IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 6, October 2026
Impact Factor: 8.2

Breaking the Solubility Barrier: Design and Evaluation of Solid Dispersion Systems

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Abstract: *Solubility is an important factor that affects the dissolution and oral bioavailability of a drug. Many drugs belong to Biopharmaceutical Classification System (BCS) Class II and Class IV, which exhibit poor aqueous solubility and may show limited absorption in the body. The extent of the problem depends not only on equilibrium solubility, but also on dissolution rate, permeability, dose, Sthe pharmaceutical importance of solubility enhancement and discusses major approaches, including particle-size reduction, pH adjustment and salt formation, cosolvency, surfactants and micellar systems, cyclodextrin complexation, cocrystals, lipid-based formulations, nanotechnology and solid dispersions. The review gives particular attention to solid dispersions, including their mechanisms, carrier selection, classification, preparation methods, evaluation and stability challenges. It also highlights the role of solid dispersion in improving drug dissolution and the potential oral bioavailability of poorly soluble drugs. Overall, solid dispersion is a valuable formulation approach for developing drug products with improved dissolution characteristics and better therapeutic potential*

Keywords: Poorly soluble drugs, solubility enhancement, solid dispersion, hydrophilic carriers, dissolution rate, bioavailability

I. INTRODUCTION

Solubility is the amount of a substance that can dissolve in a specified solvent under defined conditions of temperature and pressure to form a saturated solution. In pharmaceutics, aqueous solubility is important because a drug administered orally generally must dissolve in gastrointestinal fluid before it can be absorbed. However, solubility is only one determinant of oral drug absorption; dissolution rate, intestinal permeability, dose, precipitation, transit time and formulation properties also influence performance [1–4]. Poorly water-soluble compounds can show slow or incomplete dissolution, variable absorption and difficulty achieving reproducible exposure. These challenges may affect both new drug development and reformulation of existing medicines.

According to the United States Pharmacopeia (USP), the approximate solubility of pharmaceutical substances is expressed using descriptive terms based on the number of parts of solvent required to dissolve one part of solute. These terms include very soluble, freely soluble, soluble, sparingly soluble, slightly soluble, very slightly soluble, and practically insoluble.

This classification helps describe the solubility characteristics of pharmaceutical substances. Poor aqueous solubility is an important challenge in drug formulation because it may limit drug dissolution and oral absorption. Therefore, techniques such as solid dispersion are investigated to improve the solubility and dissolution rate of poorly water-soluble drugs. The Biopharmaceutics Classification System (BCS) provides a useful framework for considering solubility alongside permeability; drugs with low solubility may require formulation strategies that improve dissolution or maintain drug in a dissolved or supersaturated state.

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www.ijarsct.co.in
DOI: 10.48175/IJARSCT-40373

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Standard USP Solubility Scale

(As per United States Pharmacopeia)

Grade	Description	Approximate Amount of Solvent (mL per 1 g of Solute)	
1 (Very soluble)	Soluble – the substance dissolves in less than 1 part of solvent.	< 1 mL	
2 (Freely soluble)	Soluble – the substance dissolves in 1 to 10 parts of solvent.	1 – 10 mL	
3 (Soluble)	Soluble – the substance dissolves in 10 to 30 parts of solvent.	10 – 30 mL	
4 (Sparingly soluble)	Slightly soluble – the substance dissolves in 30 to 100 parts of solvent.	30 – 100 mL	
5 (Very slightly soluble)	Very slightly soluble – the substance dissolves in 100 to 1,000 parts of solvent.	100 – 1,000 mL	
6 (Practically insoluble)	Practically insoluble – the substance dissolves in more than 1,000 parts of solvent.	> 1,000 mL	

Summary of BCS Classification

Class	Solubility	Permeability	Absorption	Example
I	High	High	High	Paracetamol
II	Low	High	Variable (depends on solubility)	Ibuprofen
III	High	Low	Variable (depends on permeability)	Ranitidine
IV	Low	Low	Low	Carbamazepine

AIM

Formulation and Evaluation of Solid Dispersion for Solubility Enhancement of Poorly Water-Soluble Drugs.

