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Evaluations of Novel Formulation for Poorly Soluble Drugs

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Abstract: *Poor aqueous solubility is one of the major challenges in pharmaceutical formulation development, as it directly affects dissolution rate, absorption, and oral bioavailability of drugs. Ibuprofen, a widely used non-steroidal anti-inflammatory drug (NSAID), belongs to Biopharmaceutical Classification System (BCS) Class II and exhibits poor water solubility, leading to delayed dissolution and variable therapeutic response.*

The present study was aimed at development and evaluation of novel solid dispersion formulations of Ibuprofen for enhancement of solubility and dissolution rate. Solid dispersions were prepared using hydrophilic carriers such as PEG 6000 and PVP K30 by solvent evaporation method in different drug-to-polymer ratios.

Preformulation studies including organoleptic evaluation, melting point determination, solubility study, drug-excipient compatibility study, and λmax determination were performed. The prepared formulations were evaluated for percentage yield, drug content, solubility enhancement, dissolution profile, and FTIR analysis.

The results demonstrated significant improvement in aqueous solubility and dissolution rate of Ibuprofen compared to pure drug. Among all formulations, formulation F3 containing higher concentration of PEG 6000 showed maximum drug release and superior dissolution characteristics.

FTIR studies confirmed compatibility between drug and selected carriers without significant interaction. The enhancement in dissolution may be attributed to improved wettability, reduction in crystallinity, increased surface area, and molecular dispersion of drug within hydrophilic carrier matrix.

The study concluded that solid dispersion technology is an effective, economical, and promising approach for improving solubility and dissolution characteristics of poorly soluble drugs like Ibuprofen, thereby enhancing oral bioavailability and therapeutic efficacy.

Keywords: *Biopharmaceutical Classification System*

I. INTRODUCTION

1.Novel Drug Delivery Systems

Novel drug delivery systems are advanced techniques designed to improve therapeutic efficacy, safety, and patient compliance. These systems help in controlling drug release, improving bioavailability, and reducing adverse effects.

One of the major problems associated with oral drug delivery is poor aqueous solubility of drugs. Nearly 40% of newly discovered drugs exhibit poor solubility in water, which leads to poor dissolution and reduced absorption

2. Poorly soluble drugs

Poorly soluble drugs dissolve slowly in gastrointestinal fluids, leading to delayed onset of action, poor bioavailability, variable absorption and reduced therapeutic efficacy

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According to the Biopharmaceutical Classification System (BCS), drugs are classified into four categories:

CLASS	SOLUBILTY	PEARMEABILITY
Class I	High	High
Class II	Low	High
Class III	High	Low
Class IV	Low	Low

Ibuprofen belongs to BCS Class II.

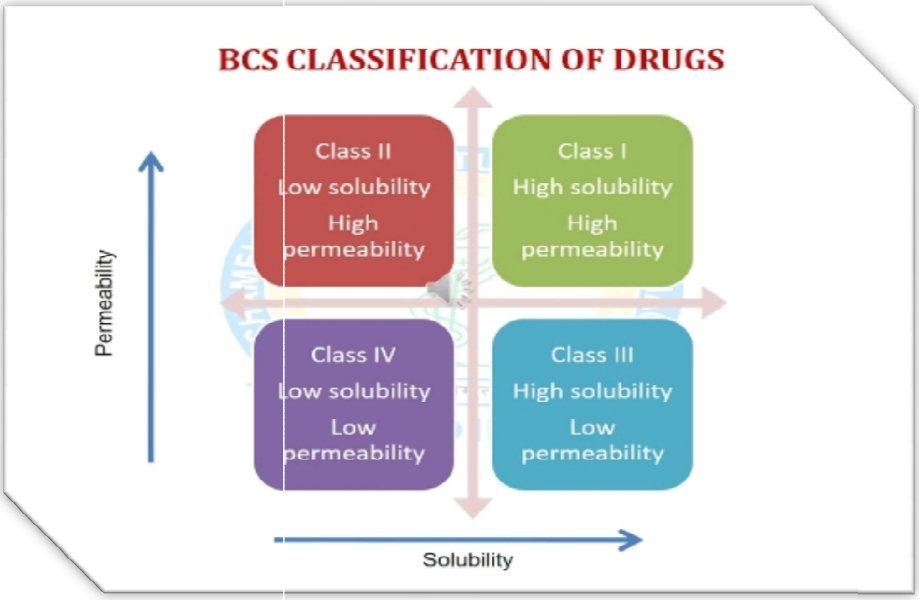

Fig .1 Bcs Classification

3 .Techniques for Solubility Enhancement

- Particle size reduction
- Solid dispersion
- Inclusion complexation
- Nanoemulsion
- Nanosuspensions
- Use of surfactants
- Salt formation

Among these, solid dispersion is one of the most effective and economical methods.

