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SOLID DISPERSIONS: A Comprehensive Review on Formulation Approaches, Carriers, and Applications in Solubility Enhancement

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ABSTRACT

Poor aqueous solubility continues to pose a significant challenge in the development of effective oral drug delivery systems, particularly for drugs belonging to Biopharmaceutics Classification System (BCS) classes II and IV, which are characterized by low solubility and often variable absorption. Enhancing the solubility and dissolution rate of such compounds is essential for improving their therapeutic performance and ensuring consistent bioavailability. Among the various formulation approaches explored, solid dispersion technology has gained considerable attention as one of the most promising and versatile strategies for addressing solubility-related limitations.

Solid dispersions consist of a poorly soluble active pharmaceutical ingredient molecularly dispersed or finely distributed within a hydrophilic carrier matrix. This system enhances drug dissolution by promoting improved wettability, reducing particle size to the molecular or colloidal level, and transforming the drug from a crystalline to an amorphous state. Over the years, advancements in materials science and processing techniques have led to the evolution of first-, second-, and third-generation solid dispersions, each offering improved stability, formulation flexibility, and performance.

This review provides a comprehensive discussion on the principles and mechanisms underlying solubility enhancement through solid dispersions, along with detailed insights into carrier selection, preparation methods, and characterization techniques. Furthermore, the applications, current challenges, and limitations associated with solid dispersion systems are explored. Finally, emerging trends and future prospects are highlighted, emphasizing the potential of novel carriers, advanced manufacturing technologies, and improved stabilization strategies to further expand the utility of solid dispersions in modern drug delivery.

KEYWORDS: Solid dispersions, solubility, hydrophilic carriers, dissolution rate, bioavailability

I. INTRODUCTION

The increasing number of poorly water-soluble drug candidates presents significant challenge in the development of effective oral formulations. Nearly 40% of marketed drugs and 60% of compounds under development exhibit low aqueous solubility, limiting dissolution and bioavailability. Solid dispersion technology offers a reliable approach for overcoming this issue by incorporating drugs into hydrophilic polymer matrices, thus enhancing dissolution performance. Solid dispersions involve molecular mixing of drug and carrier, amorphization, improved wettability, and inhibition of recrystallization.

SOLID DISPERSION

There are various techniques for solubility enhancement. Solid dispersion is the most preferred strategy adopted for solubility enhancement. The term solid dispersion refers to a groupof solid products consisting of at least two different components, generally a hydrophilic matrix and a hydrophobic drug. The matrix can be either crystalline or amorphous; amorphous has more solubility than crystalline substances because no energy is required to break up the crystal lattice of a drug during the dissolution process. Drug solubility and wettability may be increased by surrounding hydrophilic carriers.

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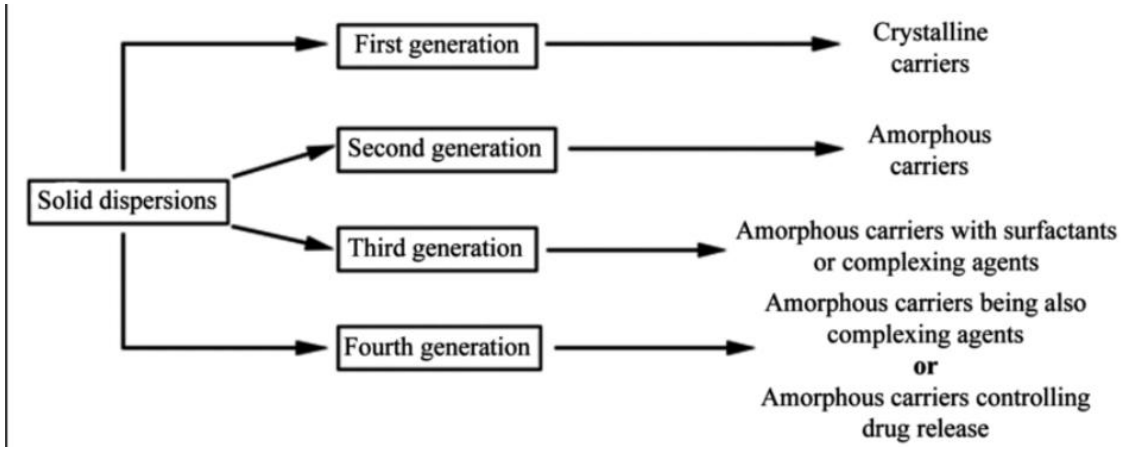
EVOLUTION OF SOLID DISPERSION TECHNOLOGY



a) First Generation Solid Dispersions[1,2]

In this generation, both the drug and carrier exist in a crystalline state. Carriers mainly act as diluents to reduce drug particle size and improve wettability. However, due to crystallinity, dissolution enhancement is limited.

