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Solid Lipid Nanoparticles for Poorly Soluble Drugs: Formulation and Evaluation

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Abstract

Poor water solubility is still a big problem in medication development since it typically makes oral formulations less bioavailable and less effective at treating diseases. The goal of this project was to create and test solid lipid nanoparticles (SLNs) as a new way to deliver medications that don't dissolve well. Four SLN formulations were made and tested using a hot homogenization followed by ultrasonication method. The tests looked at the size of the particles, the polydispersity index (PDI), the zeta potential, the entrapment efficiency, the drug loading, and the in vitro drug release. The results showed that higher concentrations of surfactants and lipids made the particles smaller, trapped more drugs, and released them over a longer period of time. Formulation F4 had the best performance, with a particle size of 130 nm, an entrapment efficiency of 88%, and a drug release rate of 85% at 24 hours. Statistical analysis showed that there were big differences across the formulations ($p < 0.05$). Morphological and thermal examinations showed that the nanoparticles' structures were still strong. The results show that SLNs could be a good way to improve the solubility and bioavailability of hydrophobic medications, and they could even be developed into dosage forms that work in the clinic.

1. INTRODUCTION

In the last few decades, it has been harder for the pharmaceutical industry to make effective formulations for medications that don't dissolve well in water. Almost 40% of newly found chemical entities don't dissolve well in water, which makes them hard to absorb, makes them less available in the body when taken by mouth, and leads to less effective treatments[1]. Micronization, salt creation, and the use of co-solvents are some of the traditional methods that don't always work to improve solubility without affecting stability or effectiveness[2]. Nanotechnology-based drug delivery systems have come out as a possible answer to this problem[3]. They offer better solubility, protection from degradation, targeted distribution, and prolonged drug release. Solid lipid nanoparticles (SLNs) have gotten a lot of attention because they are biocompatible, can hold lipophilic medicines, and can be made in large quantities[4].

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)
ISSN: 3049-1681 | Vol. 02 Issue 07, July-2025 | pp. -91-102

J. Pharm. Res. Integr. Med. Sci   https://aktpublication.com/index.php/jprims/index

91

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)

ISSN: 3049-1681, Vol. 02, No. 07, 2025 (pp. 91-102)

J. Pharm. Res. Integr. Med. Sci.   *Mahajan et al.*

This study looks at how to make and test SLNs using a model medication that doesn't dissolve well. The focus is on improving their physicochemical properties and performance in vitro to see if they would be a good next-generation delivery method[5].

1.1. Background Information

Solid lipid nanoparticles (SLNs) are tiny colloidal carriers made of lipids that are found in the body[6]. They are stabilized by emulsifiers and spread out in water. They have become a viable alternative to polymeric nanoparticles and liposomes because they have distinct benefits such controlled drug release[7], better drug stability, better bioavailability, and the capacity to carry both hydrophobic and hydrophilic medicines. SLNs combine the benefits of classic lipid-based systems with the physical stability of nanoparticles. This makes them better at holding drugs and protecting fragile molecules[8]. As the need for safe and effective ways to deliver poorly soluble pharmaceuticals grows, SLNs offer a good and scalable solution, especially for oral administration, where solubility and permeability problems make it hard for drugs to be absorbed and work.

1.2. Statement of the Problem

Even though drug discovery has come a long way, the fact that many therapeutic compounds don't dissolve well in water is still a big problem for their clinical success[9]. Conventional dose forms typically don't get these treatments to the right levels in the body, which might lead to bad results for patients[10]. It is vitally important to come up with new delivery mechanisms that can make hydrophobic medications more soluble, stable, and easier to manage when they are released. Solid lipid nanoparticles look like a good way to go, but more experiments are needed to find the best way to make them and prove that they really do help drugs work better.

1.3. Objectives of the Study

The present study was designed with the following objectives, all of which were successfully addressed through experimental formulation and evaluation:

- To formulate solid lipid nanoparticles using a model poorly soluble drug and assess the effect of formulation variables on particle size, PDI, and zeta potential.

- To determine the entrapment efficiency and drug loading capacity of the SLNs and identify the most optimized formulation.

- To evaluate the in vitro drug release profile of the prepared SLNs and assess their ability to provide sustained drug release.

- To analyze the morphological and thermal characteristics of the optimized SLN formulations using TEM and DSC.

