

SOLID DISPERSIONS: A COMPREHENSIVE REVIEW OF SOLUBILITY ENHANCEMENT STRATEGIES FOR POORLY WATER-SOLUBLE DRUGS

Krishan Pal Singh Lodhi, Reena Shende*, Satkar Prasad, Shailesh Kumar Ghatuwar

RKDF School of Pharmaceutical Sciences, BHABHA University, Bhopal (M.P.)

*Corresponding Author's E mail: emi.89ryadav@gmail.com

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ABSTRACT

Solid dispersions have garnered substantial attention as a promising strategy to enhance the dissolution rate and, consequently, the bioavailability of poorly water-soluble drugs. By dispersing such drugs in water-soluble carriers, solid dispersion systems have effectively minimized solubility-related limitations and improved drug release profiles. This solubilization technique primarily focuses on binary drug-polymer systems, where efficient drug dispersion and stabilization are crucial for successful formulation development. As a result, solid dispersion has emerged as a valuable tool for enhancing the performance of low-solubility compounds. Although considerable research advancements have been made in understanding solid dispersion systems, their widespread commercial application remains limited. This review highlights key aspects such as drug solubility, Biopharmaceutics Classification System (BCS) categorization, and the role of carriers. It also discusses various preparation methods, recent technological developments, and types of solid dispersions categorized by carrier type and molecular arrangement. Furthermore, the article outlines the mechanisms, formulation techniques, and currently marketed products developed using solid dispersion technologies.

Keywords: Solubilization; Dissolution; Solubility; Biopharmaceutics; Enhancement.

INTRODUCTION

The oral route is the most convenience route for drug administration and mode of delivery¹. From the patient's standpoint, swallowing and medication is a comfortable and familiar method of taking medication. As a result, orally delivered drugs are often more effective than alternative modes of administration, such as parenteral, in terms of patient compliance and drug treatment. When an active substance is given orally, it must first dissolve in the stomach and/or intestinal fluids before it can pass through the GI tract's membranes and reach systemic circulation². & therefore, water solubility and/or membrane permeability of the drug molecule are significant contributors to drug absorption from the gastrointestinal (GI) tract, which causes low medication bioavailability of the medications. Consequently, a drug with weak aqueous solubility usually shows a dissolution rate of limited

absorption, while a drug with weak membrane permeability usually shows a permeation rate of limited absorption³. In Pharmaceutical the oral bioavailability can be improved by two main strategies enhancing the solubility and dissolution rate of poorly water-soluble drugs and improving the membrane permeability of poorly permeable drugs⁴. Several techniques—such as salt formation, cyclodextrin complexation, solvent solubilization, and particle size reduction—have been employed to enhance drug solubility. However, these methods often face drawbacks like low yield, high cost, and limited improvement in solubility⁵. In contrast, solid dispersion technology offers a more versatile solution by enabling diverse formulation options for poorly soluble drugs⁶. It is especially beneficial for BCS Class II drugs, which are characterized by poor water solubility but high permeability—where dissolution is the rate-limiting step for absorption⁷. Considering that 40% of newly discovered chemical entities are water-insoluble⁸, addressing solubility challenges is critical to unlocking their therapeutic potential⁹. Solid dispersions, defined as the dispersion of hydrophobic drugs in hydrophilic carriers via fusion, solvent evaporation, or melting-solvent methods, are among the most promising approaches to enhance solubility and bioavailability³.

Solubility

At a specific temperature and pressure, the solubility of a substance represents the quantity that dissolves in a solution when equilibrium is established between the dissolved portion and any undissolved excess. The dissolved component is termed the "solute," the liquid medium in which it dissolves is called the "solvent," and their combination is known as the "solution"¹⁰. Table 1 provides definitions for key solubility-related terms.