The main disadvantage of first-generation Solid dispersion is crystalline nature which leads to less solubility as compare to amorphous form, however, they possess good thermodynamic stability.

First generation solid dispersionwere generally prepared using crystalline carriers like urea, mannitol, sorbitol, citric acid.

b) Second Generation Solid Dispersions

In second generation instead of crystalline carriers, amorphous carriers were used to disperse drugs which are generally polymers. Polymeric carriers can be of fully synthetic origin like povidone, polyethylene glycols and polymethacrylates whereas natural product-based polymers comprise of cellulose derivatives like hydroxypropyl methylcellulose, ethyl cellulose or starch derivatives, like cyclodextrins.

Amorphous solid dispersions are further classified as solid solutions, solid suspension or mixture of both as per molecular interaction of drug and carrier.

Amorphous carriers: Polyethylene glycol, Povidone, Polyvinyl acetate, Polymethacrylate,cellulose derivatives.

c) Third Generation Solid Dispersions

In third-generation solid dispersion surfactants carrier or mixture of polymer are used as carrier. If carrier has surface active or self-emulsifying properties, the dissolution profile of poorly soluble drug can be improved and hence result in increased bioavailability, better dissolution and enhanced stability.

Typically used surfactants as solid dispersion carriers are Polaxamer407/188, Gelucire44/14, Compritol888 ATO27,Tween 80, Sodium lauryl sulfate (SLS), Inulin.

d) Fourth Generation Solid Dispersions(Controlled-release SDs)

These are designed to improve solubility while controlling drug release, avoiding burst release and maintaining therapeutic levels thereby Improving solubility and controlled release behavior.

Common carriers:Ethyl cellulose, Eudragit RS/RL, Cellulose acetate phthalate, Sustained-release polymers

II. METHODS OF PREPARATION

Common Methods Used for Preparation of Solid Dispersion[3,4]

1. Kneading technique[5]

In this method, the carrier is permeated with water and transformed into a paste. The drug is then added and kneaded for a particular time. The kneaded mixture is then dried and passed through a sieve if necessary, this improves drug–carrier interaction by mechanical energy.This technique isSimple, uses minimal solvent and economical.

Limitations: Less uniform than solvent evaporation, limited dissolution enhancement.

2. Lyophilization

It is an alternative technique to solvent evaporation in which the molecular mixture technique is used where the drug and carrier are dissolved in a common solvent, frozen, and sublimed leads to Formation of porous, amorphous solid dispersions. This technique is advantageous forexcellent

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dissolution improvement and suitable for thermolabile drugs
Limitations: Time-consuming, High operational cost

3. Melt Agglomeration technique

Melt agglomeration is a solvent-free technique used to prepare solid dispersions and granules by using a molten binder (carrier) to agglomerate drug particles. The molten carrier coats and binds the drug, forming granules or pellets with improved wettability and dissolution.This technique combines the advantages of granulation and solid dispersion in a single step.

Advantages: Solvent-free and eco-friendly,combines granulation + solid dispersion, Improved flow and compressibility, Suitable for scale-up, Enhances dissolution and bioavailability.

Limitations: Not suitable for heat-sensitive drugs, Risk of drug degradation at high temperature, Requires careful temperature control.

4. Electrospinning method

Electrospinning is an advanced technique used to prepare nanofibrous solid dispersions of poorly soluble drugs. The method uses a high-voltage electric field to produce ultra-fine polymer fibers containing the drug in an amorphous state. Because the fibers have very highsurface area and porosity, they show extremely rapid dissolution.Itraconazole/HPMC has been prepared using this technique.

Advantages: Produces nanofibers with huge surface area, Very rapid dissolution and drug release, High drug loading possible, Suitable for thermolabile drugs, Prevents drug recrystallization

Limitations: Limited large-scale production, Requires high voltage equipment, Solvent handling needed.

5. Melting method(Fusion Method)[5,6]

The melting (fusion) method is one of the **oldest and simplest techniques** used to prepare solid dispersions. In this method, the drug is dispersed in a molten carrier and the mixture is rapidly cooled to obtain a solid mass in which the drug is molecularly or finely dispersed. It is crushed and sieved.