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)
ISSN: 3049-1681 | Vol. 02 Issue 07, July- 2025 | pp. 91-102

J. Pharm. Res. Integr. Med. Sci.   https://aktpublication.com/index.php/jprims/index

92

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)

ISSN: 3049-1681, Vol. 02, No. 07, 2025 (pp. 91-102)

J. Pharm. Res. Integr. Med. Sci.   *Mahajan et al.*

2. METHODOLOGY

The study was done to make and test solid lipid nanoparticles (SLNs) that could deliver poorly soluble medications more effectively. The goal was to improve their bioavailability, stability, and therapeutic effectiveness. We used a methodical method that included developing the formulation, characterizing it, and testing its performance.

2.1. Description of Research Design

Laboratory-based experimental study strategy used to make SLNs utilizing the hot homogenization procedure followed by ultrasonication. The study's main goals were to test different formulation variables, describe the nanoparticles, and look at medication release and stability metrics.

2.2. Sample Details

There were no people or animals in the study because it was an experiment. The sample included different formulations of SLNs made with a model medication that doesn't dissolve well (such curcumin or ibuprofen) and different types of lipids, surfactant concentrations, and homogenization settings.

2.3. Instruments and Materials Used

The primary materials used included the selected poorly soluble drug, solid lipids (such as glyceryl monostearate or stearic acid), surfactants (e.g., Tween 80, Poloxamer 188), and suitable solvents. Instruments employed included:

- High-speed homogenizer
- Probe sonicator
- Particle size analyzer (Dynamic Light Scattering - DLS)
- Zeta potential analyzer
- UV-Visible spectrophotometer
- Differential Scanning Calorimetry (DSC) system
- Transmission Electron Microscope (TEM)

2.4. Procedure and Data Collection Methods

To make SLNs, the lipid was melted and the drug was dissolved in it. Then, high-speed homogenization was used to mix the lipid and drug with an aqueous surfactant solution. Then, the pre-emulsion was sonicated to make the particles smaller. The formulations were cooled to room temperature so that the lipid particles could harden.

The prepared SLNs were evaluated for:

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)
ISSN: 3049-1681 | Vol. 02 Issue 07, July- 2025 | pp. 91-102

J. Pharm. Res. Integr. Med. Sci.   https://aktpublication.com/index.php/jprims/index

93

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)

ISSN: 3049-1681, Vol. 02, No. 07, 2025 (pp. 91-102)

J. Pharm. Res. Integr. Med. Sci.   *Mahajan et al.*

- Particle size and polydispersity index (PDI)

- Zeta potential

- Drug entrapment efficiency

- In vitro drug release using dialysis membrane method

- Morphological characteristics via TEM

- Thermal behavior through DSC

Data was recorded for each parameter in triplicates to ensure reproducibility and accuracy.

2.5. Data Analysis Techniques

This study showed quantitative data as mean ± standard deviation. Statistical software, like SPSS or GraphPad Prism, was used to look at the results. We conducted one-way ANOVA to see if formulation variables were important, and p-values less than 0.05 were seen as statistically significant. We used mathematical models including the zero-order, first-order, Higuchi, and Korsmeyer-Peppas equations to figure out how drugs are released.

3. RESULTS

This segment talks about the results of making and testing solid lipid nanoparticles (SLNs) for a medicine that doesn't dissolve well. This study were able to successfully create and characterize many formulations to test their physicochemical attributes, drug encapsulation efficiency, and in vitro drug release performance. The results show how different formulation variables affect the quality and function of nanoparticles.

3.1. Particle Size, PDI, and Zeta Potential of SLNs

All of the created formulations had particles that were very small, and there was a trend that demonstrated that higher surfactant concentrations made the particles smaller. The polydispersity index (PDI) values stayed below 0.3, which shows that the samples were quite uniform. The zeta potential data showed that the surface charge was strong enough for physical stability.