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4. Solid Dispersion

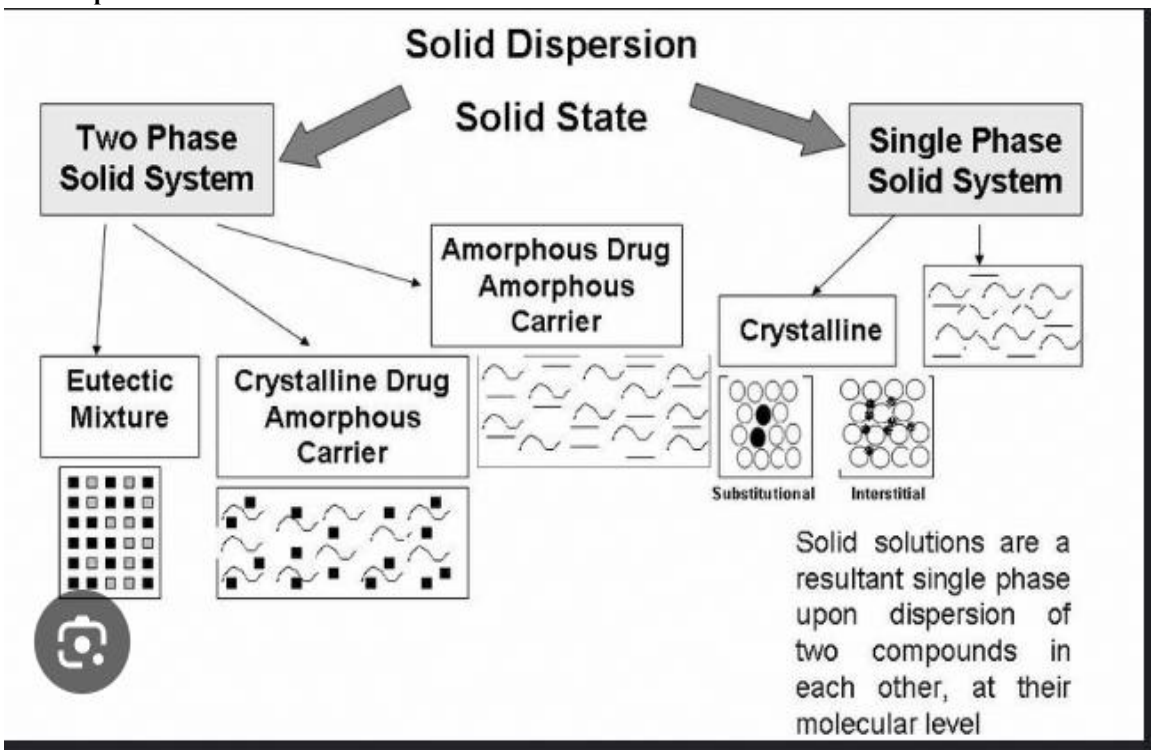

Fig 2.Solid Dispersion

Solid dispersion is defined as dispersion of one or more active ingredients in an inert carrier matrix in solid state.

Advantage

- Improved dissolution rate
- Enhanced wettability
- Reduced particle size
- Improved bioavailability
- Rapid drug release

Disadvantages

- Stability issues
- Moisture sensitivity
- Difficulty in scale-up.

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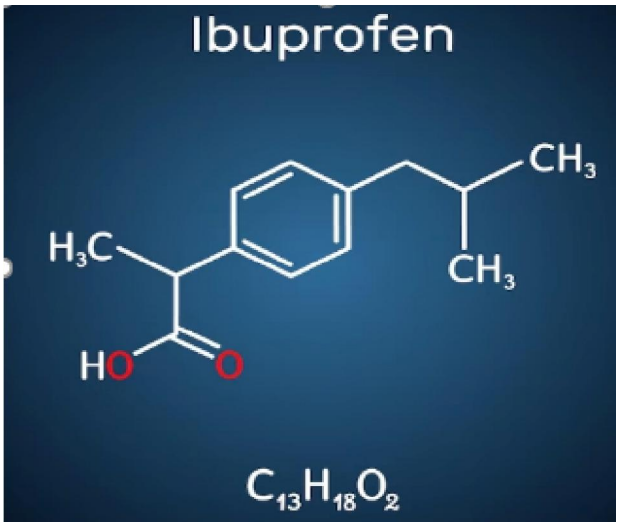
Drug Profile

1. IBUPROFEN



Structure Of Ibuprofen

Category : Non-Steroidal Anti-Inflammatory Drug (NSAID)

Chemical Name 2-(4-isobutylphenyl) propionic acid)

Molecular Formula: C13H18O2

Molecular Weight : 206.28 g/mol

Melting Point : 75°C – 78°C

Solubility: Poorly soluble in water

USES :

Ibuprofen is highly effective at managing mild to moderate discomfort caused by

1. Pain: Headaches, migraines, muscle aches, backaches, dental pain, and menstrual cramps

2. . Swelling and stiffness associated with conditions like osteoarthritis and rheumatoid arthritis.Fever: Reducing body temperature when ill.