OBJECTIVE

- To describe the solvent evaporation method and its general preparation procedure
- To review different carriers and preparation methods used in solid dispersion technology.
- To understand how improved solubility and dissolution can contribute to better drug absorption and bioavailability.
- To study the importance of solubility enhancement of poorly water-soluble drugs.
- To review solid dispersion as a technique for improving drug solubility and dissolution rate.

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Plan of Work

Literature Review
↓
Selection of Drug and Carrier
↓
Pre-formulation Studies
↓
Preparation of Solid Dispersion
↓
Formulation Development Using Different Drug-to-Carrier Ratios
↓
Evaluation of Prepared Formulations
↓
Solubility and Dissolution Comparison with Pure Drug
↓
Data Analysis and Interpretation
↓
Conclusion and Report Preparation

MATERIAL AND METHOD

SOLUBILITY ENHANCEMENT

Solubility enhancement is an important approach in pharmaceutical formulation used to improve the solubility and dissolution rate of poorly water-soluble drugs. Many drugs show low aqueous solubility, which can limit their dissolution and absorption after oral administration, potentially resulting in reduced bioavailability.

Significance of Solubility Enhancement:-

1. Improves Drug Solubility
2. Increases Dissolution Rate
3. Enhances Bioavailability
4. Improves Therapeutic Effectiveness
5. Reduces Variability in Drug Absorption
6. Supports Oral Drug Delivery
7. Improves Drug Formulation
8. Provides an Effective Formulation Approach
9. May Improve Patient Compliance
10. Supports Pharmaceutical Research

Various techniques, such as particle size reduction, salt formation, surfactant addition, complexation, and solid dispersion, are used to overcome these limitations. Among these techniques, solid dispersion is widely investigated because it can improve drug wettability, reduce crystallinity, and enhance the dissolution rate by dispersing the drug in a suitable carrier. Thus, solubility enhancement plays an important role in developing effective and reliable pharmaceutical formulations.

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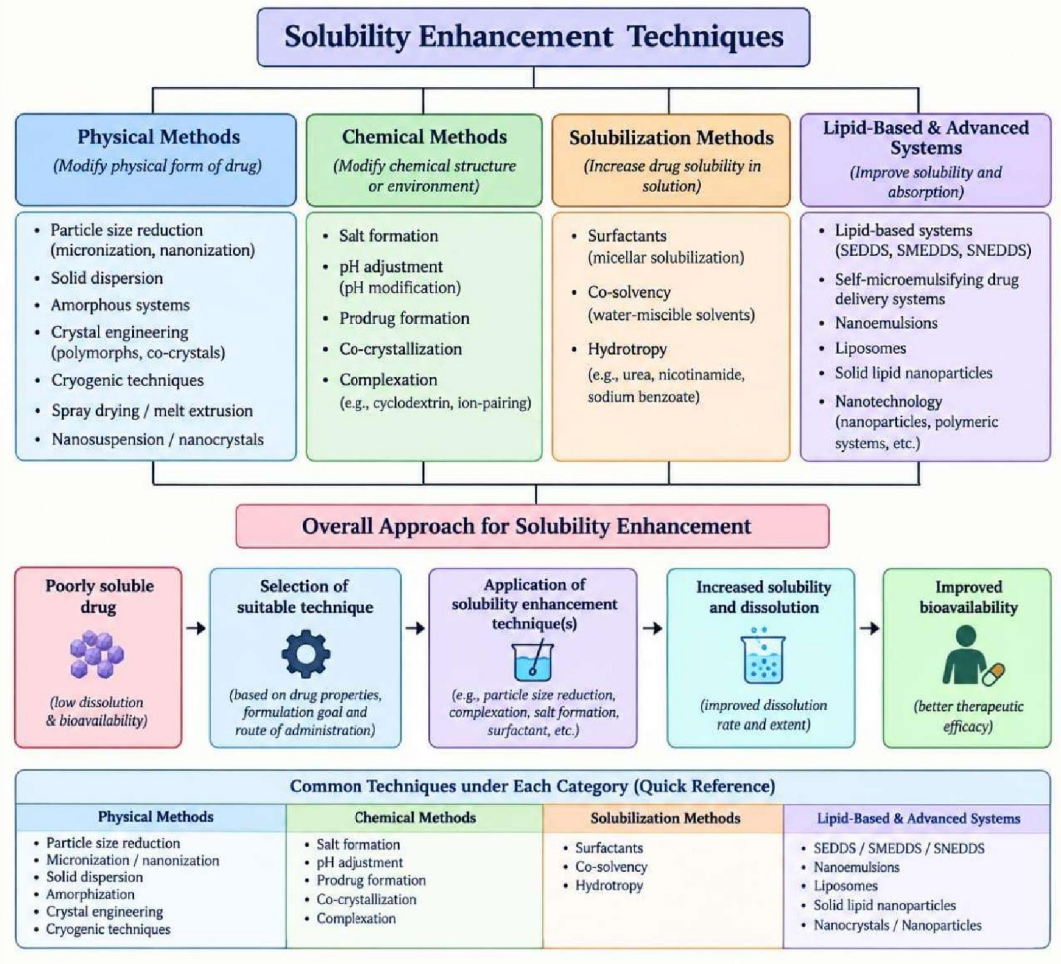
TECHNIQUES OF SOLUBILITY ENHANCEMENT