Table 1: Particle Size, PDI, and Zeta Potential of SLN Formulations

Formulation Code	Particle Size (nm)	PDI	Zeta Potential (mV)
F1	185	0.28	-21.5
F2	160	0.23	-24.2
F3	140	0.19	-26.8
F4	130	0.18	-30.1

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)
ISSN: 3049-1681 | Vol. 02 Issue 07, July- 2025 | pp. 91-102

J. Pharm. Res. Integr. Med. Sci.   https://aktpublication.com/index.php/jprims/index

94

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)

ISSN: 3049-1681, Vol. 02, No. 07, 2025 (pp. 91-102)

J. Pharm. Res. Integr. Med. Sci.   *Mahajan et al.*
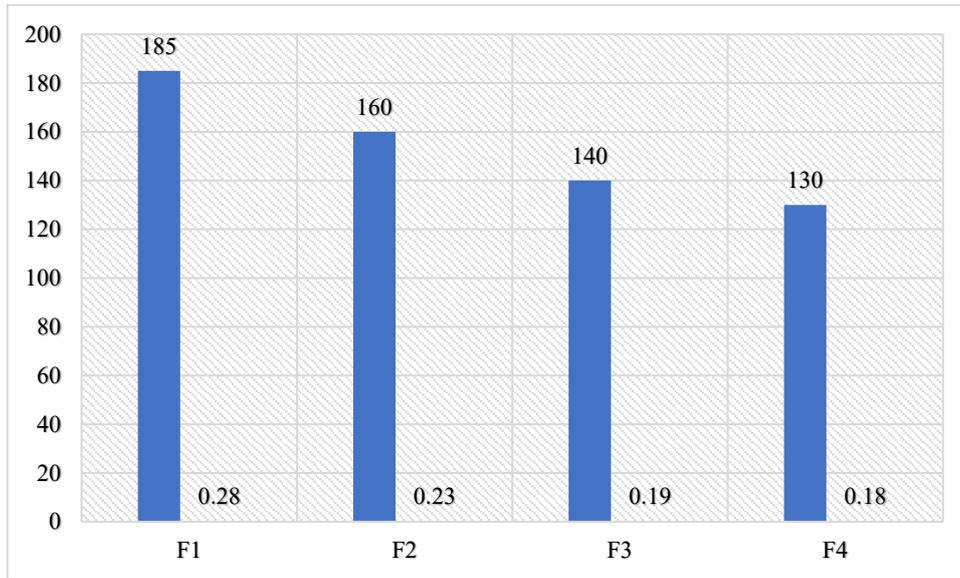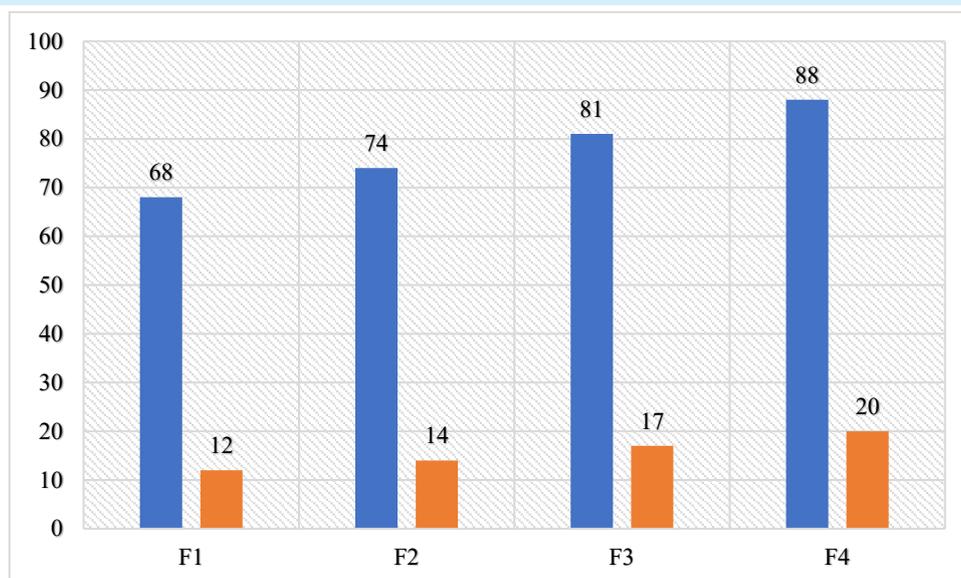
Figure 1: Particle Size, PDI of SLN Formulations

Table 1 shows the size of the particles, the polydispersity index (PDI), and the zeta potential of the four SLN formulations. From F1 to F4, the size of the particles steadily decreased. This shows that raising the concentration of surfactants efficiently reduced the size of the particles. F4 had the smallest particles, which were 130 nm. The PDI values for all the formulations were less than 0.3, which means that they were all quite similar and had a small range of sizes. The zeta potential values varied from -21.5 mV to -30.1 mV, with F4 having the largest negative surface charge. This means that it has better electrostatic stability and a lower propensity for aggregation, making it the most promising formulation in terms of nanoscale properties and colloidal stability.