Advantages: Simple and economical, No solvent required, Easy to perform at laboratory scale, Suitable for large-scale production.

Limitations: Not suitable for heat-sensitive drugs, Risk of drug degradation,Possibility of phase separation during cooling.

6. Spray drying method[7,8]

Spray drying is a widely used technique for preparing amorphous solid dispersions of poorly water-soluble drugs. In this method, a solution containing the drug and polymeric carrier is rapidly converted into dry powder by spraying into a stream of hot air. The extremely fast solvent evaporation leads to formation of uniform, porous, amorphous particles, which significantly enhance drug dissolution and bioavailability.

Advantages: Produces uniform, fine particles, High surface area → faster dissolution, Suitable for thermolabile drugs,Excellent content uniformity, High degree of amorphization.

Limitations: Expensive equipment,Use of organic solvents, Powder loss during collection, Requires optimization of process parameters.

7. Hot-melt extrusion (Melt extrusion)method[8,9]

Hot-melt extrusion (HME) is a solvent-free, continuous manufacturing technique widely used to prepare amorphous solid dispersions of poorly soluble drugs. In this process, the drug and polymer are melted and mixed under controlled temperature and shear inside an extruder to form a homogeneous dispersion.

Advantages: Solvent-free process, Continuous and scalable manufacturing, Excellent content uniformity,Improved stability of amorphous dispersionsandSuitable for industrial production.

Limitations: Not suitable for heat-sensitive drugs, High equipment cost, Requires polymers with suitable melting properties.

8. Melting solvent method

The melting–solvent method is a hybrid technique that combines the advantages of the fusion method and solvent evaporation method. In this approach, the carrier is melted while the drug is dissolved in a suitable solvent and then incorporated into the molten carrier. This method is particularly useful when the drug has a high melting point or is difficult to disperse directly by the melting method.

Advantages: Combines benefits of melting and solvent methods, Better drug distribution than fusion method, Suitable for high melting point drugs, Improved dissolution and bioavailability.

Limitations: Use of organic solvent, Risk of residual solvent, Additional processing step.

9. Supercritical fluid technology[8]

Supercritical fluid technology is a modern technique used to prepare amorphous solid dispersions and nanoparticles of poorly soluble drugs using fluids at conditions above their critical temperature and pressure. The most commonly used supercritical

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fluid in pharmaceuticals is carbon dioxide (CO_2) due to its safety, low toxicity, and easy removal.

Advantages: Solvent-free or minimal solvent residues**,** Low temperature process (suitable for thermolabile drugs)**,** Produces nano/micro-sized particles**,** High purity and uniformity**,** environmental friendly ("green technology")

Limitations: Expensive equipment**,** High pressure operation**,** Limited solubility of some drugs in CO_2

10. **Solvent method**[10,11]

This method is also known as the solvent evaporation method in which a physical mixture of the drug and carrier is dissolved in a common solvent and is evaporated until a clear solvent-free is obtained. The main advantage is that the thermal decomposition of the drug or the carrier can be prevented because the organic solvents require a low temp for evaporation. The disadvantages of this method are difficulty in removing the solvent and the higher cost of preparation.

Advantages: Suitable for heat-sensitive drugs**,** Good homogeneity and molecular dispersion**,** Significant improvement in dissolution**,** Simple laboratory process.

Limitations: Risk of residual solvent**,** Scale-up challenges**,** Environmental and safety concerns.

SELECTION OF CARRIERS

Carriers play major role in formulation of solid dispersion[12]. They can be hydrophilic or hydrophobic or water swellable. Depending on their characteristics they can be used as release retardant or release enhancers[13]. Also the dissolution characteristics of drug molecules are dependent on nature of carriers.[14]

criteria for selection of carrier

• It should be water soluble.
• It should be economical, inert and non-toxic.
• It should be heat stable.
• Chemically compatible with drug.

