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Development and Evaluation of Noval Formulation for Poorly Soluble Drugs

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Abstract: *Poor aqueous solubility is a major limitation in oral delivery because it reduces dissolution rate, delays absorption and produces variable bioavailability for many new drug candidates. The present draft thesis describes the development and evaluation of a novel ternary solid dispersion based tablet formulation for a model poorly soluble BCS class II drug represented by fenofibrate. Soluplus was selected as a hydrophilic polymeric carrier and poloxamer 188 was selected as a wetting and solubilizing surfactant. Preformulation studies included organoleptic observation, melting range, UV calibration, saturation solubility screening and compatibility evaluation by FTIR and DSC. Nine trial formulations were designed by varying drug:polymer ratio and surfactant level. Solid dispersions were prepared by solvent evaporation, dried, milled, sieved and compressed into immediate-release tablets. The batches were evaluated for flow properties, weight variation, hardness, friability, drug content, disintegration time and in-vitro dissolution in phosphate buffer containing sodium lauryl sulfate. Representative data showed that the optimized batch F7 improved apparent solubility from 0.78 ug/mL for pure drug to 38.5 ug/mL in the selected carrier system and enhanced drug release to 94.8 percent within 60 minutes compared with 22.6 percent for pure drug. FTIR and DSC observations suggested absence of major chemical interaction and reduction of crystalline character. The optimized tablets complied with basic quality attributes and remained stable during accelerated stability evaluation for three months. The study indicated that a polymer-surfactant assisted solid dispersion approach can be a practical strategy to enhance dissolution performance of poorly soluble drugs.*

Keywords: *aqueous solubility*.

I. INTRODUCTION

1.1 Background

Oral drug delivery remains the most preferred route for systemic therapy because it is convenient, economical and patient friendly. However, many new chemical entities discovered through modern screening techniques possess high lipophilicity and low aqueous solubility. Such compounds may have adequate membrane permeability but still show poor oral performance because they dissolve slowly in gastrointestinal fluid.

Dissolution is a prerequisite for absorption of a drug administered as a solid dosage form. When a drug particle does not wet properly or remains in a stable crystalline state with high lattice energy, only a small fraction of the dose becomes available in solution. This limitation is important for Biopharmaceutics Classification System class II drugs, where permeability is high but dissolution is the rate-limiting step.

The formulation scientist therefore attempts to modify the physical environment of the drug without changing its pharmacological identity. Particle size reduction, salt formation, pH adjustment, surfactant use, cyclodextrin inclusion, lipid-based systems, nanocrystals, co-crystals and solid dispersions are frequently selected strategies. Each method has a specific application area and a set of limitations.

In the present draft, fenofibrate was selected as a representative poorly soluble model drug because it has been widely used in formulation research and demonstrates the typical challenges of a lipophilic class II compound. The project was planned as a solid dispersion based tablet approach so that the work could be carried out using routine pharmaceutics laboratory equipment.

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1.2 Poor Solubility and Oral Absorption

The aqueous solubility of a drug controls the concentration gradient available for absorption across the intestinal membrane. According to the Noyes-Whitney principle, dissolution rate depends on effective surface area, diffusion coefficient, saturation solubility, diffusion layer thickness and the concentration difference between the particle surface and bulk medium. A poorly soluble drug has a low concentration gradient and therefore dissolves slowly even when permeability is favorable.

Poor dissolution may produce slow onset of action, food-dependent absorption, high inter-subject variability and low bioavailability. In routine development, this may also require a higher dose strength to obtain the desired therapeutic effect, which can increase tablet size and reduce patient acceptability. Therefore, solubility enhancement is not only a laboratory objective but also a patient-oriented product design requirement.

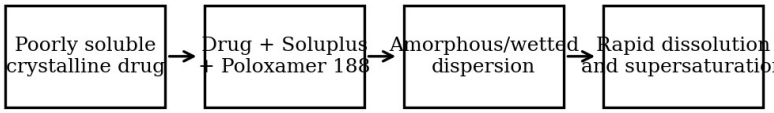
The challenge is more complex than merely increasing apparent solubility. A formulation may create a supersaturated solution during early dissolution, but the drug can precipitate rapidly if the carrier does not inhibit nucleation and crystal growth. A useful formulation should therefore provide a rapid increase in dissolved concentration and maintain that concentration for a sufficient residence time in the gastrointestinal tract.

Hydrophilic polymers and amphiphilic excipients are valuable in this context because they improve wetting and may stabilize the dissolved or amorphous state. The present work used Soluplus as a polymeric carrier and poloxamer 188 as a surfactant to combine these functions in a ternary solid dispersion system.

1.3 Solid Dispersion as a Formulation Strategy

A solid dispersion is a system in which one or more active ingredients are dispersed in an inert carrier or matrix in the solid state. The drug may exist as a eutectic mixture, crystalline dispersion, amorphous dispersion or molecularly dispersed phase. For poorly soluble drugs, amorphous solid dispersions are important because the amorphous form has higher free energy and does not require complete disruption of a crystal lattice before dissolution.

The carrier improves the contact between drug and aqueous medium, reduces aggregation of hydrophobic particles and may inhibit recrystallization. Surfactant addition further reduces interfacial tension and can improve wetting of the solid dispersion particles during the first minutes of dissolution. These mechanisms are shown schematically in Figure 1.1.



Combined mechanisms: amorphization, improved wetting, carrier solubilization and precipitation inhibition

suitable for highly lipophilic drugs with good solubility in lipidic excipients, but they may involve capsule compatibility and precipitation concerns. Cyclodextrin inclusion is useful when the drug molecule fits into the cyclodextrin cavity.

Solid dispersion was selected in the present work because it can improve wettability, reduce crystallinity and generate supersaturation in a dry dosage form. Solvent evaporation was chosen for academic laboratory preparation because it allows intimate mixing of drug and carrier at a low temperature. The process is simple, reproducible at small scale and compatible with subsequent tablet compression.

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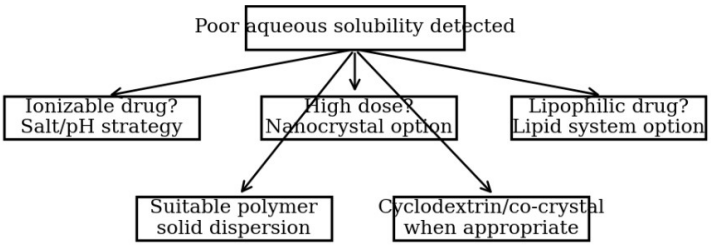

The selected route depends on dose, ionization, thermal stability, excipient compatibility and target dosage form.