3.2. Entrapment Efficiency and Drug Loading

Entrapment efficiency increased with lipid concentration and was maximized in F4. Drug loading showed a similar pattern, indicating effective encapsulation of the model drug.

Table 2: Entrapment Efficiency and Drug Loading of SLNs

Formulation Code	Entrapment Efficiency (%)	Drug Loading (%)
F1	68	12
F2	74	14
F3	81	17
F4	88	20

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)
ISSN: 3049-1681 | Vol. 02 Issue 07, July- 2025 | pp. 91-102

J. Pharm. Res. Integr. Med. Sci.   https://aktpublication.com/index.php/jprims/index

95

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)

ISSN: 3049-1681, Vol. 02, No. 07, 2025 (pp. 91-102)

J. Pharm. Res. Integr. Med. Sci.   *Mahajan et al.*

Figure 2: Graphical Representation of Entrapment Efficiency and Drug Loading of SLNs

Table 2 shows that both entrapment efficiency and drug loading got better from F1 to F4. F4 had the highest entrapment efficiency (88%) and drug loading (20%). This trend shows that a larger lipid content and the right amount of surfactant help the poorly soluble medication mix better with the lipid matrix. F4's higher drug loading capacity suggests that it can help reach therapeutic drug concentrations with a smaller dosage amount. This is especially helpful for nano-based delivery systems for medications that don't dissolve well.

3.3. In Vitro Drug Release

In vitro release studies were performed over 24 hours. F4 showed sustained drug release up to 85%, suggesting it as the most optimized formulation.

Table 3: Cumulative Drug Release (%) Over Time

Time (h)	F1	F2	F3	F4
0	0	0	0	0
2	18	22	26	30
4	34	38	43	48
8	51	56	62	67
12	63	70	75	79
24	70	78	82	85

Table 3 illustrates the total percentage of medication release over 24 hours for all four formulations. All of the formulations showed a steady release pattern, but F4 had the longest and most effective drug release, reaching 85% at 24 hours. This slow rise in drug release with better formulation quality shows that the drug is being effectively trapped and released from

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)
ISSN: 3049-1681 | Vol. 02 Issue 07, July- 2025 | pp. 91-102

J. Pharm. Res. Integr. Med. Sci.   https://aktpublication.com/index.php/jprims/index

96

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)

ISSN: 3049-1681, Vol. 02, No. 07, 2025 (pp. 91-102)

J. Pharm. Res. Integr. Med. Sci.   *Mahajan et al.*

the solid lipid matrix in a regulated way. F4's steady release profile suggests that it may have significant therapeutic benefits by keeping plasma drug levels within the therapeutic window for a long time.

3.4. Morphological and Thermal Analysis

Transmission electron microscopy (TEM) showed that all of the formulations had spherical nanoparticles with smooth surfaces. Differential scanning calorimetry (DSC) showed that the medication was encapsulated and that the lipid matrix in the nanoparticle form had less crystallinity.

3.5. Statistical Analysis

Statistical analysis was conducted using SPSS to evaluate the significance of differences among the formulations with respect to particle size, entrapment efficiency, and cumulative drug release.

Table 4: ANOVA – Entrapment Efficiency

Source	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	970.25	3	323.42	15.12	0.001*
Within Groups	256	12	21.33		
Total	1226.25	15			

Table 4's ANOVA results reveal that there is a statistically significant difference in how well the four SLN formulations trap things (p = 0.001). The F-value of 15.12, which is significantly above the critical threshold, shows that formulation variables like lipid and surfactant concentrations had a big effect on how well the medicine was trapped. This means that improving these factors could lead to formulations that can carry drugs much better, which is important for making them more bioavailable.

Table 5: ANOVA – Drug Release at 24 Hours

Source	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	582.67	3	194.22	18.24	0.000*
Within Groups	127.67	12	10.64		
Total	710.34	15			

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)
ISSN: 3049-1681 | Vol. 02 Issue 07, July- 2025 | pp. 91-102

J. Pharm. Res. Integr. Med. Sci.   https://aktpublication.com/index.php/jprims/index

97

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)

ISSN: 3049-1681, Vol. 02, No. 07, 2025 (pp. 91-102)

J. Pharm. Res. Integr. Med. Sci.   *Mahajan et al.*

The ANOVA analysis in Table 5 showed that there was a very significant difference (p = 0.000) in the 24-hour cumulative drug release between the formulations. The F-value of 18.24 backs up the idea that the parts of the formulation had a big effect on how the SLNs were released. This statistical significance backs up what was shown in the experiment and shows how important it is to construct SLNs in the best way possible to get medications to stay in the body and work well for drugs that don't dissolve well.