Table 1: Key solubility terms

Solubility Category	Approximate Amount of Solvent per Part of Solute	Concentration Range (mg/mL)	Representative Solubility Value (mg/mL)
Very soluble	Less than 1 part	More than 1000	1000
Freely soluble	Between 1 and 10 parts	100–1000	100
Soluble	Between 10 and 30 parts	33–100	33
Sparingly soluble	Between 30 and 100 parts	10–33	10
Slightly soluble	Between 100 and 1000 parts	1–10	1
Very slightly soluble	Between 1000 and 10000 parts	0.1–1	0.1
Practically insoluble	More than 10000 parts	Less than 0.1	0.01

Biopharmaceutical Classification System (BCS)

Developed by Amidon *et al.* in 1995, the **BCS** classifies drugs based on their aqueous solubility and intestinal permeability into four categories (see Table 2)⁷. For **BCS Class II drugs**—characterized by low solubility and high permeability—improving solubility and dissolution in GI fluids is key to enhancing oral bioavailability^{11,12}.

The **WHO model list of essential medicines** applies BCS classification based on available data. Among 130 orally administered drugs, only 61 were classifiable: 84% were Class I, 17% Class II, 49% Class III, and 10% Class IV¹⁰.

Table 2: Drugs classification as per the BCS system

BCS Class	Drug Permeability	Drug Solubility
Class I	High	High
Class II	High	Low
Class III	Low	High
Class IV	Low	Low

Mechanisms of Solubilization via Solid Dispersion

Solid dispersions enhance drug solubility by dispersing poorly soluble drugs in hydrophilic polymer carriers, eliminating crystallinity and forming molecular dispersions¹³. Upon contact with aqueous media, the carrier dissolves, releasing the drug as fine particles, thereby increasing surface area and dissolution rate. Surfactants are often added to prevent drug recrystallization and further improve solubility, although challenges such as thermodynamic instability persist¹⁴. Solid dispersion techniques serve several pharmaceutical purposes, including:

- (i) enhancing drug solubility,
- (ii) improving drug stability,
- (iii) masking unpleasant drug taste, and
- (iv) achieving desired release profiles.

Types of Solid Dispersions

Solid dispersions are classified based on the carrier used or their molecular arrangement, as outlined below. Figure 1 illustrates the various types of solid dispersions.

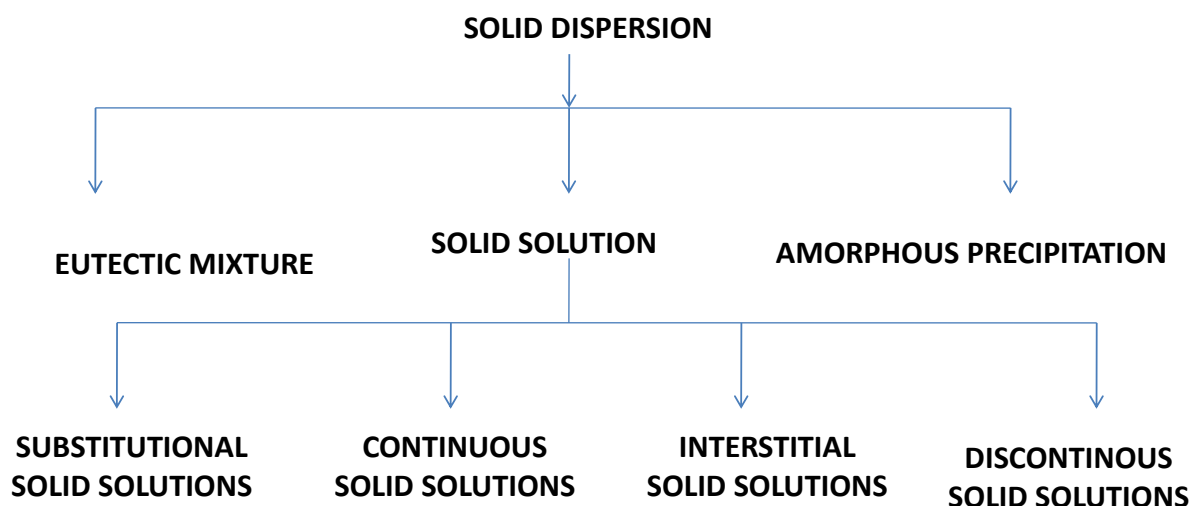


Fig.1: Types of solid dispersion

Classification Based on Carrier Type

Based on the carrier solid dispersions are categorized into four generations¹⁵.

First Generation: These employ crystalline carriers, such as urea or sugars, and were the earliest used in solid dispersions¹⁶. Their crystalline nature makes them thermodynamically stable, but this limits drug release compared to amorphous forms¹⁷.

