

Table No: 3 Solubility of Lasmiditan

Medium	**Solubility**
DMSO	Soluble
Ethanol	Slightly soluble
5.5 pH Phosphate buffer	Excellent

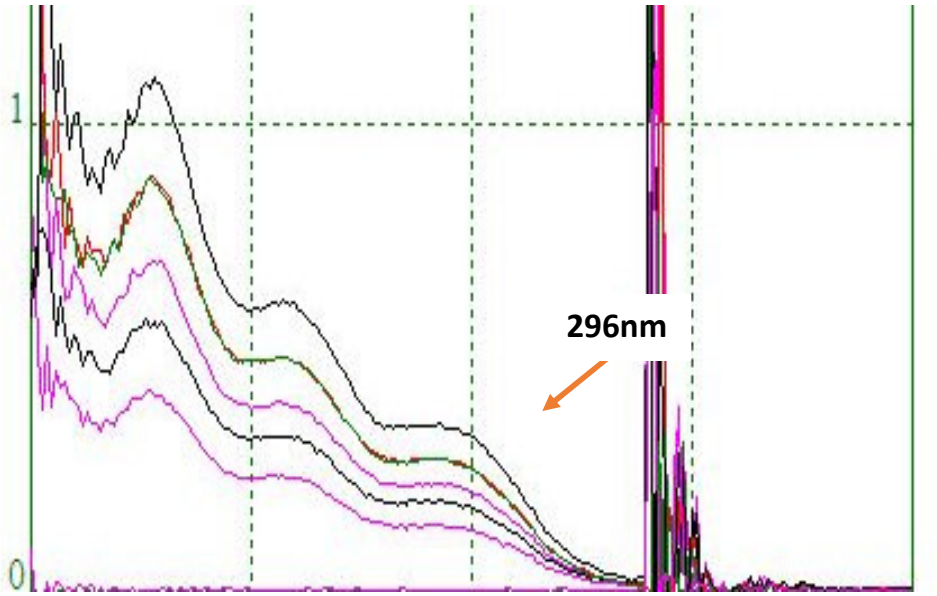

Figure No: 1 (UV Spectra of Lasmiditan)

The standard curve is prepared in the concentration range of 2-10µg/ml. Different volumes of standard stock solutions were prepared transferred to 10ml volumetric flasks and volume has been made up with0.1N HCI. The absorbance were measured at 296nm against the corresponding blank solution.

Table No: 4 Calibration data of Lasmiditan in 0.1 N HCI at 296 nm

Sl. No	**Concentration (µg/ml)**	**Absorbance**
1	2	0.0355
2	4	0.0866
3	6	0.1388
4	8	0.1771
5	10	0.2235
Y=0.0233x-0.0076 (n=3)		R^2 =0.9971

FIGURE NO. 2 Standard Curve of Lasmiditan In 0.1 N HCI at 296 nm

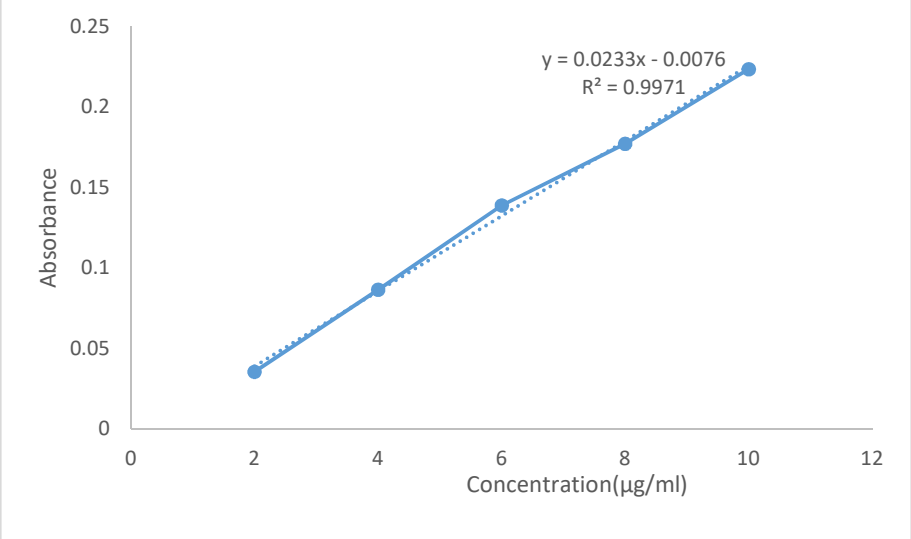

Table No: 5 Calibration data of Lasmiditan in pH-6.8 Phosphate buffer at 296 nm

Sl.N	Concentration (µg/ml)	Absorbance
1	2	0.2121
2	4	0.4152
3	6	0.5931
4	8	0.7931
5	10	0.8963