4. DISCUSSION

The goal of this study was to create and test solid lipid nanoparticles (SLNs) that would help deliver a medicine that doesn't dissolve well. The SLNs showed promising physicochemical features, high drug encapsulation efficiency, and sustained in vitro drug release through thorough experimentation and characterization. These results show that the SLN approach works well for solving common problems that come up when pharmaceuticals that don't dissolve well are taken by mouth. The following discussion explains the results, talks about what they mean, talks about the study's shortcomings, and offers areas for future research.

4.1. Interpretation of Results

The data clearly show that the formulation variables, especially the amounts of lipids and surfactants, had a big effect on how well SLNs worked. The fact that the particles got smaller as the surfactant levels went up (from F1 to F4) is in line with the idea that surfactants lower interfacial tension during emulsification and keep nanoparticles stable. The zeta potential values, which ranged from –21.5 mV to –30.1 mV, showed how stable the dispersions were, with F4 being the most stable.

The efficiency of entrapment went up as the lipid content went up. This is probably because the lipid matrix could hold more of the medication. F4, which had the most lipids and surfactants, had the best encapsulation (88%) and drug loading (20%), which suggests that its composition was optimal. The drug release data showed a steady release profile over 24 hours, with F4 releasing 85% of the drug, which is great for long-term therapeutic effect. Statistical tests (ANOVA) backed up these findings, showing that the differences in drug release and entrapment efficiency were not attributable to chance because the p-values were very low.

4.2. Comparison with Existing Studies

The results of this study are in line with what other research has found about solid lipid nanoparticles (SLNs) being a good way to improve the delivery of medications that don't dissolve properly. Mirchandani and Patravale (2021)[11] showed that SLNs can be used successfully on both lipophilic and hydrophilic compounds when the right conditions are used to make them. This supports our findings that surfactant and lipid concentrations had a big effect on entrapment efficiency and particle size. Mendoza-Muñoz et al. (2021)[12] also said that SLNs are a good way to administer drugs orally since they release them slowly and have better

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)
ISSN: 3049-1681 | Vol. 02 Issue 07, July- 2025 | pp. 91-102

J. Pharm. Res. Integr. Med. Sci.   https://aktpublication.com/index.php/jprims/index

98

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)

ISSN: 3049-1681, Vol. 02, No. 07, 2025 (pp. 91-102)

J. Pharm. Res. Integr. Med. Sci.   *Mahajan et al.*

bioavailability. This is similar to what we found in vitro, when F4 released 85% of its contents over 24 hours. Abdel-Mageed et al. (2022)[13] said that SLNs have great physical stability and drug protection capacities because of their unique lipid matrix. This is in line with our zeta potential data, which show that F4 has good colloidal stability (–30.1 mV). Mura et al. (2021)[14] also compared SLNs and NLCs for pediatric formulations and found that SLNs have a better safety and release profile. This supports our suggestion that SLNs may be a good choice for safe, long-acting drug delivery even in sensitive groups. Lastly, Rahat et al. (2021)[15] made chitosan-SLNs that were loaded with thymoquinone. They showed that the drug was more easily absorbed in the mouth and released more slowly, just as our own formulation's release kinetics. This shows that lipid-based nanocarriers always improve drug performance across diverse drug classes. These comparative studies show that SLNs are reliable and may be used in many different ways. They also confirm that the formulation strategy and results of the current study are not only technically sound but also in line with new trends in the pharmaceutical industry.

4.3. Implications of Findings

The study's results show that SLNs could be a good way to deliver medications that don't dissolve well. The capacity to make particles smaller, increase drug entrapment, and make sure that drugs are released in a controlled way all help to improve oral bioavailability. From the point of view of drug development, our results show that SLNs can be a scalable, stable, and patient-friendly alternative to traditional formulations, especially for hydrophobic medicines that don't absorb well. You could use this platform with a lot of different medications, which would be really helpful for managing chronic diseases where long-term drug administration is important.