3 Fever: Reducing body temperature when ill

Dosage & Administration:

1. Adults (OTC): Standard over-the-counter doses are typically 200 mg every 4 to 6 hours as needed, without exceeding 1,200 mg in a 24-hour period

2. Prescription: Doctors may prescribe higher doses (400 mg, 600 mg, or 800 mg) for chronic inflammation, up to a maximum of 3,200 mg daily

3. Best Practice: Always take ibuprofen with food, milk, or a full glass of water to reduce the risk of an upset stomac

Side Effects & Precaution

While generally safe for short-term use, taking ibuprofen improperly can cause adverse effect such as

1 Common: Nausea, dizziness, mild indigestion, or heartburn

2 Gastrointestinal Risks: Long-term use can increase the risk of stomach ulcers and gastrointestinal bleeding.

3 Cardiovascular & Renal Impact: Frequent use can cause fluid retention, elevate blood pressure, or strain the kidneys.

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Review of Literature

Researchers reported that PEG-based solid dispersions significantly improved dissolution rate of poorly soluble drugs. Studies showed that solvent evaporation method produces uniform dispersion and enhances wettability. PVP K30 was found effective in reducing crystallinity and increasing dissolution.

Many researchers have worked on enhancement of solubility and dissolution rate of poorly soluble drugs using solid dispersion technology. Various hydrophilic carriers and preparation methods have been investigated to improve oral bioavailability.

[1] Chiou and Riegelman introduced the concept of solid dispersion and reported that dispersion of poorly soluble drugs in water-soluble carriers significantly improves dissolution rate and absorption. Their work established solid dispersion as an important solubility enhancement technique.

Findings

Improved dissolution rate

Enhanced drug absorption

Better wettability of drug particles

Reference

Chiou WL, Riegelman S. Pharmaceutical applications of solid dispersion systems. Journal of Pharmaceutical Sciences. 1971;60(9):1281–1302.

[2] Sekiguchi and Obi studied eutectic mixtures and observed that reduction in particle size and improved wettability enhanced dissolution of poorly soluble drugs. Their findings contributed to development of modern solid dispersion systems.

Findings

Reduction in crystallinity

Improved surface area

Enhanced dissolution behavior

Reference

Sekiguchi K, Obi N. Studies on absorption of eutectic mixtures. Chemical and Pharmaceutical Bulletin. 1961;9(11):866–872.

[3].Ford et al. reported that hydrophilic carriers such as PEG improve wettability and reduce crystallinity of drugs, leading to increased dissolution rate and better drug release characteristics.

Findings

Improved wettability

Reduced crystallinity

Enhanced drug release

Reference

Ford JL. The current status of solid dispersions. Pharmaceutical Acta Helvetiae. 1986;61(3):69–88.

[4].Craig reviewed different preparation methods of solid dispersions and concluded that solvent evaporation method is one of the most effective techniques for enhancing dissolution of poorly soluble drugs.

Findings

Uniform dispersion of drug

Improved dissolution profile

Suitable for thermolabile drugs

Reference

Craig DQM. The mechanisms of drug release from solid dispersions in water-soluble polymers. International Journal of Pharmaceutics. 2002;231(2):131–144.

[5].Leuner and Dressman reported that solid dispersion technology is a promising approach for improving oral bioavailability of poorly water-soluble drugs.

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Findings
Increased oral bioavailability
Improved solubility
Enhanced therapeutic efficacy
Reference
Leuner C, Dressman J. Improving drug solubility for oral delivery using solid dispersions. European Journal of Pharmaceutics and Biopharmaceutics. 2000;50(1):47–60.

[6].Studies on Ibuprofen solid dispersions prepared using PEG 6000 demonstrated significant enhancement in dissolution rate compared to pure Ibuprofen.
Findings
Faster dissolution
Better wettability
Improved drug release
Reference
Dixit ND, Kulkarni PK, Puthli SP. Enhancement of dissolution rate of Ibuprofen by solid dispersion technique. International Journal of Pharmacy and Pharmaceutical Sciences. 2010;2(1):55–60.

[7] .Vasconcelos et al. reviewed solid dispersion systems and stated that hydrophilic polymers improve dissolution by converting crystalline drug into amorphous form.
Findings
Reduced crystallinity
Increased surface area
Enhanced dissolution characteristics
Reference
Vasconcelos T, Sarmento B, Costa P. Solid dispersions as strategy to improve oral bioavailability of poor water soluble drugs. Drug Discovery Today. 2007;12(23-24):1068–1075.

[8] .PVP K30-based formulations were investigated by various researchers and were found effective in enhancing wettability and dissolution rate of BCS Class II drugs.
Findings
Improved hydrophilicity
Enhanced dissolution
Stable formulation system
Reference
Sharma DK, Joshi SB. Solubility enhancement strategies for poorly water-soluble drugs. Asian Journal of Pharmaceutics. 2007;1(1):9–19.

[9] .Mohanachandran et al. reviewed various solubility enhancement techniques and concluded that solid dispersion is one of the most effective methods for BCS Class II drugs.
Findings
Enhanced dissolution rate
Improved bioavailability
Better oral absorption
Reference
Mohanachandran PS, Sindhumol PG, Kiran TS. Enhancement of solubility and dissolution rate: An overview. International Journal of Comprehensive Pharmacy. 2010;1(1):1–10.

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[10] .Yadav and Yadav studied enhancement of solubility of BCS Class II drugs using solid dispersion systems and found significant improvement in dissolution characteristics.

Findings

Increased surface area

Improved drug release

Enhanced dissolution efficiency

Reference

Yadav VB, Yadav AV. Enhancement of solubility and dissolution rate of BCS Class II pharmaceuticals by solid dispersion technique. International Journal of ChemTech Research. 2009;1(2):183–187.