SOLID DISPERSION: DEFINITION AND CONCEPT

Solid dispersion is a system in which one or more active pharmaceutical ingredients are dispersed in an inert or suitable carrier in the solid state.

The drug may exist as crystalline particles, amorphous material or a combination of physical states, depending on the formulation and preparation process.

In a typical formulation, the drug is combined with a hydrophilic carrier. When the formulation contacts water, the carrier may improve wetting and help distribute the drug throughout the dissolution medium.

Types of solid dispersion

First-generation solid dispersions: These commonly use crystalline carriers, such as urea, and may contain the drug in a crystalline state.

Second-generation solid dispersions: These use polymeric carriers, including PVP and PEG, and may contain the drug in a molecularly dispersed or amorphous state.

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Third-generation solid dispersions: These may incorporate surfactants or other functional excipients to improve wetting, solubilization or dissolution performance.

This classification is a simplified historical description. Actual solid dispersions vary in composition, drug physical state and performance.

MECHANISM OF SOLUBILITY AND DISSOLUTION ENHANCEMENT

Solid dispersion may improve drug dissolution through several mechanisms.

Improved wettability

Hydrophilic carriers can improve contact between the drug and water. Better wetting may allow water to penetrate the formulation more effectively.

Reduction in effective particle size

When the drug is dispersed within a carrier, the effective size of drug-rich domains may be smaller than that of the original drug particles. This can increase the surface area available for dissolution.

Reduction in crystallinity

Some preparation methods reduce the crystalline order of the drug and may produce an amorphous form. Amorphous material has a different energetic state from the corresponding crystalline material and may show improved apparent solubility or dissolution.

Molecular dispersion

The drug may be distributed at a molecular level within the carrier. This can reduce the presence of large crystalline drug particles and promote dissolution.

Supersaturation and precipitation inhibition

Some polymers help maintain a temporarily elevated dissolved drug concentration by slowing precipitation or crystallization. The extent of this effect depends on the drug, polymer and dissolution conditions.

These mechanisms may operate together, but they do not occur in every solid dispersion. Improved dissolution must be confirmed experimentally.

CARRIERS USED IN SOLID DISPERSION

Carrier selection is an important part of formulation development. A suitable carrier should have appropriate compatibility with the drug, acceptable pharmaceutical quality, suitable processing characteristics and adequate stability.

Carrier	Main characteristics	Potential role
PVP K30	Water-soluble polymer	Supports drug dispersion and may inhibit recrystallization
PEG 6000	Hydrophilic polymer	May improve wetting and dissolution
HPMC	Hydrophilic cellulose derivative	Can support dispersion and inhibit precipitation
Poloxamer 188	Non-ionic surfactant	Can improve wetting and solubilization
Soluplus	Amphiphilic polymeric excipient	Used in selected amorphous solid dispersion systems

The carrier should be selected after considering drug solubility, drug–polymer interactions, glass-transition behaviour where relevant, processing conditions and physical stability.

No carrier is universally best for all poorly water-soluble drugs.

