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FORMULATION AND *IN VITRO* EVALUATION OF ACARBOSE-LOADED SOLID LIPID NANOPARTICLES

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ABSTRACT

The present study aimed to formulate and evaluate Acarbose-loaded solid lipid nanoparticles (SLNs) to enhance their therapeutic efficacy and overcome limitations related to their low oral bioavailability. SLNs were prepared using glyceryl monostearate as a lipid carrier and Tween 80 as a surfactant by the solvent evaporation/emulsification technique. Preformulation studies, including solubility, FTIR, and DSC analysis, confirmed the compatibility of the drug with selected excipients. Nine formulations (F1– F9) were developed and characterized for particle size, polydispersity index (PDI), zeta potential, drug content, entrapment efficiency, and surface morphology by SEM. Among all batches, formulation F6 exhibited superior attributes, including a mean size of 312 nm, a zeta potential of −26.4 mV, a drug content of 94.35%, and an entrapment efficiency of 88.15%. In vitro drug release studies using the dialysis bag method demonstrated a sustained release pattern over 24 hours, with F6 achieving 89.45% cumulative release, indicating controlled drug delivery potential. Stability studies conducted under various storage conditions for three months revealed no significant changes in the physicochemical properties.. The results suggest that Acarbose-loaded SLNs can serve as a promising nanocarrier system for improving bioavailability and providing sustained drug release in the management of diabetes mellitus.

KEYWORDS: Nanoparticle, Acarbose, Diabetes, Controlled drug delivery.

INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both, leading to altered metabolism of carbohydrate, fats, and proteins.[1] Historical accounts from Ayurvedic texts describe polyuria, polydipsia, and weight loss, symptoms now recognized as typical of diabetes.[2] The term "diabetes" was introduced by the Greek physician Aretaeus to describe excessive urination, and "mellitus" (meaning honey-sweet) was added in the 18th century to reflect the presence of glucose in urine.[3] Today, diabetes is classified into type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), gestational diabetes, and secondary forms linked to other medical conditions.[4] Type 1 results from autoimmune destruction of pancreatic β-cells, leading to absolute insulin deficiency, while type 2 is characterized by insulin resistance and progressive β-cell dysfunction.[5]

Management strategies aim to maintain blood glucose within a normal range and prevent micro- vascular and macro-vascular complications.[6] In T1DM, insulin therapy is mandatory, whereas T2DM is typically

managed through lifestyle modifications and oral antidiabetic drugs such as biguanides, sulfonylureas, thiazolidinediones, DPP-4 inhibitors, SGLT-2 inhibitors, and α-glucosidase inhibitors.[7] Despite the availability of these agents, many patients fail to achieve optimal glycemic control due to side effects, poor adherence, and limited drug bioavailability.[8] Acarbose, an α-glucosidase inhibitor derived from microbial fermentation, acts locally in the small intestine by competitively inhibiting enzymes responsible for carbohydrate breakdown, thereby slowing glucose absorption and blunting postprandial hyperglycemia. It is particularly beneficial in managing early- stage T2DM and impaired glucose tolerance.[9] However, its therapeutic use is restricted by extremely low oral bioavailability (< 2%), short intestinal residence time, hydrophilic nature, and dose-dependent gastrointestinal side effects including bloating, flatulence, and diarrhea.[10] These limitations necessitate frequent dosing and can reduce patient compliance. Nanotechnology offers promising solutions to many drug delivery challenges, especially for compounds with poor absorption and stability.[11] Nanocarriers such as liposomes, polymeric nanoparticles, and solid lipid nanoparticles (SLNs) can enhance drug stability, protect against enzymatic degradation, control release, and potentially improve bioavailability.[12] SLNs, introduced in the early 1990s, are submicron carriers (50–1000 nm) composed of physiological lipids solid at room and body temperature, stabilized by surfactants in an aqueous dispersion.[13] Their solid lipid matrix allows the incorporation of active agents while providing controlled drug release and improved stability compared to conventional emulsions or liposomes.[14] SLNs are produced using methods such as high-pressure homogenization, solvent emulsification–evaporation, and microemulsion techniques.[15]

The advantages of SLNs include bio-compatibility, the possibility of large-scale production without toxic organic solvents, protection of labile drugs from degradation, and the potential to modify release profiles.[16] They can improve the bioavailability of poorly soluble drugs, enable site-specific targeting, and reduce systemic side effects.[17] However, Solid lipid nanoparticles (SLNs) present some drawbacks, such as low drug loading efficiency, drug expulsion during storage due to lipid crystallization, and an initial burst release of the drug.[18] Optimizing formulation parameters- such as lipid selection, surfactant type and concentration, and processing conditions-can overcome these drawbacks and yield nanoparticles with desirable particle size, polydispersity index (PDI), high entrapment efficiency, and long-term stability.[19] Commonly used lipids include glyceryl monostearate, glyceryl behenate, and stearic acid, while stabilizers like Tween 80, Poloxamer 188, or lecithin prevent aggregation and maintain dispersion stability .[20]

SLNs have been successfully applied across various delivery routes, including oral, parenteral, transdermal, and ocular administration. Oral SLN formulations have enhanced the bioavailability of drugs such as simvastatin and anti-tubercular agents.[21, 22] Parenterally, they have been used for anticancer drugs like doxorubicin to improve tumor targeting.[23] Topical applications include enhanced dermal penetration of anti-inflammatory drugs and cosmetic actives.[24] Their versatility extends to gene delivery, vaccine adjuvants, and nutraceutical encapsulation.[25] Given these advantages, SLNs are a suitable platform for improving the delivery of hydrophilic drugs like acarbose, which require protection from gastrointestinal degradation and controlled release for prolonged therapeutic action.