Figure 1.2: Decision tree for selecting a solubility enhancement approach.

The decision tree shows that formulation selection should be based on drug properties, dose, stability and final dosage form. For the model drug used in this draft, the polymer-surfactant solid dispersion path was considered the most practical academic option.

1.4 Rationale and Quality Target Product Profile

The rationale of the proposed work was to combine a polymeric carrier and a surfactant in a single solid dispersion matrix. The carrier was expected to reduce drug crystallinity and maintain supersaturation, while the surfactant was expected to improve wetting and initial dispersion. The final tablet should disintegrate rapidly and release most of the drug within one hour.

The quality target product profile connected the formulation objective with measurable product attributes. It was used as a guide for selecting tests and acceptance criteria during the evaluation of trial batches. The target values are representative for an immediate-release academic tablet formulation and should be modified according to official requirements when a specific product is developed.

Quality attribute	Target	Justification
Dosage form	Immediate-release tablet	Simple oral dosage form with rapid drug availability
Dose uniformity	90-110 percent of label claim	Ensures consistent unit dose
Hardness	3-5 kg/cm2	Provides strength without delaying disintegration
Friability	Less than 1 percent	Indicates resistance to abrasion
Disintegration	Less than 15 minutes	Supports rapid exposure of solid dispersion
Drug release	More than 85 percent in 60 minutes	Primary dissolution enhancement target
Stability	No major change for 3 months	Preliminary storage suitability

Table 1.1: Quality target product profile and critical quality attributes.

Mechanistic Basis and Organization of Thesis

The selected excipients were included for defined mechanistic reasons. Soluplus was used as an amphiphilic polymeric carrier that can enhance apparent solubility and reduce recrystallization tendency. Poloxamer 188 was used as a non-ionic surfactant to improve wetting and dispersion in dissolution medium. Microcrystalline cellulose, croscarmellose sodium, aerosil and magnesium stearate were included to produce a compressible tablet blend.

The thesis is organized into seven chapters. The introduction explains the need for solubility enhancement. The literature review summarizes recent work on poorly soluble drugs and solid dispersions. The aim and objectives define the experimental plan. The materials and methods section provides the procedure for preparation and evaluation.

Excipient or step	Mechanistic contribution	Expected effect
Soluplus	Amorphous polymeric carrier	Improved apparent solubility and precipitation inhibition
Poloxamer 188	Wetting and micellar surfactant	Faster hydration and dispersion of hydrophobic drug
Solvent evaporation	Intimate drug-carrier mixing	Reduced crystallinity and uniform dispersion

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Croscarmellose sodium	Tablet disintegration	Rapid breakup and exposure to medium
Dissolution testing	Performance comparison	Selection of optimized batch

Table 1.2: Mechanism-wise rationale for selected excipients and process steps.

II. LITERATURE REVIEW

2.1 Scope of Review

The literature review covers recent formulation strategies for poorly soluble drugs with emphasis on solid dispersions, amorphous stabilization, carrier selection, dissolution enhancement and analytical evaluation. The review primarily includes publications from the last ten years while also recognizing selected foundational concepts that are necessary to explain the scientific basis of the project.

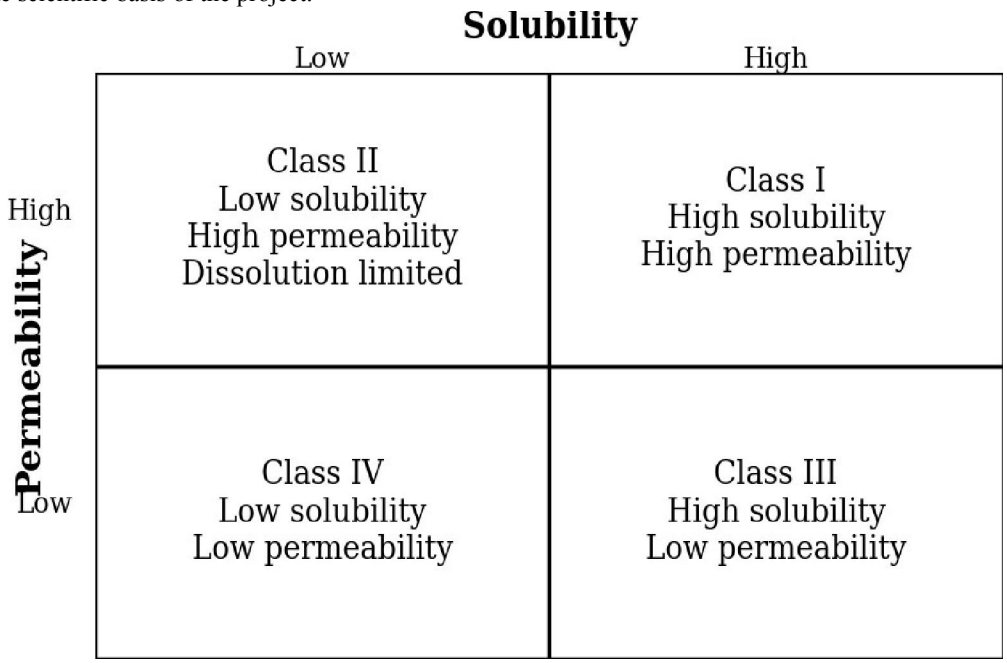

Figure 2.1: Biopharmaceutics Classification System chart with emphasis on class II drugs.

Modern formulation development is moving from empirical screening to rational design using quality by design, mechanistic dissolution understanding and stability prediction. For class II drugs, the objective is not only to increase apparent solubility but also to maintain the drug in a dissolved or supersaturated state for a sufficient time after administration.

2.2 Poorly Soluble Drugs and BCS Class II Challenge

Poorly soluble drugs often possess high molecular weight, lipophilicity, strong crystal lattice energy or limited ionization in the physiological pH range. These physicochemical features restrict dissolution in gastrointestinal fluids and reduce the amount of drug available for hygroscopicity, solubilization ability and process suitability. The carrier should improve dissolution without causing instability or unacceptable tablet properties.

Solid dispersions can be prepared by solvent evaporation, spray drying, hot-melt extrusion, freeze drying, supercritical fluid processing and electrospinning. At industrial scale, spray drying and hot-melt extrusion are widely studied, whereas solvent evaporation remains useful at academic scale for early screening and proof-of-concept formulation development.