Summary of Literature Review

The literature review revealed that:

Solid dispersion technology is highly effective for poorly soluble drugs.

PEG 6000 and PVP K30 are suitable hydrophilic carriers.

Solvent evaporation method provides uniform drug dispersion.

Reduction in crystallinity and improved wettability enhance dissolution rate.

Ibuprofen solid dispersions significantly improve drug release and oral bioavailability.

Therefore, the present study was undertaken to develop and evaluate novel solid dispersion formulations of Ibuprofen using hydrophilic carriers for enhancement of solubility and dissolution rate.

Need of Study

 Poor water solubility is one of the major obstacles in formulation development. Improving solubility is essential for enhancing oral bioavailability and therapeutic efficacy.

 Poor aqueous solubility is one of the major challenges in pharmaceutical formulation development. A large number of newly discovered drugs exhibit low solubility in water, which leads to poor dissolution rate, delayed absorption, low bioavailability, and reduced therapeutic effectiveness after oral administration.

 Ibuprofen is a widely used non-steroidal anti-inflammatory drug (NSAID) employed in the treatment of pain, inflammation, and fever. It belongs to Biopharmaceutical Classification System (BCS) Class II drugs, which are characterized by low solubility and high permeability. Due to its poor aqueous solubility, Ibuprofen exhibits slower dissolution in gastrointestinal fluids, resulting in variable absorption and reduced bioavailability.

 Conventional dosage forms of poorly soluble drugs often fail to provide rapid therapeutic action because dissolution becomes the rate-limiting step in drug absorption.

 Therefore, enhancement of solubility and dissolution rate is essential for improving therapeutic efficacy and patient compliance.

 Novel formulation approaches such as solid dispersion technology have gained considerable importance for improving solubility characteristics of poorly soluble drugs. In solid dispersion systems, the drug is dispersed in hydrophilic carriers like PEG 6000 and PVP K30, which improve wettability, reduce crystallinity, and increase surface area available for dissolution.

 The present study was undertaken to develop and evaluate solid dispersion formulations of Ibuprofen using hydrophilic carriers in order to enhance solubility, dissolution rate, and ultimately oral bioavailability

Aim:

To Develop And Evaluate Novel Solid Dispersion Formulations Of Ibuprofen For Enhancement Of Solubility, Dissolution Rate, And Oral Bioavailability.

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Objectives :

1. To Prepare Solid Dispersion Formulations Of Ibuprofen Using Suitable Hydrophilic Carriers Such As PEG 6000 And PVP K30.
2. To Improve The Aqueous Solubility Of Poorly Soluble Drug Ibuprofen.
3. To Enhance The Dissolution Rate Of Ibuprofen By Employing Solid Dispersion Technique.
4. To Evaluate The Prepared Formulations For Physicochemical Parameters Such As:

Percentage Yield
Drug Content
Solubility
Dissolution Profile

5. To Study Drug-Excipient Compatibility Using FTIR Analysis.
6. To Compare The Dissolution Characteristics Of Pure Ibuprofen With Prepared Solid Dispersion Formulations.

Materials and Methods

Materials Required : Drug: Ibuprofen
Polymers: 1.PEG 6000
2.PVP K30
Solvents : 1. Ethanol
2.Distilled Water
Chemicals and Reagents: 1.Phosphate Buffer pH 7.2
2. Hydrochloric Acid
3.Potassium Dihydrogen Phosphate
4. Sodium Hydroxide
Instruments and Equipment:

1. Analytical Balance
2. UV–Visible Spectrophotometer
3. Hot Air Oven
4. Beakers and Glassware
5. Magnetic Strirer

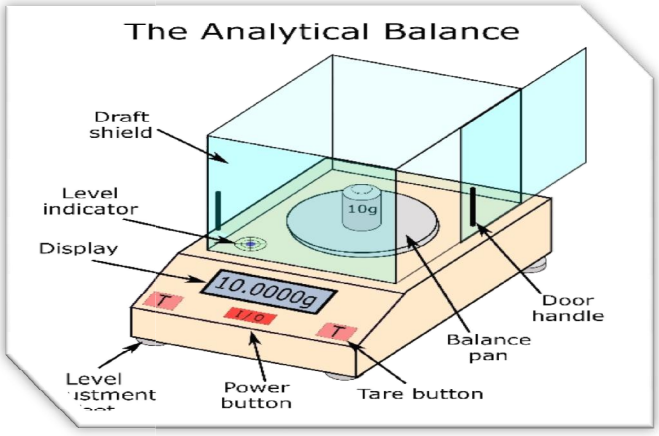

Fig .3 Analytical Balance

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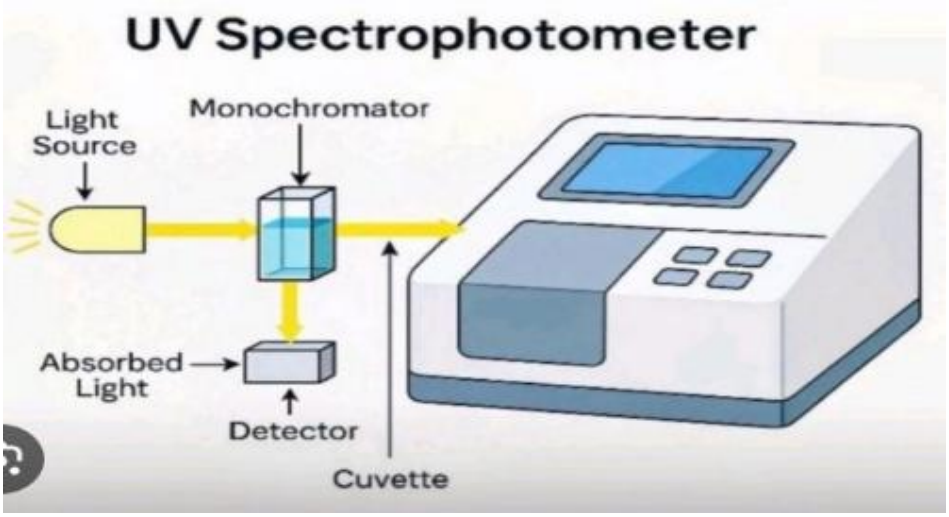

Fig 4. UV Spectrophotometer

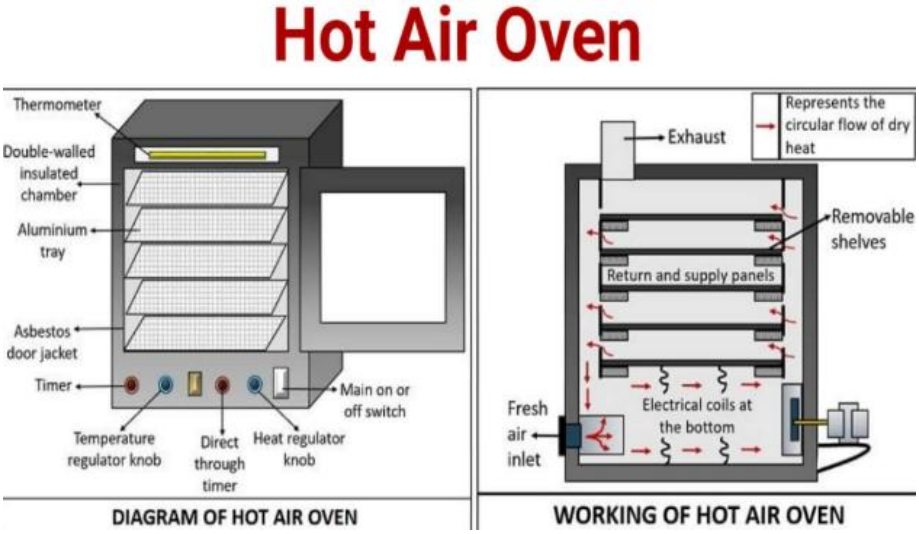

Fig .5 Hot Air Oven

Fig 6. Glassware And Beakers

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Fig 7. Magnetic Stirer

Fig 8. Solvent Evaporation Method

Method Used:
Solvent Evaporation Method
1. Drug and carrier were accurately weighed.
2. Both were dissolved in ethanol.
3. Solution was stirred continuously.

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4. Solvent was evaporated.
5. Solid mass obtained was dried.
6. Product was pulverized and sieve.

Solvent Evaporation Method

The solvent evaporation method was used for the preparation of solid dispersion of Ibuprofen with suitable carrier polymers such as PEG 6000 or Polyvinylpyrrolidone K30 (PVP K30). The detailed procedure is as follows:

1. Accurate Weighing of Drug and Carrier

Required quantities of the drug and carrier were accurately weighed according to the desired drug-to-polymer ratio (1:1, 1:2, or 1:3) using a calibrated analytical balance. Accurate weighing is essential to maintain uniformity and reproducibility of the formulation.

Example:

Ibuprofen – 1 g

PVP K30 – 2 g (for 1:2 ratio)

The weighed materials were transferred into a clean and dry beaker.

2. Dissolution of Drug and Carrier in Ethanol

The weighed drug and carrier were dissolved in a sufficient quantity of ethanol to obtain a clear homogeneous solution. Ethanol was selected as the solvent because it can dissolve both the drug and polymer effectively.

The solvent was added gradually while mixing to avoid lump formation. Dissolution was continued until both components dissolved completely and a transparent solution was obtained.

Purpose:

To ensure molecular level mixing of drug and carrier

To improve uniform distribution of drug in polymer matrix

3. Continuous Stirring of the Solution

The prepared solution was stirred continuously using a magnetic stirrer for approximately 20–30 minutes at moderate speed. Continuous stirring ensured proper mixing and prevented sedimentation of the drug particles.

The temperature was maintained below the boiling point of ethanol to avoid rapid solvent loss and precipitation of the drug.

Importance of stirring:

Produces uniform dispersion

Enhances interaction between drug and polymer

Prevents aggregation

4. Evaporation of Solvent

After complete mixing, the solvent was evaporated by placing the beaker on a water bath or hot plate maintained at 40–50°C. Evaporation was continued until a thick solid mass was obtained.

The solvent removal process was carried out slowly and uniformly to ensure proper incorporation of the drug into the carrier matrix.