Considering the pharmacological potential of acarbose and the formulation advantages of SLNs, this study is designed to address the key limitations of conventional acarbose therapy. By encapsulating acarbose within an optimized SLN system, the formulation is expected to achieve nano-range particle size, high entrapment efficiency, and sustained drug release in the intestinal environment. Therefore, it is hypothesized that acarbose-loaded SLNs will enhance drug stability, modulate release kinetics, and improve therapeutic performance, ultimately offering a more effective nanotechnology-based strategy for diabetes management.

MATERIALS AND METHODS

Materials

Acarbose was obtained from Yarrow Chem Products (India). Glyceryl monostearate, Tween 80, chloroform, n-propanol, and sodium chloride were procured from Chennai Chemicals (India). Potassium dihydrogen orthophosphate and disodium hydrogen orthophosphate were supplied by Loba Chemie (India). All chemicals and reagents used in this study were of analytical grade and utilized without further purification.

Methods

Solubility Studies

The solubility of Acarbose was determined in different solvents, namely distilled water, chloroform, methanol, and phosphate buffer (pH 7.4). Excess amounts of the drug were added to each solvent and shaken under controlled conditions until equilibrium was reached, after which the solutions were filtered, suitably diluted, and analyzed spectrophotometrically to quantify the dissolved drug.

Standard Curve of Acarbose

A standard stock solution was prepared by accurately weighing 25 mg of acarbose into a 25 mL volumetric flask, dissolving it in methanol, and making up the volume to obtain a concentration of 1000 µg/mL. From this stock, 10 mL was transferred into a 100 mL volumetric flask and diluted with methanol to yield a working standard solution of 100 µg/mL.[26]

Fourier Transform Infrared (FTIR) Spectroscopic Studies

Drug–excipient compatibility was assessed using a Fourier transform infrared (FTIR). Infrared (IR) spectra were recorded for the pure drug, its physical mixtures with excipients, and the optimized formulation. Baseline correction was performed using dried potassium bromide (KBr), and the samples (drug, formulation mixture, and KBr) were finely ground, compressed into pellets, and analyzed over the specified wavelength range.[27]

Differential Scanning Calorimetry (DSC)

Thermal characteristics of the samples were analyzed using DSC. Approximately 2–5 mg of each sample was accurately weighed into an aluminum pan, sealed, and placed under a nitrogen atmosphere. Heating was carried out from room temperature to 250 °C at a controlled rate. The resulting thermograms were evaluated to determine melting points, degree of crystallinity, and possible drug– excipient interactions.[28]

Preparation of Acarbose-Loaded Solid Lipid Nanoparticles

The selection of a suitable preparation method is influenced by both the physicochemical properties of the drug and formulation variables such as lipid concentration, type of stabilizer, and processing conditions. Commonly employed techniques for SLN preparation include solvent emulsification– evaporation, microemulsion-based methods, high-shear homogenization, ultrasonication, and high- pressure homogenization.[15] In the present study, the solvent evaporation method was selected due to its compatibility with the drug and formulation requirements. This technique is based on the precipitation of glyceryl monostearate (GMS) from an oil-in-water (O/W) emulsion to form SLNs.[29, 30] In this process, GMS is dissolved in a water-immiscible organic solvent, such as chloroform, and subsequently emulsified into an aqueous phase containing a suitable surfactant. Upon evaporation of the organic solvent, GMS precipitates within the aqueous medium, resulting in the formation of a nanoparticle dispersion. A key advantage of this method is that it eliminates the need for heat, making it suitable for incorporating thermolabile drugs. However, its limitations include the requirement for relatively large volumes of organic solvents, which can pose potential toxicity risks from residual solvent traces and raise environmental safety concerns. The solid lipid nanoparticles (SLNs) of Acarbose were prepared using glyceryl monostearate as the lipid matrix, chloroform as the organic solvent, and Tween 80 as the surfactant. A total of nine formulations (F1–F9) were designed by varying the lipid concentration (4%, 6%, and 8% w/w) and surfactant concentration (1%, 1.5%, and 2% v/v), while keeping the drug content constant at 10 mg. The detailed composition of each formulation is presented in Table 1.

Table 1: Composition of Acarbose-Loaded SLN Formulations.