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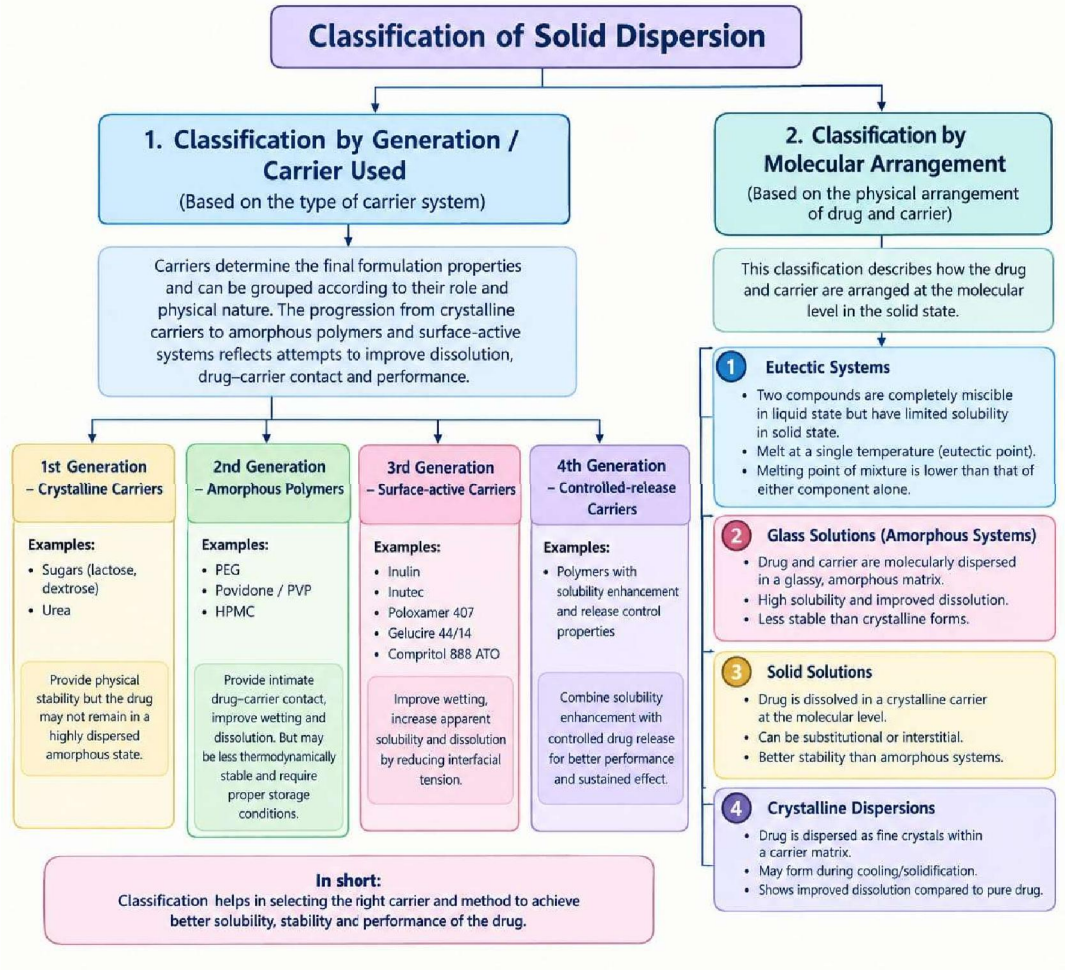
Classification

Solid dispersions may be described by the physical arrangement of drug and carrier (for example, eutectic mixtures, crystalline solid solutions, amorphous solid solutions, glass solutions or glass suspensions) or by the carrier system used.



ADVANTAGES OF SOLID DISPERSION

Solid dispersion is an effective formulation approach for improving the pharmaceutical performance of poorly water-soluble drugs.