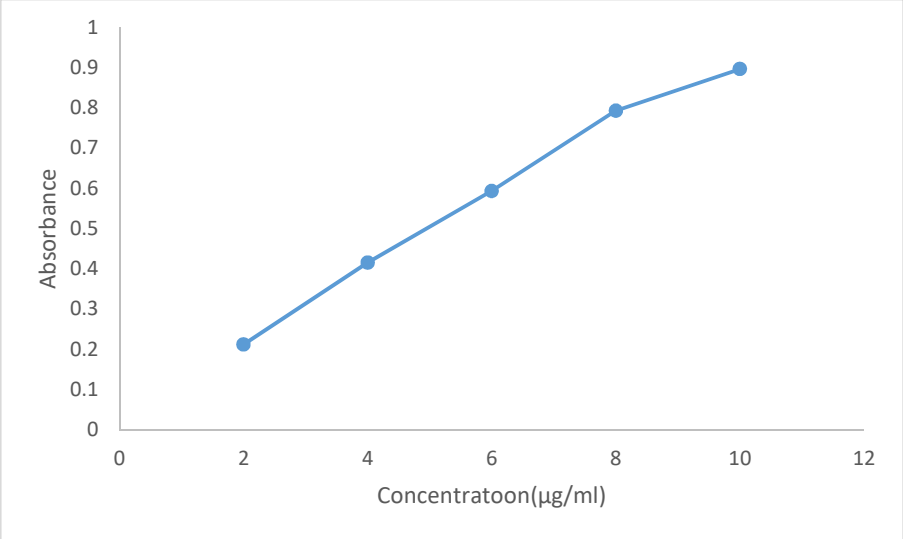

Figure No: 3 Standard curve of Lasmiditan in pH-6.8 Phosphate buffe

FTIR

Pure Lasmiditan IR spectra are displayed in Figure 5. Lasmiditan's spectra exhibit peaks at 1755.28 C= O cm 1 for NH- stretching, 1618.33 cm 1 for C=C stretching, 1276.92 cm 1 for C-N amine bond, 516.94 cm 1 for halogen compound (C-Cl) link, 2997.48 (alkane compound), 2947.33, 2883.68 with O-H bond, and 1188.19 with C-N bond. Lasmiditan-formulated NLC spectra exhibit a shift in the pure drug's spectral peaks, proving the presence of drug in these formulations