Formulation	Acarbose (mg)	Glyceryl mono Stearate (% w/w)	Chloroform (ml)	Tween 80 (% v/v)
F1	10	4	Q.S	1
F2	10	4	Q.S	1.5
F3	10	4	Q.S	2
F4	10	6	Q.S	1
F5	10	6	Q.S	1.5
F6	10	6	Q.S	2
F7	10	8	Q.S	1
F8	10	8	Q.S	1.5
F9	10	8	Q.S	2

Drug Content Analysis

The drug content of the SLN formulation was determined after lysing the nanoparticles in 50% n-propanol. One milliliter of the dispersion was mixed with an equal volume of 50% n-propanol and thoroughly agitated to ensure complete lysis. The mixture was suitably diluted with phosphate-buffered saline (pH 7.4), and absorbance was measured at 206 nm using a UV–visible spectrophotometer.[31]

Entrapment Efficiency

Entrapment efficiency was assessed by centrifuging 1 mL of the nanoparticle dispersion at 14,000 rpm for 60 minutes at 4 °C in a refrigerated centrifuge. This separated the unentrapped drug from the nanoparticles. The concentration of the drug in the supernatant was determined spectrophotometrically at 240 nm. Entrapment efficiency (EE%) was calculated using the equation.[32]

Entrapment Efficiency (%)=Total DrugTotal Drug−Free Drug ×100

Particle Size and Size Distribution Analysis

The mean particle size and size distribution of the formulations were determined using a Malvern Zetasizer at 25 °C. Before measurement, the optimized formulation (F6) was incubated for two days and then suitably diluted with distilled water. Particle size distribution was represented by the polydispersity index (PDI), a measure of the uniformity and homogeneity of the nanoparticle population.[33]

Zeta Potential Measurement

The surface charge of the formulations was determined

by measuring the zeta potential using a Malvern Zetasizer. Appropriate dilution with distilled water was performed before analysis to ensure accurate measurements and prevent multiple scattering effects.[33]

In Vitro Drug Release Studies

The drug release profile of the SLN suspension was assessed using the dialysis bag technique. A fixed volume of the formulation was transferred into a dialysis membrane (effective length 5 cm) serving as the donor compartment. The dialysis bag was immersed in 100 mL of phosphate buffer (pH 7.4) in a beaker, maintained at 37 ± 1 °C, serving as the receptor compartment. The release medium was stirred at 50 rpm using a magnetic stirrer, and at specified time intervals, 5 mL aliquots were withdrawn and replaced with an equal volume of fresh phosphate buffer to maintain sink conditions. The samples were analyzed at 206 nm using a UV–visible spectrophotometer.[34]

Stability Studies

Stability testing was performed to evaluate potential drug leakage from the nanoparticles during storage. The selected formulation was stored in sealed glass ampoules under three different conditions: 4 ± 2 °C / 75% RH, 25 ± 2 °C / 40% RH, and 40 ± 2 °C / 25% RH for three months. At predetermined intervals, samples were withdrawn and assessed for any signs of aggregation as well as residual drug content to determine formulation stability over time.[35]

RESULTS AND DISCUSSION

Solubility Studies

Acarbose solubility was assessed in various solvents, and the results are presented in Table 2

Table 2: Solubility of Acarbose.

Solvents	Solubility
Water	soluble
Methanol	soluble
Chloroform	soluble
Phosphate buffer	soluble

Calibration Curve for Acarbose

A calibration curve for Acarbose was constructed by measuring the absorbance of standard solutions at 206 nm over the concentration range of 24–40 µg/mL. The absorbance values increased proportionally with concentration, indicating good linearity. The corresponding data are presented in Table 3 and Figure 1.

Table 3: Standard Calibration Curve for Acarbose.

Concentration (µg/ml)	Absorbance (nm)
24	0.001
28	0.003
32	0.005
36	0.006
40	0.008

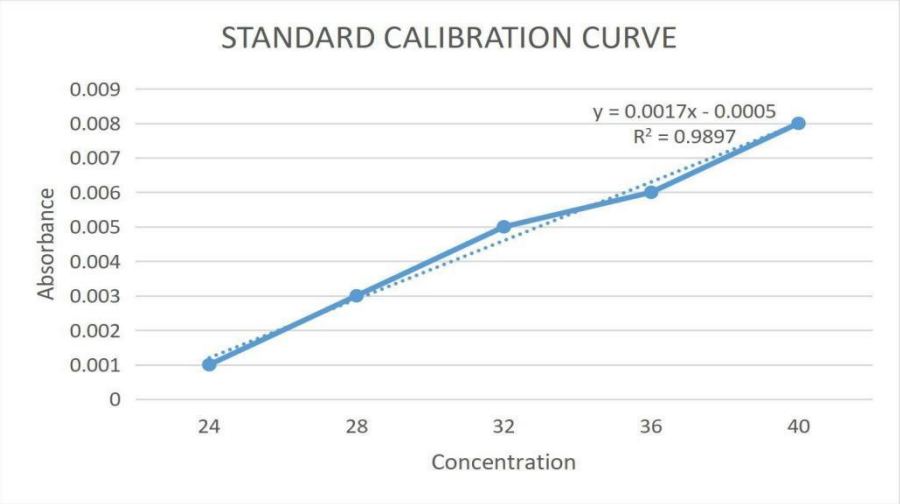

Fig. 1: Standard calibration graph of Acarbose.