Precautions:

Temperature should not exceed the degradation temperature of the drug

Complete removal of ethanol is necessary

Purpose:

To obtain solid dispersion after removal of volatile solvent

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5. Drying of the Obtained Solid Mass

The solid mass obtained after solvent evaporation was dried further in a hot air oven at 40°C for 24 hours or kept in a desiccator until constant weight was achieved.

This step ensured complete removal of residual solvent and moisture from the formulation.

Importance of drying:

Prevents microbial growth

Improves stability of formulation

Avoids residual solvent contamination

6. Pulverization and Sieving

The dried solid mass was collected and triturated gently using mortar and pestle to obtain a fine powder. The powder was then passed through sieve number 60 or 80 to obtain uniform particle size distribution.

Purpose of pulverization and sieving:

To obtain free-flowing powder

To ensure uniform particle size

To improve dissolution characteristics

The prepared solid dispersion powder was finally stored in an airtight container and kept in a desiccator for further evaluation studies.

Principle of Solvent Evaporation Method

In this method, both drug and carrier are dissolved in a common volatile solvent. Upon evaporation of the solvent, the drug gets dispersed uniformly in the polymer matrix, often in an amorphous form. This reduces crystallinity, improves wettability, and enhances the solubility and dissolution rate of poorly soluble drugs like ibuprofen.

Preformulation Studies

Preformulation studies are the preliminary investigations carried out to determine the physicochemical properties of the drug and its compatibility with excipients before formulation development. These studies help in selecting suitable formulation methods and excipients for preparation of stable and effective dosage forms.

In the present study, preformulation studies of Ibuprofen were performed as follows:

1. Organoleptic Properties

The drug sample was examined for its physical appearance, color, odor, and nature.

Parameter	Observation
Colour	White
Odour	
Appearance	Crystalline Powder
Taste	Slightly Bitter

Interpretation:

The obtained characteristics were found to comply with standard properties of Ibuprofen.

2. Melting Point Determination

Aim: To determine the melting point of Ibuprofen and confirm its purity.

Method: The melting point was determined by capillary method.

Procedure: A small quantity of Ibuprofen was filled into a capillary tube sealed at one end.

The capillary tube was placed in melting point apparatus.

Temperature at which drug started melting and completely melted was recorded.

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Observation :

Drug	Melting Point
Ibuprofen	75°C – 78°C

Interpretation
The observed melting point was found within official range, indicating purity of the drug sample.

3. Solubility Studies
Aim: To determine solubility of Ibuprofen in various solvents.

Method : An excess quantity of drug was added into different solvents and shaken until saturation was achieved.
Observation

Solvent	Solubility
Water	Slightly Soluble
Ethanol	Soluble
Methanol	Soluble
Phosphate Buffer pH 7.2	Moderately Soluble

Interpretation:
Ibuprofen showed poor aqueous solubility confirming its classification as poorly soluble drug.

4. Drug–Excipient Compatibility Study
Aim: To study compatibility between Ibuprofen and selected hydrophilic carriers.
Method: FTIR spectroscopy was performed for:
- Pure Ibuprofen
- PEG 6000
- PVP K30
- Physical mixture

Principle : FTIR detects possible interaction between drug and excipients by identifying changes in characteristic peaks
Observation
Characteristic peaks of Ibuprofen were retained in formulation mixtures without significant shifting or disappearance.
Interpretation: No major interaction was observed between drug and carriers, indicating compatibility of Ibuprofen with PEG 6000 and PVP K30.

5. Determination of λmax of Ibuprofen
Aim: To determine wavelength of maximum absorption (λmax) of Ibuprofen.
Method: Standard solution of Ibuprofen was scanned using UV spectrophotometer in the range of 200–400 nm.
Observation:

Parameter	Observation
λmax of Ibuprofen	221 nm

Interpretation: Ibuprofen showed maximum absorbance at 221 nm which was selected for further analytical studies.

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6. Calibration Curve of Ibuprofen

Aim: To prepare calibration curve of Ibuprofen in phosphate buffer pH 7.2.

Procedure:

1. Standard stock solution was prepared.
2. Dilutions of different concentrations were made.
3. Absorbance was measured at 221 spectrophotometer
4. Graph of concentration versus absorbance was plotted.

Observation Table:

Concentration (µg/ml)	Absorbance
2	0.112
4	0.221
6	0.336
8	0.445
10	0.557

Interpretation: The calibration curve showed linear relationship between concentration and absorbance according to Beer-Lambert's law.

Where : A = Absorbance
ε = Molar absorptivity
l = Path length
c = Concentration.

Evaluation Parameters

The prepared solid dispersion formulations of Ibuprofen were evaluated for various physicochemical and performance parameters to determine their quality, solubility enhancement, and dissolution characteristics.

1.Percentage Yield

Aim: To determine efficiency of preparation method.

Procedure

- The prepared solid dispersion was collected and weighed.
- Practical yield was compared with theoretical yield.
- Percentage yield was calculated.

Interpretation

Higher percentage yield indicates minimum loss during formulation process and better efficiency of method.

2. Drug Content Estimation

Aim

To determine amount of drug present in prepared formulations.

Procedure

- Accurately weighed quantity of formulation equivalent to specific amount of Ibuprofen was dissolved in suitable solvent.
- Solution was filtered and diluted.
- Absorbance was measured using UV spectrophotometer at 221 nm.
- Drug content was calculated using calibration curve.