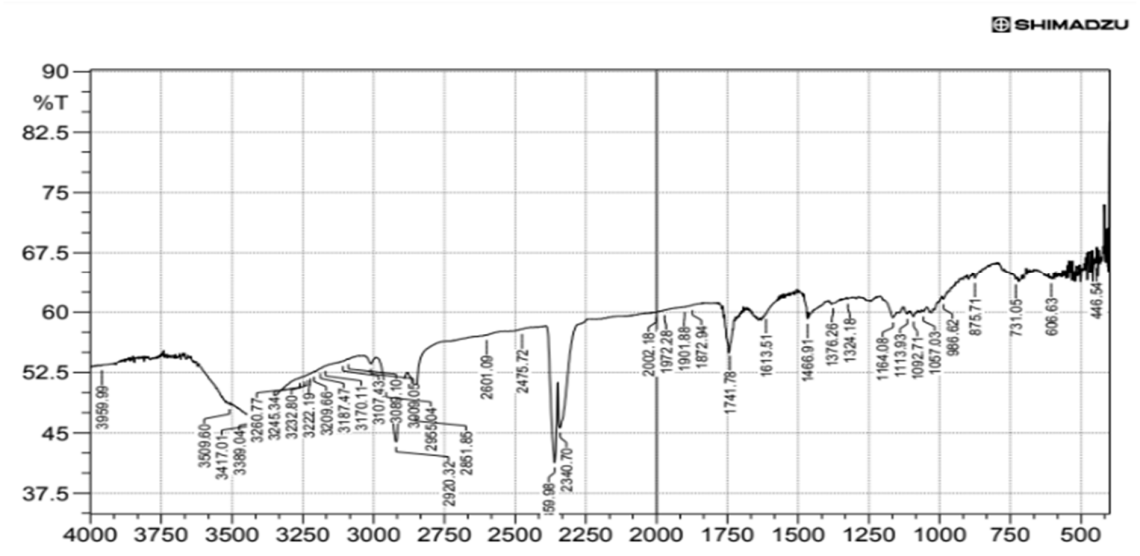

Figure No: 4 FTIR of Pure Drug

Table No: 6 Formulation Table for* Lasmiditan *loaded SLN

Ingredients	LSLN1	LSLN2	LSLN3	LSLN4	LSLN5	LSLN6	LSLN7	LSLN8	LSLN9
Lasmiditan (mg)	20	20	20	20	20	20	20	20	20
Stearic Acid(mg)	20	30	40	20	30	40	20	30	40
Olive oil(ml)	5	5	5	10	10	10	15	15	15
Propylene Glycol(ml)	5	5	5	5	5	5	5	5	5
Methanol(ml)	20	20	20	20	20	20	20	20	20

***LSLN:* Lasmiditan loaded Solid lipid Nanoparticles**

Table No: 7 Characterization of* Lasmiditan *SLN(LSLN)

Formulation	Particle size(nm)	EE%	Zeta potential(mV)
LSLN1	217±6.24	70.17±1.01	-21
LSLN2	270±8.21	72.8±2.04	-23
LSLN3	323±11.04	81.23±1.32	-20
LSLN4	243±10.45	59.37±2.36	-23
LSLN5	283±11.35	76.93±2.14	-28
LSLN6	301±12.01	61.62±1.52	-20
LSLN7	101±8.14	85.59±1.07	-28
LSLN8	156±9..47	60.82±1.47	-25
LSLN9	207±10.24	59.47±1.78	-30

(values=Mean ±SD , n=3)

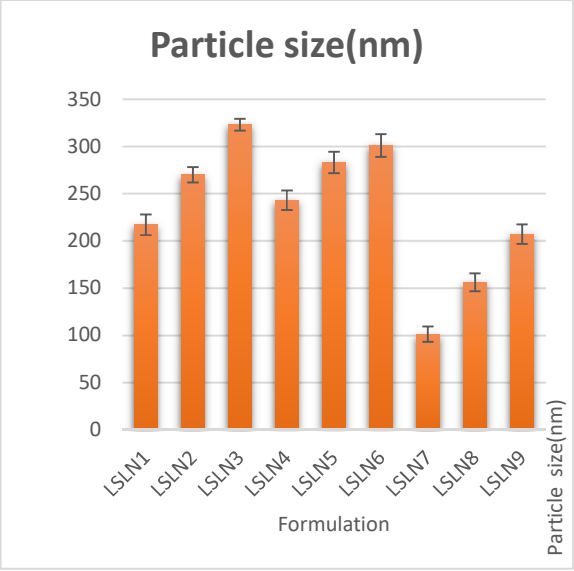

Figure No: 4a Particle size(nm)