Fourier Transform Infrared (FTIR) Spectroscopic Studies

Drug and excipient identification was performed via FTIR analysis, and compatibility was verified through the overlay spectra, as illustrated in Figures 2, 3, 4, and 5, respectively.

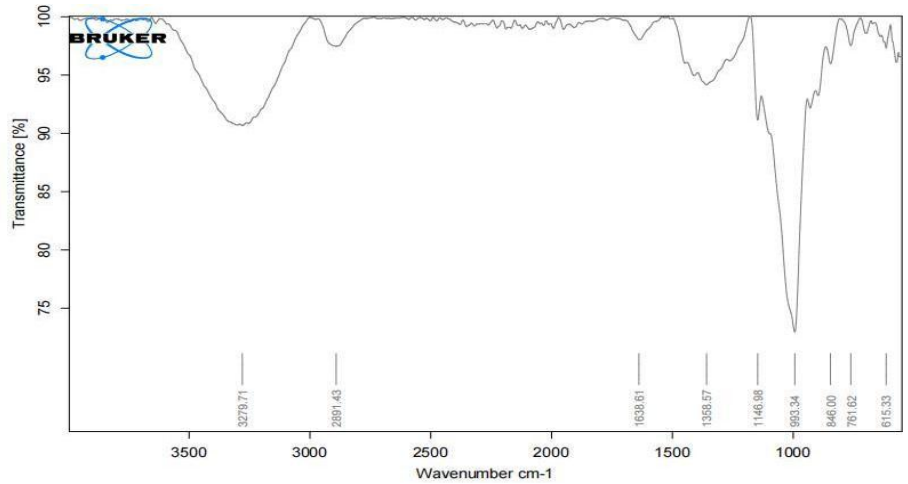

Fig. 2: IR spectra of Acarbose.

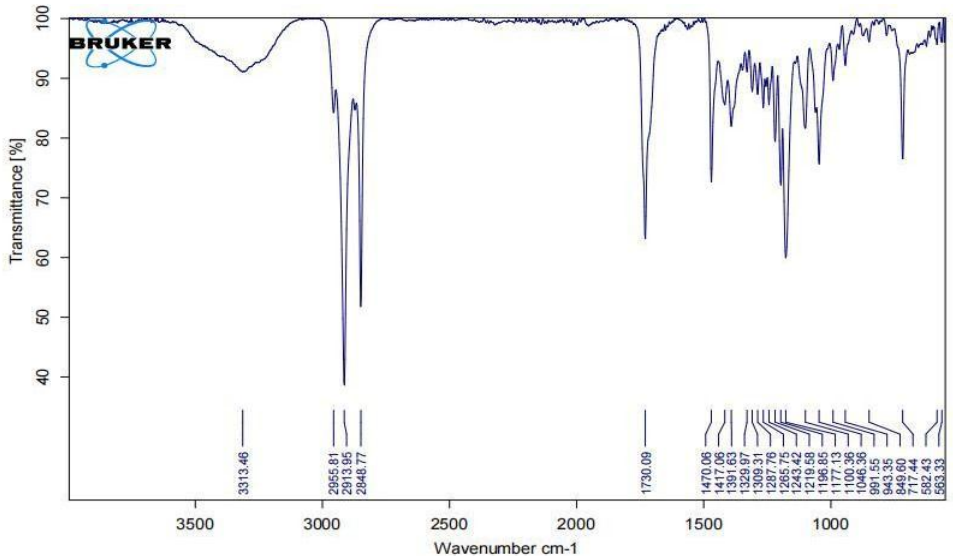

Fig. 3: IR spectra of glyceryl monostearate.