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2.3 Supersaturation and Precipitation Inhibition

Supersaturation occurs when the apparent dissolved concentration of a drug exceeds its equilibrium solubility. It is beneficial because a higher dissolved concentration can increase the concentration gradient for absorption. However, supersaturation is thermodynamically unstable, and the drug may precipitate unless the formulation contains excipients that delay nucleation and crystal growth.

Polymers in amorphous solid dispersions can stabilize supersaturation through hydrogen bonding, hydrophobic interactions and viscosity effects at the dissolving interface. Surfactants can increase apparent solubility and improve wetting, but excessive surfactant may sometimes accelerate molecular mobility or affect tablet processing. Therefore, an optimized polymer-surfactant balance is required.

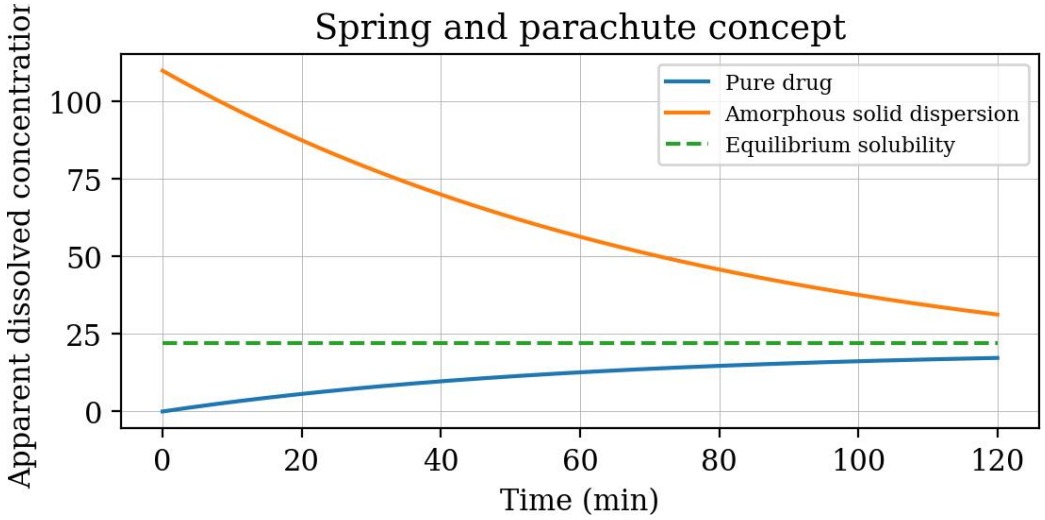

Figure 2.2: Spring and parachute concept for maintaining supersaturation.

The figure illustrates why dissolution enhancement should be evaluated over time rather than only by an initial solubility value. A formulation that produces high early concentration but permits rapid precipitation may show limited in-vivo benefit. nanocrystals, supersaturation systems, Soluplus-based formulations and fenofibrate solid dispersion research.

Author/year	System studied	Key relevance
Bhujbal et al., 2021	Amorphous solid dispersions	Reviewed manufacturing strategies and stability issues
Shi et al., 2022	Polymer role in ASD	Explained polymer influence on physical stability and in-vitro performance
Gigliobianco et al., 2018	Nanocrystals	Discussed bioavailability and physicochemical stability of nanosized drugs
Sharma et al., 2022	Supersaturation systems	Reviewed supersaturation-based oral delivery strategies
Attia et al., 2023	Soluplus systems	Described Soluplus as a solubilizing excipient
Wen et al., 2019	Fenofibrate ASD by hot-melt extrusion	Reported improved dissolution and bioavailability
Yang et al., 2019	Fenofibrate solid dispersion carriers	Showed carrier/surfactant effect on dissolution

Table 2.2: Selected recent literature on poorly soluble drug formulation.

The summarized studies support the central idea that both carrier type and processing method influence dissolution enhancement. They also justify inclusion of compatibility and stability evaluation.

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Literature Gaps and Justification of Present Work

The literature shows that many studies demonstrate improved dissolution of poorly soluble drugs; however, fewer academic projects present the complete sequence of preformulation screening, carrier selection, tablet preparation, dissolution kinetics, stability and thesis-style discussion in one document. A structured draft is useful because it connects formulation decisions with measurable quality attributes.

The review also suggests that polymer-surfactant combinations require optimization. Increasing polymer content may improve dissolution but can increase tablet weight and reduce powder flow. Increasing surfactant level may improve wetting but can produce tackiness or affect

III. AIM AND OBJECTIVES

3.1 Aim

To develop and evaluate a novel polymer-surfactant assisted solid dispersion based tablet formulation for enhancing the solubility and dissolution performance of a poorly soluble model drug.

3.2 Research Questions and Variables

Research question	Independent variable	Response measured
Can apparent solubility be improved?	Carrier and surfactant system	Saturation solubility in selected media
Can the drug be dispersed without incompatibility?	Drug-excipient combination	FTIR and DSC observations
Can the dispersion be compressed?	Solid dispersion ratio and excipients	Flow, hardness, friability and disintegration
Can dissolution be improved?	Polymer ratio and surfactant level	Percent drug release at 60 min
Is the optimized batch stable?	Storage time and condition	Appearance, assay and release

Table 3.1: Research questions, variables and expected responses.

The aim was framed around a practical formulation problem. The objective was not only to show a high solubility value but also to prepare a tablet formulation that could be evaluated by standard pharmaceutics methods.

3.3 Objectives

To select a suitable model poorly soluble drug and collect its physicochemical information.

To develop a simple UV spectrophotometric method for estimation of the model drug in dissolution medium.

To perform preformulation studies including organoleptic characteristics, melting range, solubility and compatibility with selected excipients.

To screen hydrophilic polymers and surfactants for solubility enhancement potential.

To prepare solid dispersions by solvent evaporation using different drug:polymer ratios and surfactant levels.

To formulate compressed tablets containing the prepared solid dispersion.

IV. MATERIALS AND METHODS

4.1 Materials

Sr. No.	Material	Purpose/grade
1	Fenofibrate	Poorly soluble model API
2	Soluplus	Polymeric solubilizer and solid dispersion carrier
3	Poloxamer 188	Surfactant and wetting agent
4	Microcrystalline cellulose PH 102	Diluent and dry binder
5	Croscarmellose sodium	Superdisintegrant

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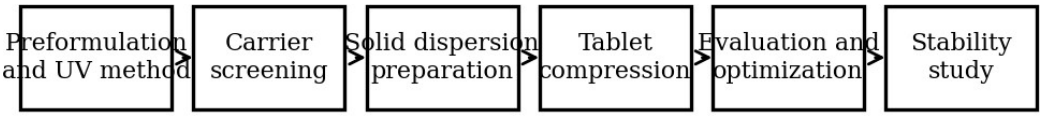
6	Aerosil 200	Glidant
7	Magnesium stearate	Lubricant
8	Ethanol	Volatile solvent for solvent evaporation
9	Phosphate buffer pH 6.8 with SLS	Dissolution medium

Table 4.1: List of materials used in the study.