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Interpretation
Uniform drug content indicates proper distribution of drug within carrier matrix.

3. Solubility Study
Aim :To evaluate enhancement of aqueous solubility of Ibuprofen.
Procedure
- Excess amount of formulation was added to distilled water.
- Samples were shaken for specified period.
- Solution was filtered and analyzed spectrophotometrically.
- Increase in solubility compared to pure drug indicates successful formulation development.

4. In-vitro Dissolution Study
Aim: To compare dissolution profile of pure drug and prepared formulations.
Apparatus and Conditions

Parameter	Condition
Apparatus	USP Type II (Paddle)
Dissolution Medium	Phosphate Buffer pH 7.2
Temperature.	37 ± 0.5°C
Rotation Speed.	50 rpm
Sampling Interval.	

Procedure
- Formulation equivalent to required dose was placed in dissolution medium.
- Samples were withdrawn at predetermined intervals.
- Equal quantity of fresh medium was replaced.
- Samples were analyzed using UV spectrophotometer.

Interpretation
Faster drug release indicates improved dissolution rate due to solid dispersion formation.

5. FTIR Spectroscopic Analysis
Aim :
To study compatibility between drug and carriers.
Principle:
FTIR spectroscopy identifies functional groups and detects possible interactions between drug and excipients.
Procedure
- Samples of pure drug and formulations were prepared.
- FTIR spectra were recorded over suitable wavelength range.
- Characteristic peaks were compared.

Interpretation
Absence of significant peak shifting indicates compatibility between drug and polymers.

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6. Physical Appearance

Parameters Evaluated

Color	Odor
Texture	Appearance

Interpretation

Uniform appearance indicates proper preparation and stability of formulation.

7. Particle Size Analysis

Aim :To determine reduction in particle size after formulation.

Interpretation

Smaller particle size increases surface area and enhances dissolution rate.

8. Stability Study

Aim:

To evaluate stability of prepared formulations under storage conditions.

Procedure

Formulations were stored at room temperature and observed for:

- Physical changes
- Drug content variation
- Dissolution changes

Interpretation

Stable formulations show no significant change during storage.

9. Wettability Study

Aim

To determine improvement in wettability of drug particles

Interpretation

Hydrophilic carriers improve wetting of drug particles and promote rapid dissolution.

10. Statistical Analysis

The obtained results were expressed as mean ± standard deviation and compared to identify optimized formulation with best dissolution characteristics.

Result

The prepared solid dispersion formulations of Ibuprofen were evaluated for various physicochemical parameters including percentage yield, drug content, solubility enhancement, dissolution study, and FTIR analysis. The obtained results are presented below.

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1. Percentage Yield

Observation Table

Formulation	Percentage Yield
F1	89%
F2	91%
F3	93%
F4	88%
F5	90%
F6	92%

Observation:

All formulations showed satisfactory percentage yield. Formulation F3 exhibited highest percentage yield of 93%

2. Drug Content Estimation

Observation Table

Formulation	Drug Content
F1	96%
F2	97%
F3	99%
F4	95%
F5	96%
F6	98%

The drug content of all formulations was found within acceptable limits, indicating uniform distribution of Ibuprofen in the carrier matrix.

3. Solubility Study:

Observation:

Prepared solid dispersion formulations showed improved aqueous solubility compared to pure Ibuprofen.

Result:

Formulations containing PEG 6000 demonstrated greater enhancement in solubility than formulations containing PVP K30.

4. In-vitro Dissolution Study

Observation Table

Formulation	Drug Release at 60 min
Pure Drug	42%
F1	68%
F2	79%
F3	94%
F4	63%
F5	74%
F6	88%

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All solid dispersion formulations showed enhanced dissolution rate compared to pure Ibuprofen. Formulation F3 exhibited maximum drug release of 94% within 60 minute

5. FTIR Analysis

Observation:

FTIR spectra of pure drug and formulations showed characteristic peaks without significant change

Result:

No significant interaction was observed between Ibuprofen and selected hydrophilic carriers, indicating compatibility of formulation component.

6. Physical Appearance

Observation:

- Prepared formulations appeared as:
- White amorphous powder
- Free-flowing
- Uniform in appearance

Result:

The formulations were physically stable and suitable for further pharmaceutical evaluation

7. Optimized Formulation

Among all formulations: F3 showed:

- Highest percentage yield
- Maximum drug content
- Best dissolution profile
- Improved solubility

Final Result:

Formulation F3 containing higher concentration of PEG 6000 was considered as optimized formulation for enhancement of solubility and dissolution rate of poorly soluble Ibuprofen.

Discussion

- The present study was carried out to develop and evaluate novel solid dispersion formulations of poorly soluble drug Ibuprofen using hydrophilic carriers such as PEG 6000 and PVP K30. The major objective of the study was to enhance aqueous solubility and dissolution rate of Ibuprofen in order to improve its oral bioavailability.
- Ibuprofen belongs to BCS Class II drugs, characterized by low solubility and high permeability. Since dissolution is the rate-limiting step in absorption of BCS Class II drugs, enhancement of dissolution rate is essential for improving therapeutic efficacy.
- Preformulation studies confirmed that Ibuprofen is poorly soluble in water but freely soluble in organic solvents such as ethanol and methanol. The observed melting point and organoleptic properties of the drug complied with standard specifications, indicating purity and suitability of the drug for formulation development.
- FTIR compatibility studies showed that characteristic peaks of Ibuprofen were retained in all formulations without significant shifting or disappearance. This confirmed absence of chemical interaction between drug and selected carriers, indicating compatibility and stability of the formulation components.