Hydrophilic carriers used in solid dispersion are classified on the basis of their origin are described below

- Synthetic hydrophilic carriers[15]: Brij35, Pluronic F-127, Compritol888 ATO, Dextrin, EudragitE, Eudragit S100, Gelucire, sorbitol, PEG, PVP, Poloxamer, Soluplus, sodium acetate, urea.
- Natural hydrophilic carriers: AegeleMarmelos gum, alginate, arginine, caffeine, chitosan, skimmed milk, soybean seeds, Gelatin50PS, neem gum, sericin.
- Modified natural hydrophilic carriers: locust beans, modified gum karaya, guar gum, modified guar gum, hupu gum, modified hupu gum, modified fenugreek gum, modified Xanthum gum.
- Semi- synthetic hydrophilic carriers: chito-oligosaccharide, ethyl cellulose, hydroxypropyl methylcellulose(HPMC), HPMC E5 LV, HPMC Mesoporous silica

Hydrophobic carriers used in solid dispersion are described below

- Lipids &Fatty acids: Stearic Acid, Palmitic Acid, Myristic Acid, Behenic Acid, Oleic Acid.
- Glycerides (most widely used): Compritol®888 ATO,Precirol®ATO 5, Glyceryl monostearate, Glyceryl distearate, Glyceryl tristearate
- Waxes: Carnauba wax, Beeswax, Cetly Alcohol, Stearyl Alcohol
- Hydrophobic Polymers: Ethyl Cellulose, Cellulose Acetate, Cellulose Acetate Butyrate, Polyvinyl Acetate, Eudragit ® RS, Eudragit ® RL
- Sugar and Polymer derivatives: Hydroxypropyl cellulose (low-substituted, hydrophobic grade), Cellulose Acetate Phthalate, Polyvinyl Acetate Phthalate.
- Miscellaneous Hydrophobic carriers: Urea (when forming eutectic systems with hydrophobic drugs), Paraffin wax, HydrogenatedVegetable oils.

MECHANISMS FOR SOLUBILITY ENHANCEMENT

Solid dispersionsenhance drug solubility through multiple mechanisms:

- **Particle size reduction**: In solid dispersions, the drug is dispersed at a very fine, often molecular or near-molecular level within the carrier matrixby micronization and nanosuspension. This leads to a significant reduction in effective particle size.
- **Improved wettability:** Hydrophilic carriers and polymers present in solid dispersions enhance the wettability of poorly water-soluble drugs. The carrier coats the drug particles and facilitates better contact with the dissolution medium. Improved wetting allows rapid penetration of gastrointestinal fluids into the drug particles, promoting faster dissolution and increased solubility.
- **Formation of amorphous drug forms:** In solid dispersions, the drug often exists in an amorphous state rather than a crystalline form. Amorphous drugs possess higher free energy and lack an ordered crystal lattice. The absence of a crystal lattice reduces the energy required

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for dissolution, leading to higher apparent solubility and faster dissolution compared to crystalline drugs.

- **Inhibition of crystallization:** Polymeric carriers in solid dispersions inhibit nucleation and crystal growth of the drug during dissolution and storage. This prevents recrystallization of the amorphous drug. Maintaining the drug in an amorphous or supersaturated state prolongs enhanced solubility and ensures consistent dissolution performance.
- **Surfactant-mediated solubilization:**Some solid dispersions contain surfactants or amphiphilic polymers that can form micelles or solubilizing domains in aqueous media. These micelles encapsulate hydrophobic drug molecules, keeping them in solution and increasing apparent solubility and drug concentration in gastrointestinal fluids**.**

These mechanisms collectively increase drug dissolution rate and concentration in gastro intestinal fluids.

TECHNIQUES EMPLOYED FOR CHARACTERIZATION OF SOLID DISPERSION

a) Fourier Transform Infrared Spectroscopy (FT-IR)[16,17]

FT-IR identifies functional groups and chemical bonds by measuring infrared absorption at different wavelengths. It is mainly used to study compatibility and intermolecular interactions.

Significance in SDs

- Retention of characteristic peaks- no chemical incompatibility
- Peak shifting or broadening – hydrogen bonding or drug-polymer interaction
- Confirms physical rather than chemical modification of drug

b) Differential Scanning Calorimetry (DSC)[18,19]

DSC measures the heat flow associated with thermal transitions of a sample as a function of temperature. In solid dispersions, DSC is used to determine the physical state of the drug (crystalline or amorphous) and to study drug- polymer interactions.