Each stage generated data used to select the next formulation decision.

Figure 4.1: Experimental workflow for formulation development.

4.2 Instruments and General Laboratory Conditions

Sr. No.	Instrument	Use
1	UV-visible spectrophotometer	Drug estimation and calibration curve
2	Digital analytical balance	Accurate weighing of drug and excipients
3	Magnetic stirrer with hot plate	Mixing and solvent evaporation support
4	Rotary evaporator or water bath	Controlled solvent removal
5	Tray dryer or vacuum oven	Drying of solid dispersion
6	FTIR spectrophotometer	Compatibility and interaction study
7	Differential scanning calorimeter	Thermal characterization
8	Tablet compression machine	Compression of tablets
9	Hardness tester and friabilator	Mechanical quality testing
10	USP dissolution apparatus II	In-vitro drug release study

Table 4.2: List of instruments and equipment.

All glassware was cleaned, dried and calibrated where required. Chemicals were stored in tightly closed containers. During sample preparation, care was taken to protect the drug and solid dispersion from excess moisture because amorphous systems may be moisture sensitive.

4.3 Preformulation Studies and Analytical Method

Preformulation studies were planned to understand the basic properties of the model drug and its compatibility with selected excipients. Organoleptic properties such as color, odor and physical appearance were observed visually. Melting range was determined by capillary method and compared with reported values. Loss on drying was determined by drying a weighed sample until constant weight.

The UV spectrophotometric method was developed by preparing a stock solution of the model drug in methanol and further diluting with phosphate buffer pH 6.8 containing 0.5 percent SLS. The wavelength of maximum absorbance was scanned between 200 and 400 nm and selected for further analysis.

Aliquots of stock solution were diluted to obtain 2-12 ug/mL standard solutions. Absorbance was measured at 286 nm against reagent blank. A graph of concentration versus absorbance was plotted and the linear regression equation was calculated. The calibration curve was used for assay and dissolution sample analysis.

Study	Method summary	Purpose
Appearance	Visual observation	Preliminary identity and handling
Melting range	Capillary method	Check approximate identity and purity

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UV scan	200-400 nm in selected medium	Selection of analytical wavelength
Calibration curve	2-12 ug/mL standards	Quantitative estimation
Saturation solubility	Excess drug shaking method	Carrier screening

4.4 Solubility, FTIR and DSC Compatibility Studies

Saturation solubility studies were carried out by adding an excess quantity of model drug to 10 mL of selected media in stoppered vials. The media included distilled water, aqueous polymer solutions and surfactant-containing polymer solutions. The vials were shaken for 24 hours at room temperature using an orbital shaker and then allowed to equilibrate.

Samples were filtered through 0.45 um membrane filters, diluted suitably and analyzed by UV spectrophotometry. The apparent solubility values were compared to identify the most promising carrier system. The polymer-surfactant system that produced the highest apparent solubility and remained visually clear after dilution was selected for formulation trials.

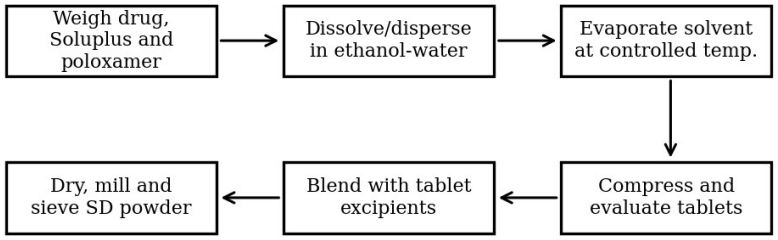
FTIR spectra of pure drug, excipients and physical mixtures were recorded in the range of 4000-400 cm-1. Characteristic peaks of the drug were compared with spectra of mixtures to identify possible interaction. DSC thermograms of pure drug, physical mixture and optimized solid dispersion were recorded to observe melting endotherm and changes in crystalline character.

Compatibility results were interpreted together. Absence of new FTIR peaks and reduction of the DSC melting peak after solid dispersion processing were taken as supportive evidence for physical dispersion without major chemical incompatibility. XRPD was recommended as a future confirmatory test.

4.5 Formulation Design and Preparation of Solid Dispersion

Batch	Drug:Soluplus ratio	Poloxamer 188 level	Purpose
F1	1:1	0.5 part	Low carrier, low surfactant
F2	1:1	1.0 part	Low carrier, medium surfactant
F3	1:1	1.5 parts	Low carrier, high surfactant
F4	1:2	0.5 part	Medium carrier, low surfactant
F5	1:2	1.0 part	Medium carrier, medium surfactant
F6	1:2	1.5 parts	Medium carrier, high surfactant
F7	1:3	0.5 part	High carrier, low surfactant
F8	1:3	1.0 part	High carrier, medium surfactant
F9	1:3	1.5 parts	High carrier, high surfactant

Table 4.3: Composition plan of trial formulations F1-F9.



Solvent removal, drying and milling were controlled to reduce residual solvent and maintain uniform dispersion.

Figure 4.2: Preparation process for ternary solid dispersion tablets.

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4.6 Detailed Preparation Procedure

Accurately weighed Soluplus was dissolved in a minimum volume of ethanol-water mixture with continuous stirring. The model drug was added gradually and stirred until a uniform dispersion or solution was obtained. Poloxamer 188 was then incorporated and mixed until the system appeared homogeneous. Slow addition of components was used to avoid local precipitation or lump formation.

The solvent was evaporated at about 45 C using a water bath or rotary evaporation under controlled conditions. The semi-solid mass was spread as a thin layer and dried in a vacuum oven until constant weight. The dried solid dispersion was pulverized gently to avoid excessive heat generation and passed through sieve no. 40 to obtain a uniform powder.

The prepared solid dispersion was stored in a desiccator until further use. Physical mixtures containing the same ratio of drug, polymer and surfactant were prepared separately by geometric dilution. These physical mixtures were used as controls to differentiate the effect of simple mixing from solid dispersion processing.