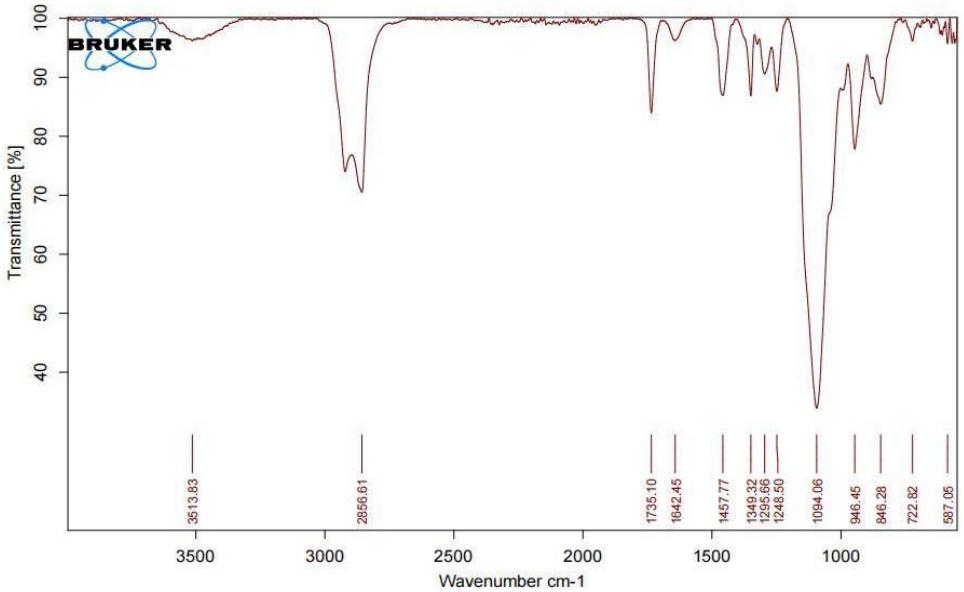

Fig. 4: IR spectra of tween 80.

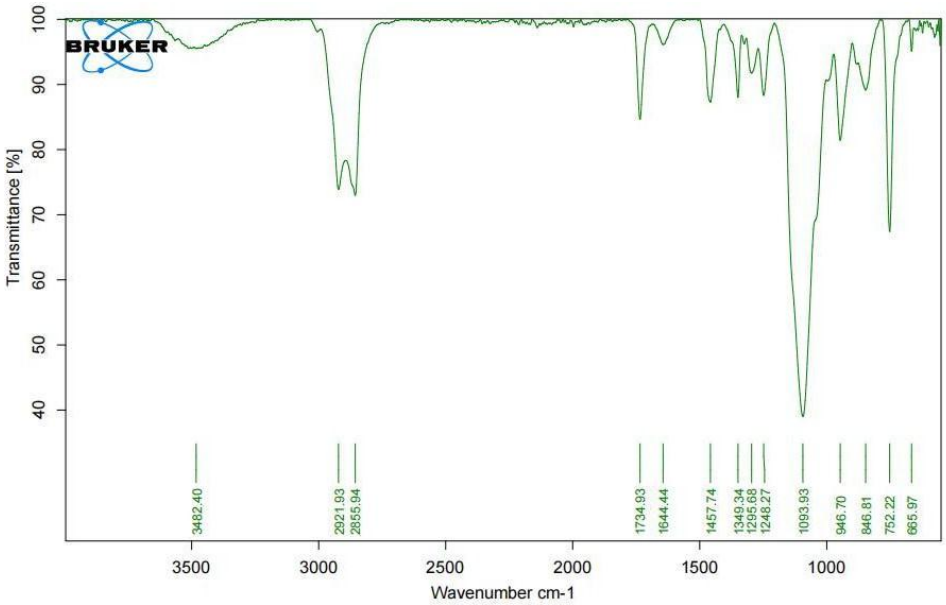

Figure 5: IR spectra of Acarbose + Glyceryl monostearate + Tween 80.

The FTIR spectrum of pure Acarbose (Figure 2) exhibited a broad absorption band at 3297.71 cm^{-1} due to O–H stretching, peaks at 2921.49 cm^{-1} corresponding to C–H stretching, and a band at 1638.51 cm^{-1} for C=O stretching. Glyceryl monostearate (Figure 3) showed characteristic peaks at 3313.46 cm^{-1} (O– H), 2915.22 and 2848.17 cm^{-1} (C–H), and a strong ester carbonyl peak at 1732.09 cm^{-1}. Tween 80 (Figure 4) displayed a broad O–H stretching band at 3518.13 cm^{-1}, C–H stretching peaks at 2926.81 cm^{-1}, and an ester C=O peak at 1735.10 cm^{-1}.

The spectrum of the physical mixture of Acarbose, glyceryl monostearate, and Tween 80 (Figure 5) retained all characteristic peaks of the individual components without significant shifts or disappearance of bands, indicating no major drug–excipient interactions and confirming compatibility for formulation.

Differential Scanning Calorimetry (DSC)

Differential scanning calorimetry (Figures 6, 7, and 8) further supported the compatibility.

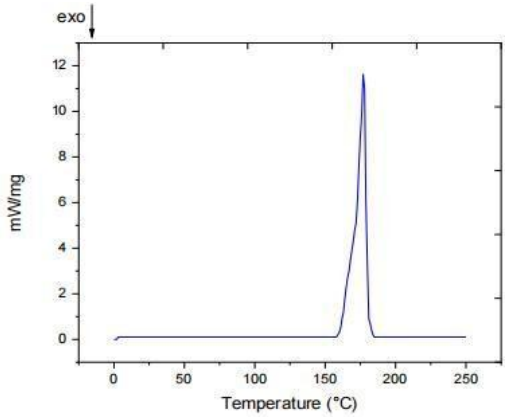

Figure 6: DSC of Acarbose.