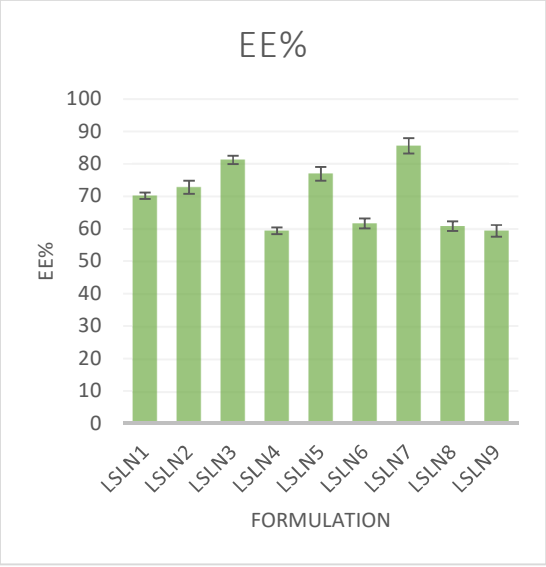

Figure No: 4b EE%

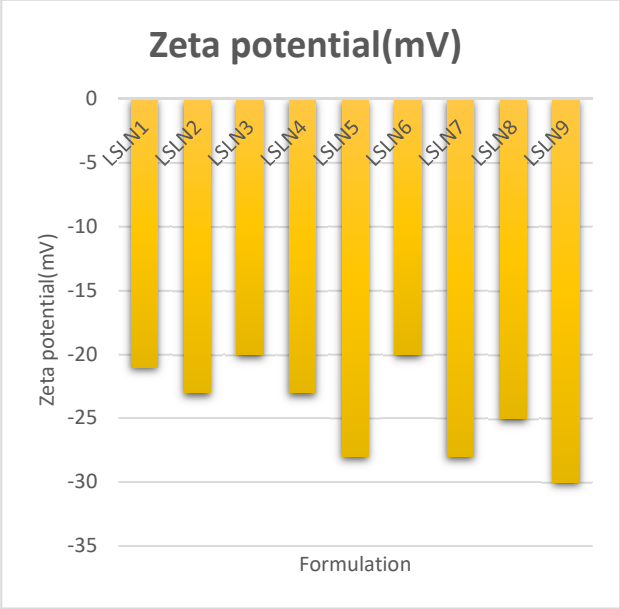

Figure No: 4c Zeta potential(mV)

Table No: 8 In vitro drug release study

Time(hr)	LSLN1	LSLN2	LSLN3	LSLN4	LSLN5	LSLN6	LSLN7	LSLN8	LSLN9
	In-vitro Release %								
0	**0**	**0**	**0**	**0**	**0**	**0**	**0**	0	0
1	30.26	28.13	11.35	15.24	21.36	8.76	**12.14**	22.35	20.26
2	51.33	48.36	32.14	28.13	41.33	12.14	**31.25**	42.14	61.33
4	79.24	68.24	45.78	50.12	56.28	31.25	**46.14**	45.78	89.24
6	98.31	85.44	68.14	67.32	61.25	46.14	**58.34**	58.14	98.44
8	-	97.14	79.14	73.19	80.32	58.34	**79.77**	89.14	-
10	-	-	99.21	78.13	99.14	79.77	**88.76**	98.21	-
12	-	-	-	82.13	-	88.76	**99.01**		-