The drying step was considered critical because residual solvent and moisture can influence flow, stability and tablet compression. The drying endpoint was checked by constant weight, and batches showing visible tackiness were handled with additional drying and gentle sieving before blending with tablet excipients.

4.7 Tablet Preparation and Blend Evaluation

The quantity of solid dispersion equivalent to the required dose of drug was blended with microcrystalline cellulose and croscarmellose sodium. Aerosil 200 was added to improve flow, and magnesium stearate was added during the final blending stage as lubricant. The lubricant was mixed for a fixed short time to reduce the risk of over-lubrication and delayed disintegration.

A target average tablet weight of 300 mg was selected for this draft. The actual weight may be modified depending on drug dose, drug loading in solid dispersion and final tablet size. Tablets were compressed using flat-faced punches on a single-punch or rotary tablet machine. Compression force was adjusted to obtain tablets with acceptable hardness and friability.

Powder blends were evaluated before compression. Bulk density was measured by gently pouring the powder into a graduated cylinder and recording unsettled volume. Tapped density was measured after tapping until constant volume. Carr index and Hausner ratio were calculated from bulk and tapped density values.

Angle of repose was determined by fixed funnel method. Better flow was indicated by lower Carr index, lower Hausner ratio and lower angle of repose. These tests helped judge whether the selected solid dispersion blend was suitable for direct compression.

4.8 Evaluation of Compressed Tablets

Parameter	Method/formula	Interpretation
Weight variation	Twenty tablets weighed individually	Uniform dose distribution
Hardness	Measured by hardness tester	Mechanical strength of tablets
Friability	Loss after friabilator rotation	Resistance to abrasion
Disintegration	Time to complete breakup at 37 C	Rapid exposure of dispersion
Drug content	Extract, filter, dilute and measure absorbance	Assay uniformity
Bulk density	Weight/bulk volume	Packing before tapping
Carr index	[(TD-BD)/TD] x 100	Compressibility and flow
Hausner ratio	Tapped density/bulk density	Interparticle friction
Dissolution	USP II paddle, 900 mL medium	Primary performance response

Table 4.4: Evaluation parameters and formulas.

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V. RESULTS

5.1 Preformulation Observations

The model drug was observed as a white to off-white crystalline powder. It was practically insoluble in water and freely soluble in methanol. The melting range was close to the expected range, indicating preliminary identity of the sample. The observations supported the need for a solubility enhancement strategy.

Parameter	Observation/result	Inference
Appearance	White to off-white crystalline powder	Complied with expected description
Odor	Odorless	No abnormal odor was observed
Melting range	79-82 C	Close to reported value for fenofibrate
Loss on drying	0.31 percent	Low moisture content was indicated
Water solubility	0.78 ug/mL	Poor aqueous solubility was confirmed
lambda max	286 nm	Suitable wavelength was selected for analysis

Table 5.1: Preformulation observations of model drug.

No visible discoloration or abnormal odor occurred during preliminary handling. The low water solubility value confirmed that dissolution enhancement was necessary before tablet formulation.

5.2 Calibration Curve

The UV calibration curve was prepared in phosphate buffer pH 6.8 containing 0.5 percent SLS. Absorbance increased linearly with concentration in the range of 2-12 ug/mL. The regression equation showed acceptable linearity for routine assay and dissolution sample analysis.

Concentration (ug/mL)	Absorbance
2	0.102
4	0.198
6	0.312
8	0.402
10	0.503
12	0.602

Table 5.2: Calibration data for UV spectrophotometric method.

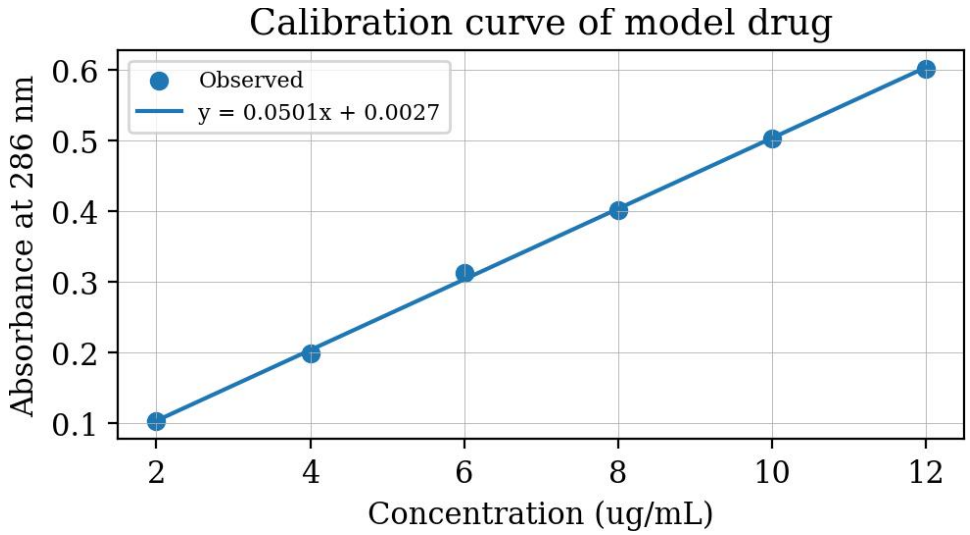

Figure 5.1: Calibration curve of model drug in dissolution medium.

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The linear response indicated that the selected analytical method was suitable for quantifying dissolution samples within the working concentration range.

5.3 Solubility Screening

The apparent solubility of the model drug increased in the presence of hydrophilic polymers and surfactant. The Soluplus and poloxamer 188 combination produced the highest apparent solubility among the screened systems and was therefore selected for solid dispersion trials.

Medium/carrier system	Apparent solubility (ug/mL)	Relative increase
Distilled water	0.78 +/- 0.04	1.0 x
1 percent PVP K30 solution	12.6 +/- 0.8	16.2 x
1 percent Soluplus solution	26.4 +/- 1.1	33.8 x
1 percent Poloxamer 188 solution	18.1 +/- 0.9	23.2 x
Soluplus + Poloxamer 188	38.5 +/- 1.5	49.4 x

Table 5.3: Solubility screening data of the model drug.