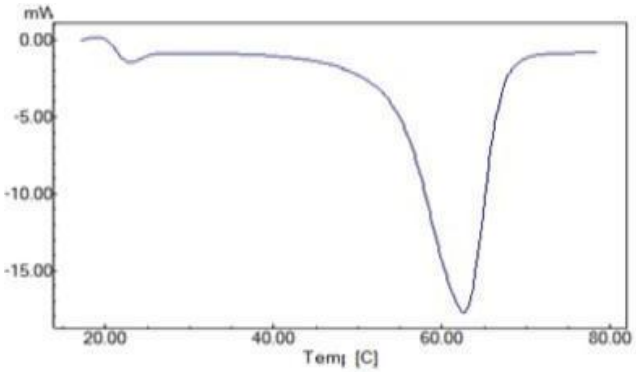

Figure 7: DSC of Glyceryl Monostearate.

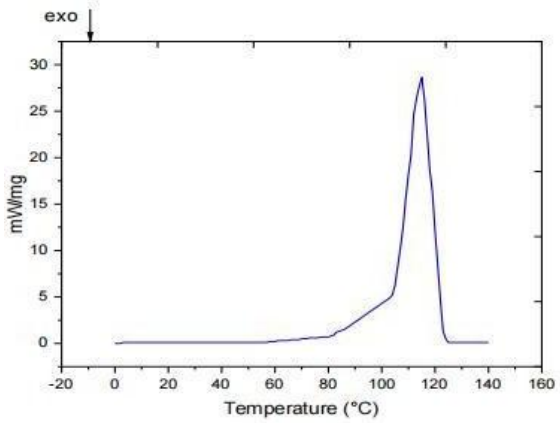

Figure 8: DSC of the Formulation F6.

Pure Acarbose (Figure 6) exhibited a sharp endothermic peak at 176.5 °C (reported melting point ~180 °C), indicating its crystalline nature. Glyceryl Mono Stearate (Figure 7) showed a melting peak between 55–65 °C. The thermogram of Formulation F6 (Figure 8) retained the characteristic peak of Acarbose without a significant shift, confirming no interaction between the drug and excipients, and indicating good

stability in the formulation.

Drug Content Estimation

Drug content analysis is an essential part of SLN characterization to ensure uniform distribution of the active ingredient with minimal batch variation. The prepared SLNs exhibited values ranging from 72.01% to 97.12%, with Formulation F6 showing the highest (97.12%) as presented in Table 4.

Table 4: Drug Content Analysis.

Formulation	Drug content (%)
F1	72.01
F2	75.30
F3	78.80
F4	81.72
F5	80.01
F6	97.12
F7	90.63
F8	86.12
F9	92.15

Entrapment Efficiency

Entrapment efficiency is a key parameter in SLN characterization, influenced by lipid and surfactant type, concentration, and HLB value. In this study, glyceryl monostearate and Tween 80 were used in varying concentrations. Efficiency was determined by centrifugation, subtracting the drug amount in the supernatant from the total drug in the formulation. Values ranged from 60.19% to 79.19%, with Formulation F6 showing the highest (79.19%), as shown in Table 5.

Table 5: Entrapment Efficiency of SLN Formulations.

Formulation	Percentage drug entrapment (%)
F1	63.62
F2	65.15
F3	62.61
F4	71.62
F5	60.19
F6	79.19
F7	74.42
F8	73.72
F9	76.26

Formulation F6 (6 g glyceryl monostearate, 2 g Tween 80) achieved higher entrapment efficiency than F7–F9, despite those having higher lipid and surfactant content, possibly due to increased viscosity. Entrapment efficiency was also found to be concentration-dependent and influenced by the HLB value of surfactants; Tween 80, with an HLB of 15.0, may have contributed to the high efficiency observed.

Scanning Electron Microscopy analysis

SEM analysis of Acarbose SLNs (Formulation F6) revealed spherical particles with smooth surfaces, ranging in size from 20 to 150 nm, which is illustrated in Figure 9.

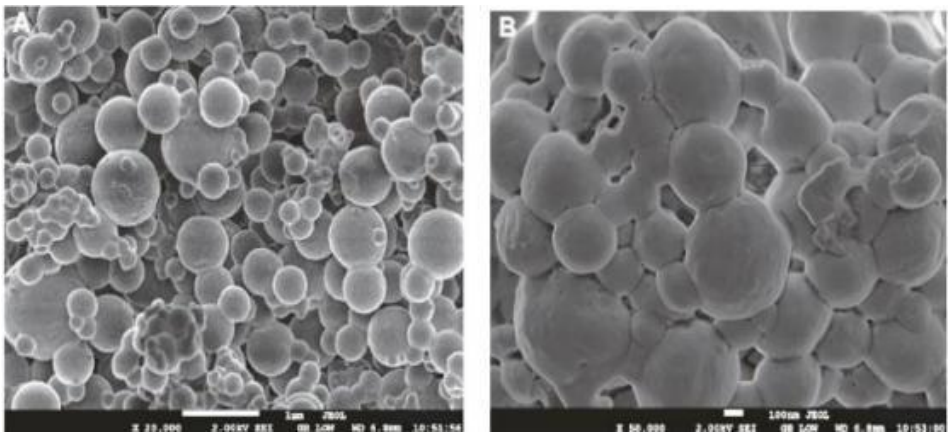

Figure 9: SEM image of F6.