The major advantages are as follows:

• Enhancement of Solubility
• Improvement in Dissolution Rate
• Increase in Surface Area
• Improvement in Wetting
• Reduction in Particle Size

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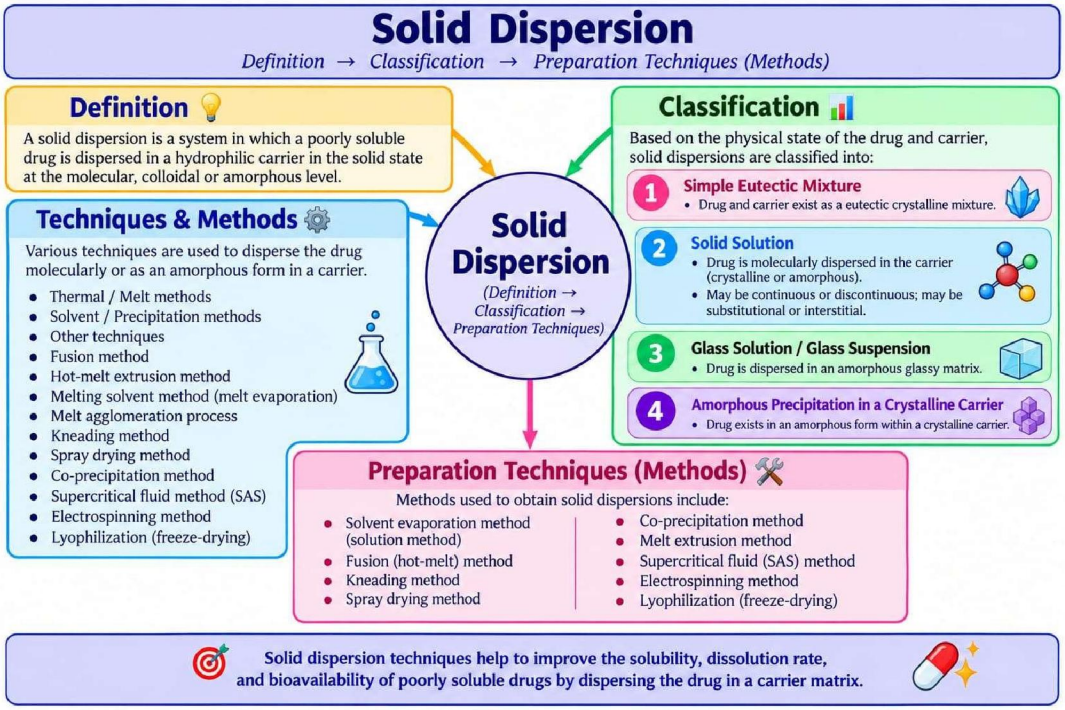
DISADVANTAGES OF SOLID DISPERSION

Despite its advantages, solid dispersion also has certain limitations that should be considered during formulation development.

- Physical Instability
- Moisture Sensitivity
- Difficulty in Maintaining Amorphous State
- Limited Physical Stability During Storage
- Carrier-Related Problems
- Difficulty in Scale-Up
- Processing Challenges

SOLID DISPERSION — METHODS, CLASSIFICATION & PREPARATION



Solvent Evaporation Method: Technique And Procedure Principle

The drug and a suitable hydrophilic carrier are dissolved in an appropriate solvent or solvent system. The solvent is then removed, leaving a solid material in which the drug is dispersed throughout the carrier.

A rotary evaporator can help remove the solvent under reduced pressure. The product is subsequently dried, collected and processed into a suitable powder.

Preparation flowchart

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Selection of drug and polymer
Dissolution in a suitable common solvent
Mixing to obtain a uniform solution
Solvent removal by evaporation
Further drying and powder processing
Solid dispersion ready for evaluation

II. CONCLUSION

Solubility is an important factor that affects the dissolution and absorption of a drug in the body. Poor water solubility can reduce the effectiveness of many drugs when taken orally. Solid dispersion is a useful approach to overcome this problem by improving the solubility and dissolution rate of poorly water-soluble drugs.

Among the different methods used for preparing solid dispersions, the solvent evaporation method is a suitable technique because it is simple and can be carried out using appropriate drug and carrier materials. The selection of a suitable carrier and the proper preparation conditions are important for obtaining a good-quality solid dispersion. Various evaluation tests can be performed to study the properties and performance of the prepared formulation.

Overall, solid dispersion has the potential to improve the dissolution and oral absorption of poorly water-soluble drugs. Further formulation studies and evaluation are required to identify suitable drug–carrier combinations and obtain stable and effective formulations.

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