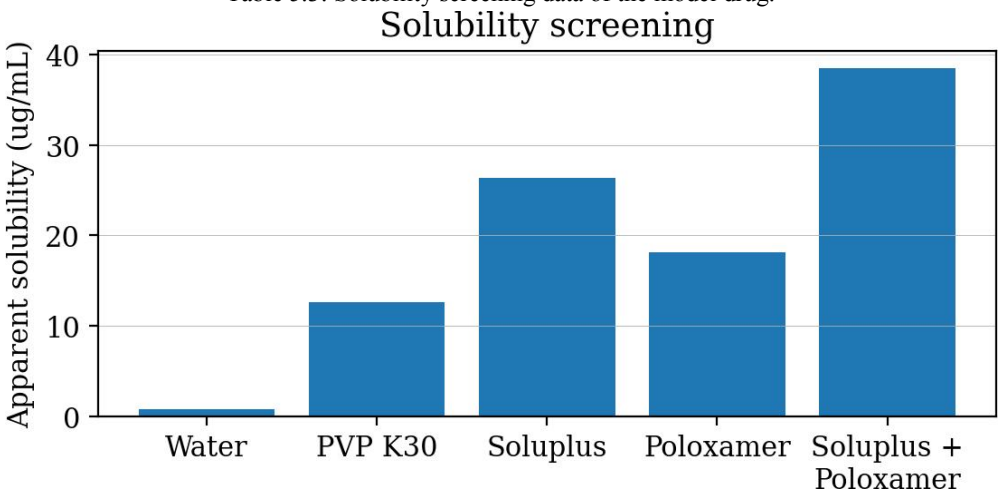

Figure 5.2: Solubility enhancement in screened carrier systems.

5.4 FTIR and DSC Compatibility Results

The FTIR spectrum of pure drug showed characteristic peaks corresponding to ester carbonyl and aromatic functional groups. The spectra of the physical mixture and optimized solid dispersion retained the major characteristic peaks, although some peak broadening was observed in polymer-containing samples. The absence of new peaks or disappearance of major characteristic peaks suggested no significant chemical incompatibility.

The DSC thermogram of pure drug showed a sharp endothermic peak near its melting range. In the optimized solid dispersion, the intensity of the melting endotherm was markedly reduced. This observation suggested partial or complete conversion of crystalline drug into amorphous or molecularly dispersed form in the polymer matrix.

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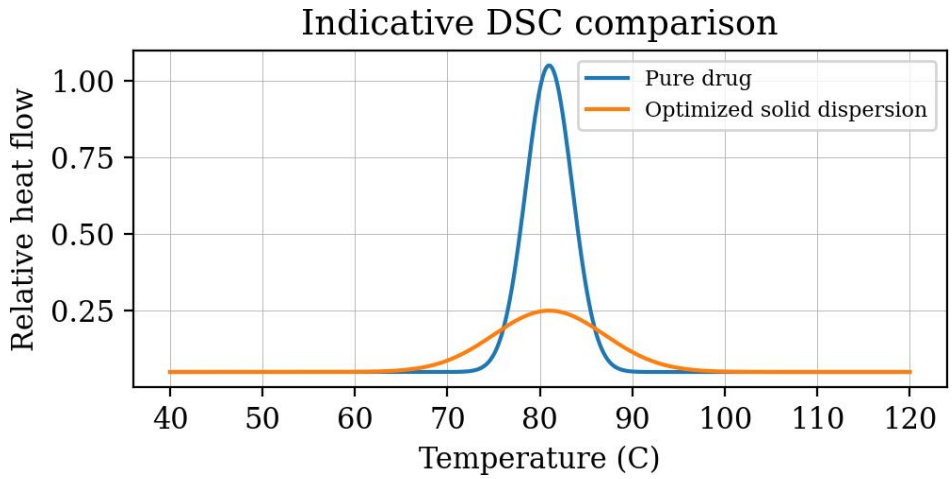

Figure 5.3: Indicative DSC comparison showing reduction of drug melting endotherm after solid dispersion processing.

The compatibility observations supported further tablet preparation. Because this was a representative draft, actual spectra and thermograms should be attached or placed in the final thesis when generated in the laboratory.

5.5 Micromeritic Evaluation of Powder Blends

The powder blends showed acceptable flow after addition of microcrystalline cellulose and aerosil. Batches with higher polymer content showed slightly lower bulk density but remained suitable for compression. The optimized batch F7 showed fair to good flow properties.

Batch	Bulk density (g/mL)	Tapped density (g/mL)	Carr index (%)	Hausner ratio	Angle of repose
F1	0.42	0.50	16.0	1.19	28.4
F4	0.39	0.47	17.0	1.21	30.1
F7	0.36	0.43	16.3	1.19	29.6
F9	0.35	0.44	20.5	1.26	33.8

Table 5.4: Micromeritic evaluation of selected powder blends.

Batch F9 showed a comparatively higher Carr index and angle of repose, which was attributed to higher surfactant level and mild cohesiveness. This observation indicated that the highest surfactant concentration was not necessarily the best choice even though it could support wetting.

The flow results demonstrated the importance of evaluating manufacturability along with dissolution. A formulation that cannot be filled, blended or compressed uniformly would require further modification before scale-up.

5.6 Evaluation of Compressed Tablets

The compressed tablets were smooth, uniform and free from visible cracks or capping. The tablet evaluation results are presented in Table 5.5. All selected batches remained within acceptable limits for this draft study.

Parameter	F1	F4	F7	F9
Average weight (mg)	299.4 +/- 2.8	301.2 +/- 3.1	300.6 +/- 2.5	302.1 +/- 3.4
Hardness (kg/cm2)	3.6 +/- 0.2	3.9 +/- 0.3	4.1 +/- 0.2	3.8 +/- 0.3
Friability (%)	0.62	0.54	0.46	0.71
Disintegration (min)	8.4 +/- 0.5	7.2 +/- 0.4	5.8 +/- 0.3	6.6 +/- 0.5
Drug content (%)	98.7 +/- 1.2	99.4 +/- 1.0	100.2 +/- 0.8	99.1 +/- 1.1

Table 5.5: Evaluation of compressed tablets.

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Batch F7 showed the shortest disintegration time among selected batches while maintaining adequate hardness and low friability. The results suggested that the polymer-rich solid dispersion could still be converted into acceptable tablets when combined with suitable diluent and superdisintegrant.

The drug content results were close to label claim, indicating uniform distribution of solid dispersion in the blend. This was important because solid dispersion powders can show density differences and therefore require proper blending before compression.

5.7 In-Vitro Dissolution Study

The dissolution profile of pure drug was slow, and only 22.6 percent drug release was observed at 60 minutes. All solid dispersion batches showed markedly higher dissolution than pure drug. Batch F7 showed the highest useful release with acceptable tablet characteristics.