Significance in SDs

- Presence of a sharp melting endotherm indicates crystalline drug
- Disappearance or reduction of the melting peak indicates conversion to amorphous form
- Shift or broadening of peaks suggests molecular interaction or solid solution formation

c) Powder X-ray Diffraction (PXRD)[20,21]

In this technique, X-rays are focused on the sample, and the resulting diffraction patterns were recorded. The position and intensity of the diffracted peaks provide information regarding the degree of crystallinity and atomic arrangement within the crystal lattice. It is the most reliable technique to distinguish between crystalline and amorphous forms

Significance in SDs

1. Sharp, intense peaks → crystalline drug
2. Reduction or absence of peaks → amorphous dispersion
3. Confirms loss of crystallinity after solid dispersion preparation

d) Scanning electron microscopy (SEM)[22]

SEM provides high- resolution images of surface morphology and particle shape. The samples were affixed onto brass stubs with double-sided adhesive tape and coated with a thin layer of gold under vacuum using a sputter coater. The surface features of the samples were then examined at magnification of 100x.

Significance in SDs

- Pure drugs usually show well-defined crystalline structures
- Solid dispersions show irregular, porous, or amorphous surfaces
- Morphological changes support reduced crystallinity and improved dissolution

e) Dissolution studies[22,23]

Dissolution testing evaluates the rate and extent of drug release from solid dispersions in a suitable dissolution medium.

Significance in SDs

- Demonstrates improvement in dissolution rate compared to pure drug
- Faster release is due to amorphization, improved wettability and reduced particle size
- Critical for predicting in-vivo performance

f) Drug content (assay)[24]

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Drug content analysis determines the actual amount of drug present in the solid dispersion compared to the theoretical value.

Significance in SDs

- Ensures uniform distribution of drug within the carrier
- Confirms accuracy of formulation method
- Poor drug content indicates loss during processing or poor mixing

g) Particle size analysis

This technique measures the size and size distribution of particles using methods such as laser diffraction or dynamic light scattering.

Significance in SDs

- Smaller particle size increases surface area
- Enhance dissolution rate and uniformity
- Indicate effective dispersion of drug within polymer matrix

h) Saturation solubility studies[25]

This test measures the maximum amount of drug that can dissolve in a solvent at equilibrium.

Significance in SDs

- Solid dispersions generally show higher solubility than pure drug
- Increased solubility results from amorphous state and drug- carrier interactions
- Correlates with enhanced dissolution and bioavailability

i) Stability studies [26]

Stability studies evaluate the physical and chemical stability of solid dispersions under specified temperature and humidity conditions.

Significance in SDs

- Detects recrystallization of amorphous drug
- Ensures consistent drug release over time
- Confirms shelf-life and formulation robustness

APPLICATIONS OF SOLID DISPERSIONS

- **Enhancement of aqueous solubility[27,28]**: solid dispersions convert crystalline drugs into an amorphous or molecularly dispersed state and improve wettability using hydrophilic carriers, leading to enhanced solubility.
  Examples: efavirenz, itraconazole, nifedipine
- **Improvement in dissolution rate:** reduction in crystallinity, decreased particle size, and improved wettability result in faster dissolution compared to pure drug.
  Example: ibuprofen, ketoprofen
- **Enhancement of oral bioavailability[28,29,30]:** enhanced solubility and dissolution lead to increased drug absorption and bioavailability.
  Examples: griseofulvin, tacrolimus
- **Dose reduction[28,29]:**improved bioavailability allows achievement of therapeutic effect at lower doses, reducing side effects.
  Examples: celecoxib, fenofibrate
- **Stabilization of amorphous drugs[31,32]**: polymers inhibit recrystallization and maintain the drug in a high energy amorphous state.
  Examples:ritonavir, indomethacin
- **Taste masking of bitter drugs:**embedding the drug in a polymer matrix reduces direct contact with taste buds.
  Example: chlorpheniramine maleate, paracetamol
- **Development of immediate-release formulations[30,31]:** rapid drug release is achieved due to fast polymer dissolution.
  Examples: domperidone, carbamazepine

CHALLENGES AND LIMITATIONS

Despite their advantages, solid dispersions face challenges including

- Physical instability due to recrystallization
- Moisture sensitivity
- Limited drug loading
- Process scalability issues
- Drug-polymer incompatibility can also compromise stability and performance.

III. FUTURE PROSPECTS

Nanotechnology, advanced polymers, 3D printing, molecular modeling and continuous manufacturing techniques like HME (hot melt extrusion) are expected to enhance the efficiency and stability of solid dispersions.

IV. CONCLUSION

Solid dispersion technology remains one of the most effective strategies for enhancing solubility and dissolution rate of poorly soluble drugs. With advancements in polymer science, preparation technologies, and analytical tools, solid dispersions continue to be aessential formulation approach in improving drug bioavailability and therapeutic effectiveness.

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