Particle Size and Size Distribution Measurements

Formulation F3 was characterized for particle size and polydispersity index (PDI) using dynamic light scattering. Results are illustrated in Table 6 and Figure 10.

Table 6: Particle Size Distribution Of Formulation F6.

1.	Average particle size (nm)	287.4
2.	Poly dispersity index (PDI)	0.345

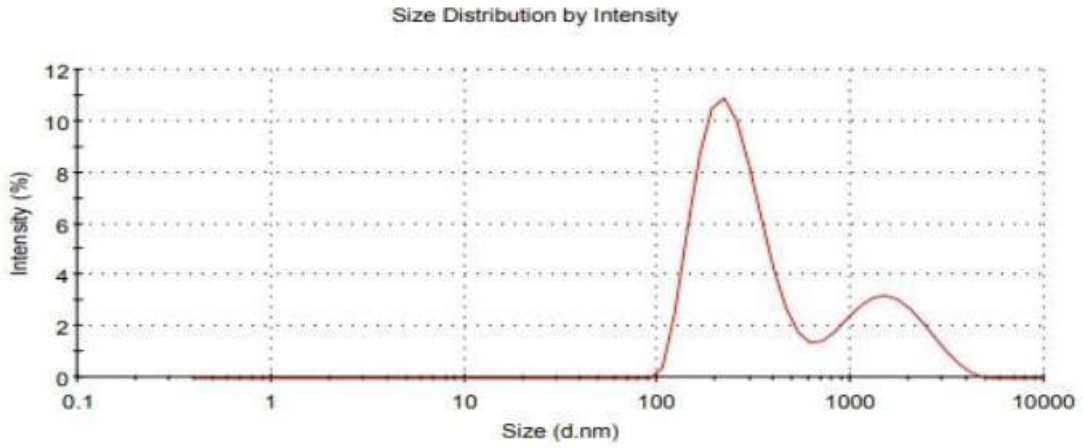

Figure 10: Particle Size Distribution Image Of Formulation F6.

ZETA POTENTIAL

The zeta potential of Formulation F6 was measured using a Malvern Zetasizer. The vesicle membrane charge, shown in Figure 11, was found to be –27.8 mV. The negative zeta potential value indicates good stability of the SLN dispersion due to electrostatic repulsion between particles.

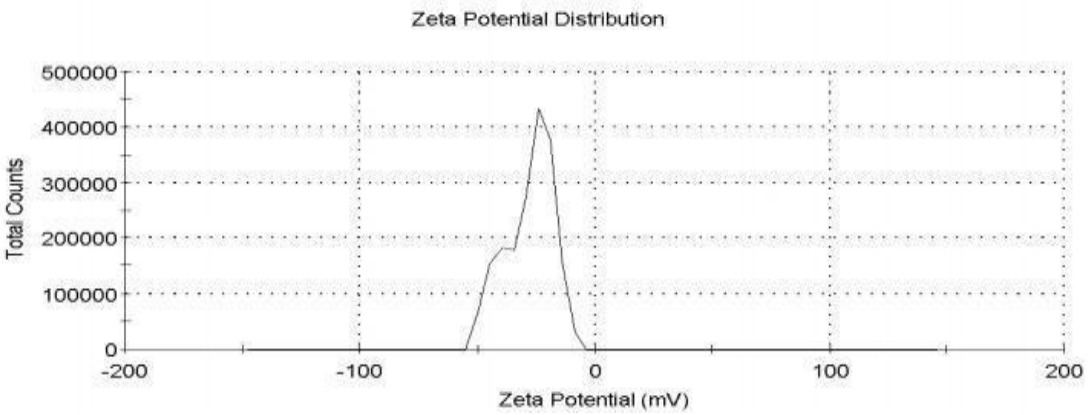

Figure 11: Zeta Potential Image Of Formulation F6 In Vitro Dissolution Studies of SLN Formulations.

In vitro drug release of all SLN formulations was evaluated using the diffusion method. The results showed that Formulation F6 exhibited the highest release (79.62%) at the 8th hour compared to the other formulations. The in vitro release data are summarized in Table 7 and graphically demonstrated in Figures 12 and 13.

Table 7: *In-vitro* dissolution of SLN formulations.