Second Generation: These utilize amorphous carriers, typically polymers¹⁸. Synthetic polymers include polyethylene glycols (PEG), povidone, polyvinylpyrrolidone, and polymethacrylates, while natural polymers include ethyl cellulose, hydroxypropyl methylcellulose (HPMC), and starch derivatives like cyclodextrins or hydroxypropyl cellulose¹⁹.

Third Generation: These incorporate carriers with surface-active properties, improving dissolution profiles. Examples include poloxamer 407, compritol 888 ATO, inutec SP1, gelucire 44/14, and inulin, which enhance polymorphic purity and in vivo bioavailability²⁰.

Fourth Generation: Known as controlled-release solid dispersions, these target poorly water-soluble drugs with short biological half-lives. They use water-soluble carriers (e.g., ethyl cellulose, Eudragit, hydroxypropyl cellulose) or water-insoluble carriers to achieve enhanced solubility and sustained drug release²¹.

Classification Based on Molecular Arrangement

Solid dispersions are also classified by their molecular structure, as depicted in Figure 2²²

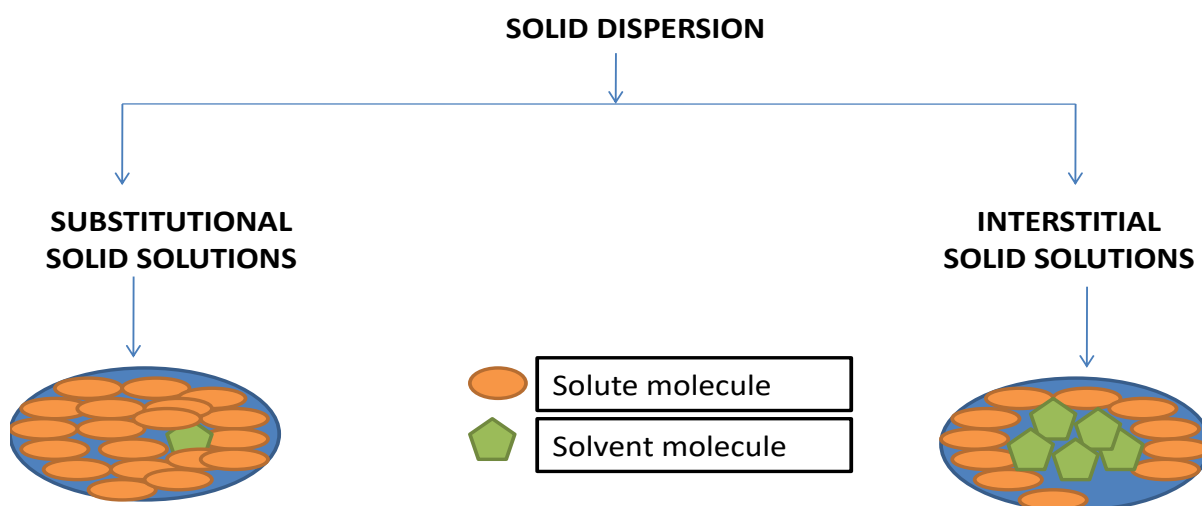


Fig 2: Solid Dispersion on the basis of molecular arrangement

Eutectic Systems

Eutectic mixtures consist of two compounds that are fully miscible in the liquid state but exhibit limited solubility in the solid state. Rapid solidification of their molten mixture yields a product with high liquid miscibility but minimal solid-solid solubility. This results in a physically intimate mixture of two crystalline phases²³.

Glass Solutions and Suspensions

A glass solution is a homogeneous amorphous system where a solute is molecularly dispersed in a glassy carrier. In contrast, glass suspensions contain precipitated particles suspended in a glassy matrix. These systems have low lattice energy and lack a sharp melting point. Common carriers include urea, citric acid, polyethylene glycol, polyvinylpyrrolidone, and sugars like dextrose, sucrose, or galactose²³.