Figure No: 5 Release kinetic parameters of Lasmiditan loaded *SLN*

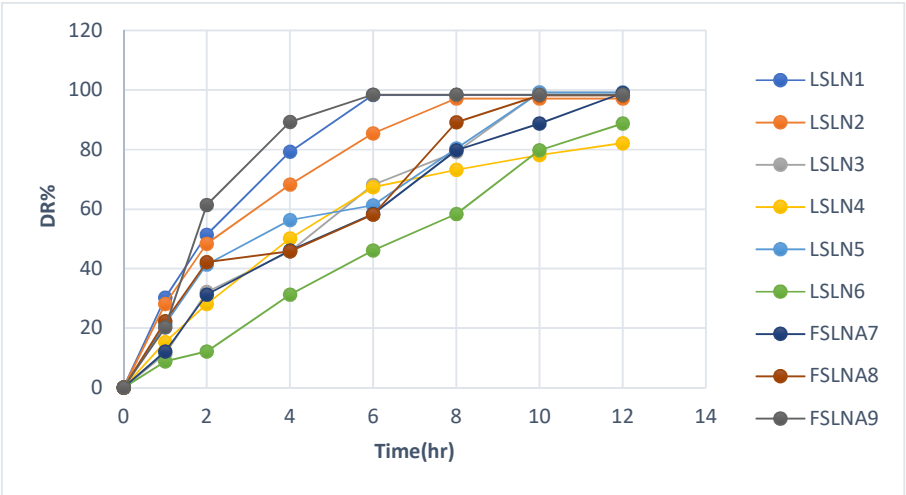

Table No: 9 Stability Results for best formula LSLN7

Formulation	Zero order	First order	Higuchi	Korsmeyer Peppas	N-values
LSLN1	0.998	0.874	0.991	0.994	0.807
LSLN2	0.947	0.894	0.947	0.944	0.718
LSLN3	0.987	0.974	0.984	0.981	0.845
LSLN4	0.997	0.875	0.991	0.998	0.866
LSLN5	0.954	0.861	0.956	0.953	0.874
LSLN6	0.965	0.876	0.968	0.968	0.841
LSLN7	0.999	0.843	0.907	0.994	0.798
LSLN8	0.968	0.872	0.975	0.960	0.872
LSLN9	0.987	0.853	0.981	0.988	0.741

Days	**25^0 C±2^0 C/60%±5%RH**			**40 ^{0} C± 2 ^{0}C /75%±5% RH**		
	Appearance	**Particle size**	**EE%**	**Appearance**	**Particle size**	**EE%**
0	Clear	101±8.14nm	85.59±1.07	Clear	101±8.14nm	85.59±1.07
30	Clear	101±8.18nm	85.58±1.17	Clear	101±8.08nm	85.78±1.17
60	Clear	101±8.24nm	85.42±1.27	Clear	101±8.34nm	85.32±1.26
90	Clear	102±8.04nm	85.39±1.27	Clear	101±7.04nm	84.39±1.29
180	Clear	102±8.44nm	84.89±1.17	Clear	102±7.14nm	84.29±1.07

Conclusion

In the present research work, solid lipid nanoparticles (SLNs) of Lasmiditan were successfully developed with the objective of improving drug encapsulation, stability, and controlled drug release characteristics. The SLNs were prepared using the solvent evaporation method, which was selected due to its simplicity, reproducibility, and suitability for lipid-based nanoparticulate systems. Stearic acid was chosen as the solid lipid because of its biocompatibility, favorable melting characteristics, and ability to efficiently entrap lipophilic drug molecules. Tween 20 was employed as the surfactant to reduce interfacial tension and stabilize the nanoparticulate dispersion, while propylene glycol (PG) was used as a co-surfactant to enhance emulsification efficiency and improve formulation stability. Methanol was used as the solvent for dissolving the lipid phase during the formulation process.

For analytical characterization, a solution of Lasmiditan Meglumine prepared in phosphate buffer pH 7.4 was scanned in the ultraviolet region between 200 and 350 nm using a LabIndia UV-1601 spectrophotometer (India). The drug exhibited a maximum absorbance (λmax) at 255 nm in phosphate buffer pH 7.4, which was subsequently utilized for quantitative estimation of drug content, entrapment efficiency, and in vitro drug release studies. A total of nine SLN formulations were prepared by varying formulation parameters, and all batches were systematically evaluated for critical quality attributes, including particle size, entrapment efficiency, and zeta potential.

The mean particle size of the prepared SLNs was found to be in the range of 101 ± 8.14 nm to 323 ±

11.04 nm, indicating successful formation of nanoparticles suitable for enhanced drug delivery. Among all the formulations, LSLN7 exhibited the smallest mean particle size, suggesting superior emulsification and stabilization. Entrapment efficiency values ranged from 59.37 ± 2.36% to 85.59 ± 1.07%, with the highest entrapment efficiency observed for formulation LSLN7, which may be attributed to optimal lipid–surfactant concentration and effective drug–lipid interaction. The zeta potential values of all nine formulations were observed between −20 and −30 mV, indicating sufficient electrostatic repulsion between particles and good colloidal stability.

Surface morphological evaluation of freeze-dried SLNs using scanning electron microscopy (SEM) revealed aggregation and fusion of particles, which could be attributed to mechanical stress induced by ice crystal formation during the freeze-drying process. In vitro drug release studies demonstrated that the optimized formulation LSLN7 exhibited the most sustained and controlled release profile, releasing 99.01% of Lasmiditan Meglumine over a period of 12 hours. Stability studies conducted at different time points and temperature conditions revealed no significant changes in physical appearance, mean particle size, or entrapment efficiency of the optimized formulation. Based on these results, it was concluded that the Lasmiditan-loaded solid lipid nanoparticle formulation LSLN7 represents the most optimized and stable formulation and is suitable for further in vivo animal studies.

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