Time in hours	Percentage drug release (%)								
	F1	F2	F3	F4	F5	F6	F	F8	F9
0	0	0	0	0	0	0	0	0	0
1	1.76	2.97	1.92	2.43	3.68	5.63	4.15	1.82	4.01
2	2.93	5.43	3.15	4.83	7.62	13.64	10.33	2.98	9.91
3	5.36	11.48	6.34	10.32	13.45	19.62	15.34	5.12	13.62
4	9.45	16.64	10.62	14.75	18.62	31.62	25.31	10.69	22.34
5	12.63	19.49	11.42	17.82	23.42	45.31	37.32	12.43	34.62
6	19.42	26.49	18.43	23.64	29.64	55.62	43.33	18.99	39.62
7	22.36	30.12	23.41	29.42	35.16	61.62	51.32	24.62	46.31
8	31.30	36.46	30.48	34.11	41.62	79.62	59.34	31.75	53.62

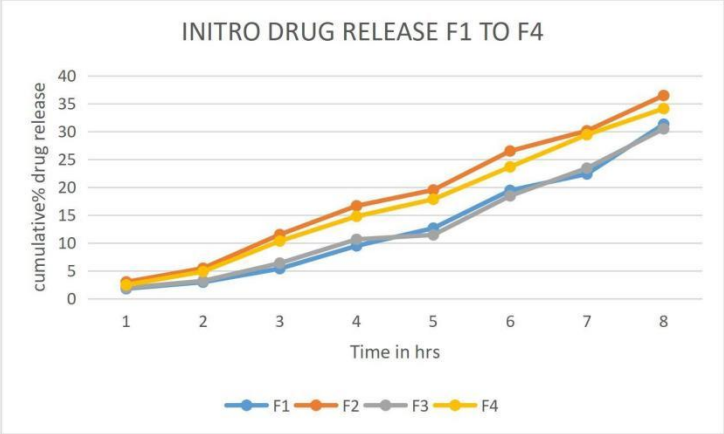

Figure 12: *In-vitro* release studies of formulations F1 to F4.

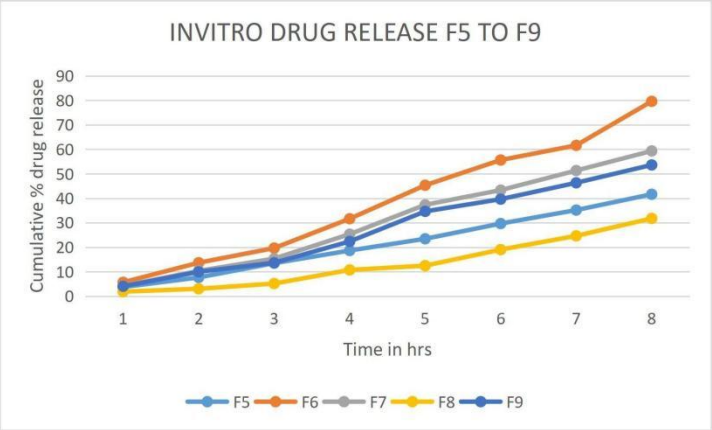

Figure 13: *In-vitro* release studies of formulations F5 to F9 Entrapment Efficiency and Stability of Nanoformulation.

The entrapment efficiency of the drug in the nanoformulation was assessed immediately after preparation and at monthly intervals during stability studies. Minimal drug leakage was observed at **4 ±** 2°C / 75% RH and 25 ± 2°C / 40% RH. The leakage at higher temperatures could be attributed to the lipid's phase transition during storage. Overall, the stability evaluation indicates that the solid lipid nanoformulation can be stored under both refrigerated and room temperature conditions. The stability studies results are given in Table 8.

Table 8: Stability studies of formulation F6.

Formulation	Temperature	Amount of drug retained (%) after months			
		Beginning phase	Month 1	Month 2	Month 3
F6	**Refrigeration 4℃ ± 2℃ and 75% RH**	100	97.88	97.02	96.22
	Room Temperature 25 ± 2 °C and 40% RH	100	97.33	95.58	94.47
	40℃ ± 2℃ and RH 70% ± 5%	100	93.57	89.01	85.48

CONCLUSION

Acarbose-loaded solid lipid nanoparticles (SLNs) were prepared by the solvent evaporation method using glyceryl monostearate, Tween 80, and cholesterol. To date, no studies have reported this specific combination for Acarbose SLNs. A calibration curve of Acarbose in phosphate buffer (pH 7.4) showed linearity, confirming compliance with Beer's law. FTIR spectra of the pure drug, excipients, and formulation indicated the absence of drug–excipient interactions, which was further supported by DSC analysis showing broad thermal transitions typical of lipid mixtures. The prepared nanoparticles displayed an average particle size of 127.62 nm and a zeta potential of –27.8 mV, signifying good stability due to interparticle repulsion. Nine different formulations were developed by varying lipid and surfactant concentrations. Among them, formulation F6 showed the highest entrapment efficiency (79.19%). SEM analysis confirmed that the particles were spherical, discrete, and uniform. In vitro release studies

demonstrated that F6 exhibited sustained release of 79.62% over 8 hours, outperforming other formulations. Drug content analysis ranged from 71.01% to 97.12%, with F6 showing the maximum value. Stability testing at 4°C and 25°C indicated minimal drug leakage, attributable to lipid phase transitions, suggesting that the formulation is stable under refrigerated and room temperature conditions. Overall, Acarbose-loaded SLNs demonstrated desirable physicochemical properties, high entrapment efficiency, sustained release, and stability. These characteristics indicate their potential to enhance the therapeutic performance of Acarbose, reduce side effects, and improve patient compliance in the management of diabetes.

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest related to this study.

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