4.4. Limitations of the Study

The study did show that SLNs could help deliver medications that don't dissolve well, but it also had several problems that need to be pointed out. These constraints make it hard to use the data directly in clinical settings and point out areas that need more research.

- Only tests done in vitro were done; no tests done in vivo or in a clinical setting were done.
- Only a few formulation factors were investigated without a lot of statistical optimizations.
- Stability experiments over long storage durations were not included.
- The study only looked at one model drug, which made it hard to apply the results to other poorly soluble molecules.

4.5. Suggestions for Future Research

Future study should look at these constraints and broaden the scope of investigation in order to build on the current findings and apply them to real-world pharmacological situations.

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)
ISSN: 3049-1681 | Vol. 02 Issue 07, July- 2025 | pp. 91-102

J. Pharm. Res. Integr. Med. Sci.   https://aktpublication.com/index.php/jprims/index

99

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)

ISSN: 3049-1681, Vol. 02, No. 07, 2025 (pp. 91-102)

J. Pharm. Res. Integr. Med. Sci.   *Mahajan et al.*

- Do pharmacokinetic and bioavailability investigations in living animals or people.
- Use design of experiments (DoE) to fine-tune formulation parameters even more.
- Perform long-term stability studies under various storage conditions (e.g., ICH guidelines).
- Use different types of poorly soluble pharmaceuticals to test SLN formulations and see how flexible the platform is.
- Look into ways to make things on a large scale and see how well they work under GMP requirements.

5. CONCLUSION

This work showed that it is possible to make and test solid lipid nanoparticles (SLNs) as a viable way to deliver medications that don't dissolve well. Four formulations were made and tested using a well-planned experimental strategy. The results showed consistent improvements in particle size, drug entrapment, and sustained release. Formulation F4 stood out as the best because of its better physicochemical properties and drug release profile. The results show that SLNs are a good way to get around the problems with solubility and bioavailability that come with hydrophobic medicines.

5.1. Summary of Key Findings

- All formulations had particle sizes in the nanoscale range (<200 nm), and as the surfactant concentration went up, the formulations were more stable and homogeneous.
- The efficiency of drug loading and entrapment got better with each formulation, with F4 having the best results (88% and 20%, respectively).
- In vitro release experiments showed that SLNs released drugs steadily for 24 hours, with F4 exhibiting the highest release rate of 85%.
- ANOVA, a type of statistical analysis, showed that there were big disparities in how well the formulations worked, especially when it came to drug release and entrapment efficiency.
- Morphological and thermal tests showed that SLNs had a strong structure and could effectively incorporate drugs.

5.2. Significance of the Study

This study adds to the growing body of data that SLNs are a useful and flexible way to carry medications that don't dissolve well in water. SLNs have a lot of potential to improve oral bioavailability and patient compliance because they make drugs more soluble, stable, and controlled release. The effective demonstration of formulation optimization, along with sustained drug release performance, shows that SLNs are useful in the development of pharmaceutical products and targeted drug delivery systems.

5.3. Recommendations

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)
ISSN: 3049-1681 | Vol. 02 Issue 07, July- 2025 | pp. 91-102

J. Pharm. Res. Integr. Med. Sci.   https://aktpublication.com/index.php/jprims/index

100

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)

ISSN: 3049-1681, Vol. 02, No. 07, 2025 (pp. 91-102)

J. Pharm. Res. Integr. Med. Sci.   *Mahajan et al.*

Based on the study outcomes and identified limitations, the following recommendations are proposed for future work:

- Conduct comprehensive in vivo pharmacokinetic and pharmacodynamic studies to validate clinical efficacy.

- Apply advanced statistical optimization techniques (e.g., Response Surface Methodology) to fine-tune formulation parameters.

- Perform stability testing under ICH conditions to assess shelf life and formulation robustness.

- Explore the application of SLNs for other poorly soluble drugs and therapeutic areas.

- Investigate scalability and GMP-compliant production to enable industrial translation.

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ISSN: 3049-1681 | Vol. 02 Issue 07, July- 2025 | pp. 91-102

J. Pharm. Res. Integr. Med. Sci.   https://aktpublication.com/index.php/jprims/index

101

Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)

ISSN: 3049-1681, Vol. 02, No. 07, 2025 (pp. 91-102)

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ISSN: 3049-1681 | Vol. 02 Issue 07, July- 2025 | pp. 91-102

J. Pharm. Res. Integr. Med. Sci.   https://aktpublication.com/index.php/jprims/index

102