Solid Solutions

Solid solutions form when two components co-crystallize into a single homogeneous phase, reducing the drug's particle size to the molecular level, which enhances dissolution compared to eutectic mixtures. They are classified based on miscibility or molecular distribution²³:

- a. Continuous Solid Solutions:** The components are miscible in all proportions, implying stronger intermolecular bonding between components than within individual components. Such systems are rare in pharmaceuticals²⁴.
- b. Discontinuous Solid Solutions:** Miscibility between components is limited²⁴.
- c. Substitutional Solid Solutions:** These form when solute molecules replace solvent molecules in the crystal lattice, requiring solute molecules to be within ~15% of the solvent molecule size²⁵.

d. Interstitial Solid Solutions: Solute molecules occupy interstitial spaces in the solvent's crystal lattice, requiring a solute molecule diameter less than 0.59 times that of the solvent²⁵.

Amorphous Precipitation in a Crystalline Matrix

In this system, the drug precipitates in an amorphous form within a crystalline carrier, rather than co-crystallizing as in eutectic systems. The high-energy amorphous state of the drug results in rapid dissolution rates²⁵.

Methods of Preparation

Numerous techniques are available for formulating solid dispersions, as outlined in Figure 3. There is no universally optimal method for enhancing the solubility of poorly water-soluble drugs; the ideal method depends on the drug's molecular characteristics, dosage, and polarity. Therefore, trial-and-error remains the most practical strategy for selecting the appropriate method.

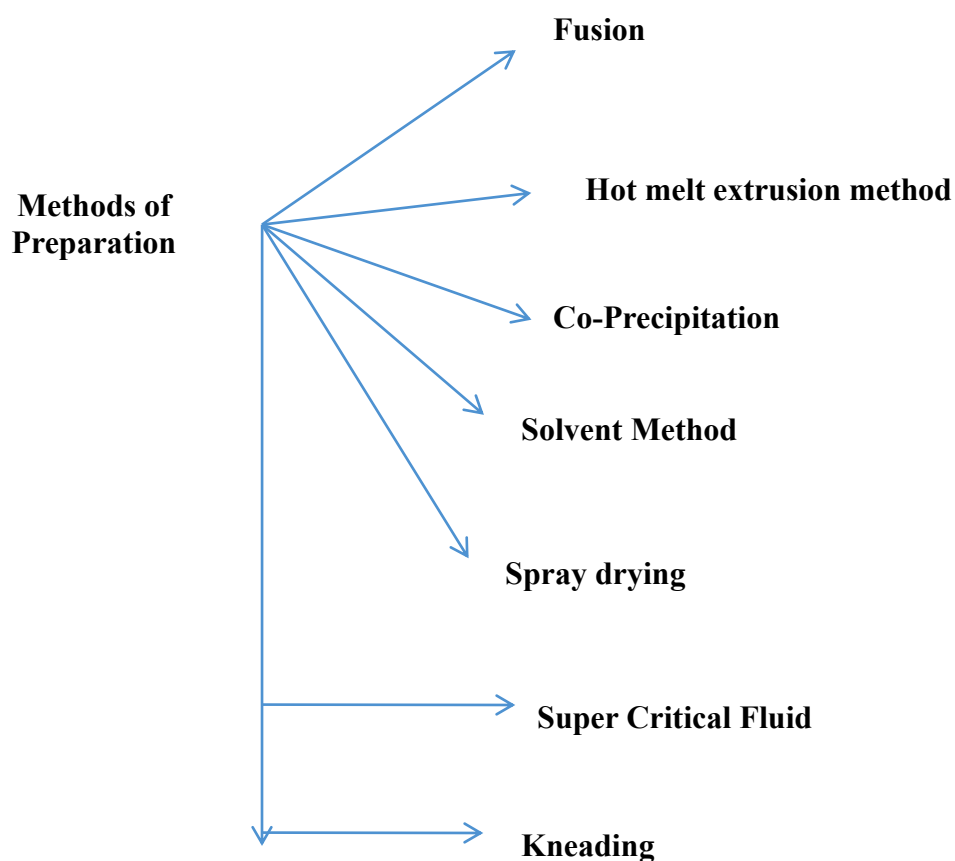


Fig 3: Methods of preparation of solid dispersion

Fusion Method

Originally introduced by Sekiguchi and Obi in 1961, the fusion (or melt) method involves heating a physical blend of drug and polymer until a homogeneous molten mixture is obtained. This is then stirred, solidified, pulverized, and sieved. Despite its efficiency, this technique presents several

challenges, such as poor miscibility between drug and polymer at high temperatures. The thermal stability of both components is crucial, and lower processing temperatures are often favored. Surfactants may help overcome miscibility issues. The final product must also resist recrystallization and phase separation¹¹.