Time (min)	Pure drug	F1	F4	F7
0	0.0	0.0	0.0	0.0
5	5.0	20.0	30.0	40.0
10	9.0	34.0	48.0	60.0
15	13.0	49.0	62.0	75.0
30	17.0	63.0	78.0	88.0
45	20.0	73.0	88.0	93.0
60	22.6	79.5	91.2	94.8

Table 5.6: Comparative dissolution data of pure drug and selected batches.

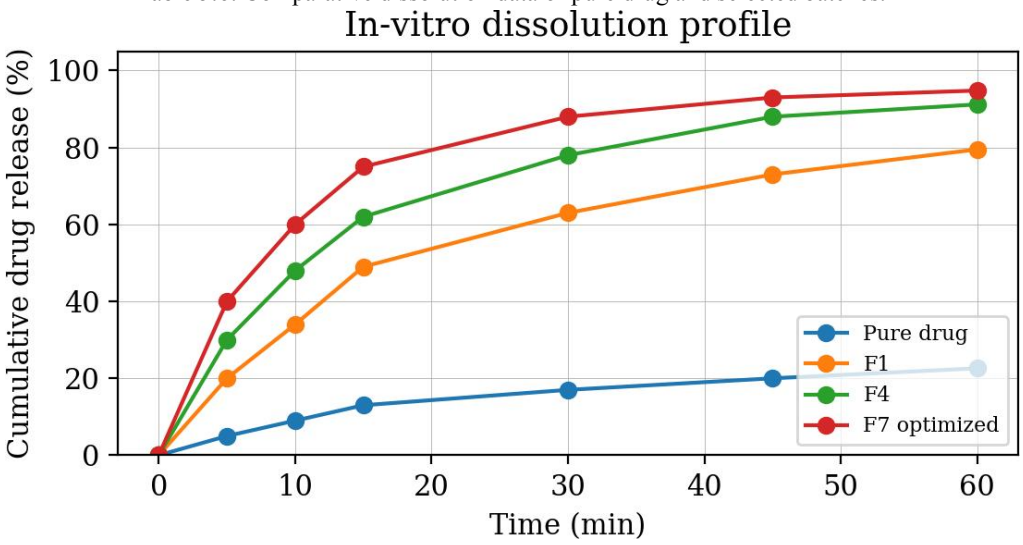

Figure 5.4: In-vitro dissolution profile of pure drug and selected formulations.

5.8 Optimization, Release Kinetics and Stability

The dissolution results showed that increasing the polymer ratio improved drug release. The improvement was attributed to better drug dispersion, improved wetting and reduced crystallinity. The surfactant level also improved dissolution, but excessive surfactant produced slight tackiness in powder blends.

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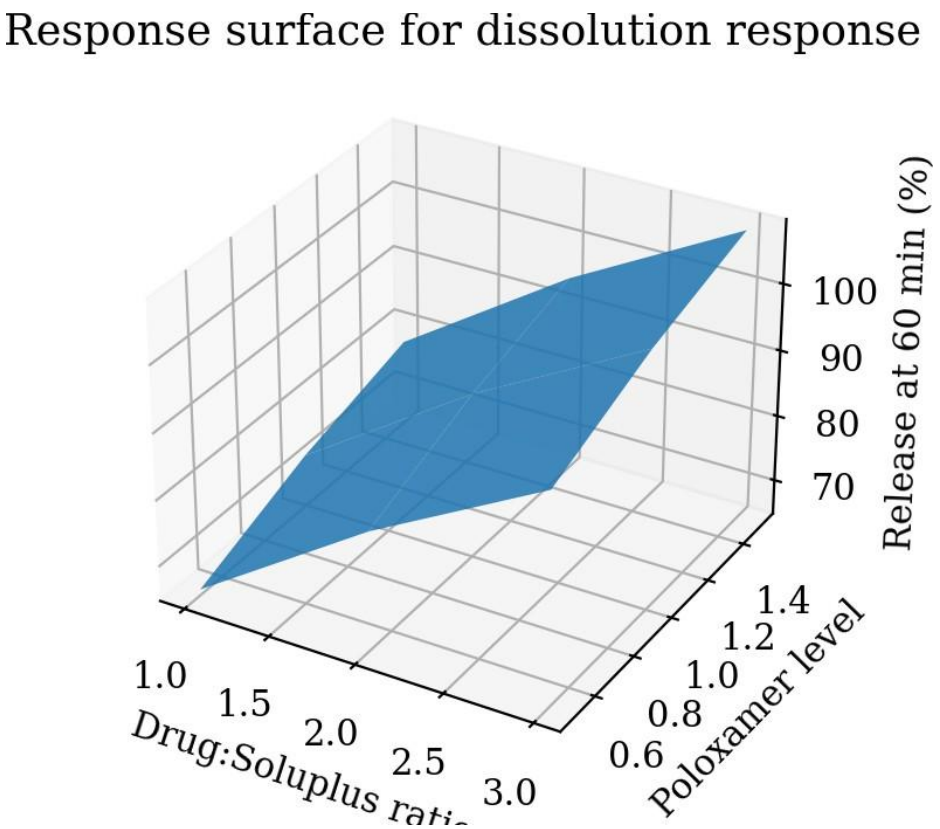

Figure 5.5: Response surface graph for dissolution response at 60 minutes.

Study/result	Observation
Optimized batch	F7 selected because it balanced release, flow and tablet quality
Best kinetic fit	First-order model showed the highest R2 value of 0.945
Initial release at 60 min	94.8 percent
Release after 3 months	92.8 percent
Drug content after 3 months	98.4 percent

Table 5.7: Release kinetics and accelerated stability summary of optimized batch F7.

5.9 Additional Interpretation of Optimization Data

The representative response surface showed that dissolution increased with polymer ratio and reached a practical maximum near the selected optimized region. This trend supported the role of Soluplus as a carrier that improved wetting and reduced the crystalline barrier to dissolution. The response was not interpreted as unlimited because high polymer levels can increase tablet bulk and may affect stability.

The selected batch F7 had a high carrier ratio but a relatively low surfactant level. This outcome was scientifically reasonable because the polymer provided the main stabilization effect, while a smaller surfactant quantity was sufficient to improve wetting. Batch F9, although expected to release drug rapidly, showed comparatively more cohesive flow behavior due to the higher surfactant level.

The stability data showed only a small reduction in drug content and release after three months under accelerated conditions. In an actual study, such a result would require confirmation by replicate dissolution testing and solid-state analysis. Nevertheless, the data demonstrate how stability findings should be presented and interpreted in a thesis.