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 Solid dispersions were successfully prepared by solvent evaporation method using different drug-to-polymer ratios. The solvent evaporation method proved to be simple, economical, and reproducible for preparation of solid dispersions.
 The percentage yield of all formulations was found satisfactory, indicating efficient recovery of prepared formulations with minimal processing loss. Drug content analysis revealed uniform distribution of Ibuprofen in hydrophilic carrier matrices.
 The prepared formulations exhibited significant enhancement in aqueous solubility compared to pure drug. This improvement may be attributed to

- Reduction in particle size
- Improved wettability
- Reduction in crystallinity
- Molecular dispersion of drug in polymer matrix

 Hydrophilic carriers improved wetting of drug particles and promoted faster penetration of dissolution medium.
 The in-vitro dissolution study demonstrated that all solid dispersion formulations released drug more rapidly than pure Ibuprofen. Formulation F3 containing higher concentration of PEG 6000 showed maximum drug release within 60 minutes.

- The enhanced dissolution profile of F3 may be due to:
- Greater hydrophilic nature of PEG 6000
- Improved wettability
- Reduced aggregation of drug particles
- Increased surface area available for dissolution.

 PEG 6000 formulations showed comparatively better performance than PVP K30 formulations, indicating superior dissolution enhancement ability of PEG 6000.
 Overall, the study confirmed that solid dispersion technology is an effective approach for enhancement of solubility and dissolution characteristics of poorly soluble drugs like Ibuprofen. The improved dissolution profile obtained in the study may result in enhanced oral bioavailability and better therapeutic response.

II. CONCLUSION

 The present study successfully developed and evaluated novel solid dispersion formulations of poorly soluble drug Ibuprofen using hydrophilic carriers such as PEG 6000 and PVP K30 by solvent evaporation method.
 Preformulation studies confirmed that Ibuprofen belongs to BCS Class II category and exhibits poor aqueous solubility, which limits its dissolution rate and oral bioavailability. FTIR compatibility studies indicated absence of significant interaction between drug and selected carriers, confirming compatibility and stability of the formulations.
 The prepared solid dispersion formulations showed satisfactory percentage yield, uniform drug content, improved wettability, and enhanced aqueous solubility compared to pure Ibuprofen.
 The in-vitro dissolution studies demonstrated significant enhancement in dissolution rate of all formulations. Among the prepared formulations, formulation F3 containing higher concentration of PEG 6000 showed maximum drug release and superior dissolution characteristics.
 The enhancement in dissolution may be attributed to:

- Reduction in crystallinity
- Increased surface area
- Improved wettability
- Molecular dispersion of drug in hydrophilic carrier matrix

 The study concluded that solid dispersion technology is an effective, economical, and reproducible approach for improving solubility and dissolution rate of poorly soluble drugs like Ibuprofen.
 Therefore, the developed novel formulations may improve oral bioavailability, therapeutic efficacy, and patient compliance, making them promising alternatives for oral drug delivery of poorly soluble drugs.

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Future Scope

The present study demonstrated successful enhancement of solubility and dissolution rate of poorly soluble Ibuprofen using solid dispersion technology. Although promising results were obtained, further research and development can be carried out to improve formulation performance and industrial applicability.

Future scope of the study includes

 Scaleup Studies:

The optimized formulation can be scaled up for large-scale industrial manufacturing to evaluate commercial feasibility and production efficiency.

 Stability Studies:

 Long-term and accelerated stability studies can be performed according to ICH guidelines to determine shelf life and storage conditions of the formulation.

 In-vivo Bioavailability Studies

 Animal and human studies can be conducted to evaluate actual enhancement in oral bioavailability and therapeutic efficacy.

 Advanced Characterization Studies

 Additional analytical techniques such as:

 DSC (Differential Scanning Calorimetry)

 XRD (X-ray Diffraction)

 SEM (Scanning Electron Microscopy)

 can be performed for detailed characterization of solid dispersion systems.

 Use of Novel Carriers

 New hydrophilic polymers and surfactants may be explored to achieve greater solubility enhancement and stability.

 Development of Different Dosage Forms

 The optimized solid dispersion can be incorporated into:

 Tablets

 Capsules

 Fast dissolving formulations

 Sustained release systems

 Application to Other Poorly Soluble Drugs

 The same formulation approach can be applied to other BCS Class II and Class IV drugs with poor aqueous solubility.

 Nanotechnology-Based Approaches

 Combination of solid dispersion with nanotechnology may further improve dissolution rate and drug absorption.

 Patent and Commercial Development

 The optimized formulation may be explored for patent filing and future pharmaceutical commercialization.

 Improvement in Patient Compliance

 Future formulations with faster onset of action and improved therapeutic response may provide better patient compliance and treatment outcomes.

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