Hot-Melt Extrusion (HME)

This method is a modern enhancement of the fusion technique. Here, a mechanical extruder ensures intensive mixing of the components under heat and pressure. HME enables the formation of various dosage forms like pellets, implants, and tablets⁴. It requires full miscibility of drug and polymer in the molten state, which can be predicted using solubility parameter diagrams¹¹.

Advantages include:

1. Fewer processing steps due to the absence of drying or compression
2. Enhanced dispersion and particle size reduction due to high shear forces
3. Suitability for continuous, large-scale manufacturing

Commonly used polymers include HPMC, HPMCAS, PVP, vinyl acetate, and polyethylene oxide⁴. HME has proven effective in improving the delivery of previously unviable drugs. For example, paracetamol and NSAIDs have been successfully formulated using HME, leading to faster drug release. A formulation using 15% polyethylene glycol released over 80% of paracetamol in 30 minutes^{36,27}.

Coprecipitation (Coevaporation) Method

This approach involves dissolving the carrier in water and the drug in an organic solvent. Once both are dissolved, the aqueous solution is mixed with the drug solution, and the solvents are evaporated. The resulting solid is dried, ground, and sieved²⁸.

Solvent Evaporation Method

This method dissolves both the drug and polymer in a common solvent, which is then evaporated to produce a solid dispersion²⁸. The primary benefit is the avoidance of thermal degradation. However, challenges include finding a single solvent suitable for both components and avoiding phase separation during drying^{29,30}. Surfactants may be used but can reduce drug loading. This technique can be costly due to solvent removal requirements. A study using furosemide found that the solvent

evaporation method outperformed kneading, coprecipitation, and physical mixtures in improving solubility³¹.

Spray Drying

Spray drying converts a solution or suspension into a dry powder in a single step. Rapid solvent evaporation during this process increases viscosity, trapping the drug in the polymer matrix. This technique can yield particles in amorphous or crystalline forms, depending on the drug's properties^{32,33}. For example, spray-dried lovastatin using modified locust bean gum showed improved solubility and dissolution. The method enhanced wettability and reduced particle size.

Supercritical Fluid Method

This method uses supercritical CO₂, which behaves like both a liquid and a gas, to dissolve drug and polymer. The solution is rapidly expanded through a nozzle, forming fine particles. This environmentally friendly approach avoids organic solvents, and residual CO₂ poses no harm^{34–36}. However, most drugs have limited solubility in CO₂, which limits this method's utility. In one study, drugs like lidocaine and benzoic acid were processed using this method, and particle size was found to correlate inversely with drug solubility in CO₂^{37,38}.

Kneading Method

This technique involves mixing the drug and carrier with minimal solvent, then triturating to form a paste. This kneading reduces particle size and enhances solubility and bioavailability. The mixture is then dried and sieved³⁹. Numerous studies have shown improved solubility using this method. For example, kneaded inclusion complexes of satranidazole and cyclodextrin significantly increased solubility^{40,41}. Azithromycin and etoricoxib also showed improved dissolution using this method^{42–45}.

Electrospinning Method

Combining nanotechnology with solid dispersion, this method creates nanofibers by applying a high voltage to a drug/polymer solution. These fibers, typically submicron in diameter, are collected as the solvent evaporates⁴⁶. This simple, low-cost approach is ideal for developing controlled-release systems. Ketoprofen and PVA fibers made using electrospinning demonstrated significantly enhanced dissolution rates. Similarly, indomethacin and griseofulvin dispersed with PVP remained stable for eight months⁴⁷.

Drawbacks of Solid Dispersions

Despite their advantages, solid dispersions face several limitations¹⁸:

- i. High cost and complexity of preparation
- ii. Difficulty in reproducing physicochemical properties
- iii. Challenges integrating into final dosage forms
- iv. Scale-up and manufacturing complications
- v. Stability concerns regarding drugs and solvents

Conclusion

Oral drug delivery remains the most widely used method due to ease of administration and patient compliance. Solid dispersion techniques offer significant promise in overcoming solubility-related challenges in oral formulations. However, selecting the optimal preparation method requires a comprehensive understanding of drug properties and processing conditions.

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