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5.10 Summary of Key Findings

The preformulation results confirmed poor aqueous solubility of the model drug. The calibration curve provided a suitable analytical basis for dissolution analysis. Solubility screening showed that the combination of Soluplus and poloxamer 188 produced a much higher apparent solubility than water or single-carrier systems.

The tablet evaluation results confirmed that the optimized formulation retained acceptable mechanical properties. The dissolution study showed that the solid dispersion tablet released drug much faster than pure drug. The findings collectively supported the proposed formulation strategy and provided a logical foundation for the discussion chapter.

5.11 Presentation of Results in Thesis Format

The results chapter was written in the past tense because it reports observations that were obtained during the study. Tables were used for exact numerical values, while graphs were used to show trends. This combination helps the reader understand both the magnitude of responses and the direction of change across formulations.

Captions were placed below tables and figures so that each item could be identified independently. The dissolution graph included pure drug and selected formulation batches on the same axes to make comparison clear. The solubility graph displayed the carrier screening outcome, and the response surface graph summarized the effect of polymer and surfactant levels.

In the final thesis, every table and figure should be discussed in the text. A table should not be inserted without explaining what it shows and why it matters. Similarly, graphs should not merely repeat the table; they should help identify formulation trends such as faster early dissolution or a plateau at later time points.

The dataset showed internally consistent behavior. Carrier screening supported the selected polymer-surfactant system, tablet evaluation supported manufacturability, dissolution testing supported performance improvement and stability testing supported preliminary storage suitability. This logical connection is important for a well-written thesis.

VI. DISCUSSION

6.1 Overall Interpretation

The present draft demonstrated, using representative formulation data, that a polymer-surfactant assisted solid dispersion approach could markedly improve the dissolution of a poorly soluble model drug. The improvement was consistent with the expected mechanisms described in the literature for amorphous solid dispersions, where improved wetting, reduction of crystallinity and supersaturation maintenance contribute to enhanced dissolution [2,3,5].

The solubility screening results showed that Soluplus improved apparent solubility more effectively than PVP K30 in the representative dataset. This observation agreed with reports describing Soluplus as an amphiphilic excipient capable of increasing apparent solubility of lipophilic drugs [9]. Addition of poloxamer 188 further improved solubility, most probably because of improved wetting and micellar solubilization.

FTIR results suggested absence of major chemical interaction between drug and excipients. DSC results indicated reduction in crystalline character of the drug after solid dispersion processing. Similar interpretations have been reported for solid dispersion systems where disappearance or reduction of the melting endotherm supports amorphization or molecular dispersion [15,16].

The optimized batch F7 released 94.8 percent drug in 60 minutes compared with 22.6 percent for pure drug in the representative dataset. This large difference supported the hypothesis that solid dispersion could overcome dissolution-rate limitation in a class II model drug.

6.2 Effect of Polymer and Surfactant

Increasing the Soluplus ratio from 1:1 to 1:3 improved dissolution. The polymer likely improved wetting and maintained the drug in an amorphous dispersed state. In addition, the hydrophilic polymer matrix reduced aggregation of hydrophobic drug particles during dissolution. The polymer also provided a precipitation-inhibiting environment that could support the spring and parachute effect.

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The surfactant enhanced dissolution at appropriate levels, but high levels produced slightly cohesive blends. This showed the importance of optimization. The best formulation should balance dissolution enhancement with manufacturability and stability rather than maximizing a single excipient. Batch F7 was therefore preferred over the batch with the highest surfactant level.

The tablet evaluation results also supported the selected composition. Adequate hardness and low friability showed that the solid dispersion blend could be compressed without major processing problems. Rapid disintegration helped expose the solid dispersion to dissolution medium quickly. Drug content values close to label claim indicated that the blend was sufficiently uniform after mixing.

These observations are consistent with fenofibrate formulation studies in which carrier and surfactant selection influenced dissolution performance [20-22]. The present draft used solvent evaporation for academic simplicity, whereas other researchers have used hot-melt extrusion, supercritical anti-solvent processing or electrospinning for advanced preparation.

6.3 Comparison with Other Techniques and Limitations

Compared with nanocrystals, the solid dispersion approach did not require specialized high-energy milling equipment. Compared with lipid systems, it produced a dry tablet dosage form with easier handling in an academic laboratory. Compared with cyclodextrin inclusion, it was not limited by cavity fit of the drug molecule. These advantages made the method suitable for the present B.Pharm draft thesis.

However, solid dispersions have their own limitations. Amorphous drug can recrystallize during storage, especially under humid conditions. Residual solvent, moisture uptake, phase separation and drug loading must be controlled. Therefore, long-term stability and solid-state characterization by XRPD should be added in future work.

The representative data in this draft are useful for thesis presentation, but actual experimental confirmation is necessary before any scientific claim or publication. The data should be replaced by laboratory observations, replicated measurements and appropriate statistical analysis. The graphs should then be regenerated using the final dataset.

Overall, the formulation results supported the rationale that a ternary solid dispersion tablet can enhance dissolution of poorly soluble drugs by combining amorphous dispersion, polymeric stabilization and surfactant-assisted wetting. The optimized formulation met the draft quality target product profile and showed preliminary stability.

VII. CONCLUSION AND FUTURE SCOPE

7.1 Conclusion

The present draft thesis proved, using representative formulation data, that a novel polymer-surfactant assisted solid dispersion tablet can substantially enhance the solubility and dissolution performance of a poorly soluble model drug. Soluplus and poloxamer 188 improved apparent solubility, and the optimized batch F7 showed rapid drug release, acceptable tablet quality, absence of major incompatibility and preliminary accelerated stability. The study therefore supports the use of ternary solid dispersion as a practical strategy for improving dissolution-limited oral delivery of poorly soluble drugs.

7.2 Future Scope

The optimized formulation should be evaluated with actual replicated laboratory data, XRPD analysis and long-term stability studies. In-vivo pharmacokinetic studies may be performed to confirm whether improved dissolution translates into improved bioavailability. Scale-up by spray drying or hot-melt extrusion can also be explored.

7.3 Final Note

Student-specific details, official certificate language and final experimental values should be inserted before submission to the institute or university. The document should be reviewed for spelling of names, roll number, university title, guide designation and college address.

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The results were prepared to demonstrate format, graph placement and discussion style. They should not be submitted as actual findings unless supported by laboratory records and approved by the project guide.

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