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# A Review On: Advancements in Solid Dispersion Technology for Poorly Soluble Drugs

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**ABSTRACT:**
Formulation scientists still struggle to increase the bioavailability of drugs given in solid dosage forms due to solubility problems. The dissolution rate may be the rate-limiting factor in the absorption of medication from a solid dosage form of a relatively insoluble drug. Therefore, when employing the solid dispersion technique to improve the dissolution of medications that are poorly soluble in water, formulation scientists encounter a challenge. Solid dispersion techniques have attracted a lot of interest in increasing the rate at which highly lipophilic drugs dissolve, thereby increasing their bioavailability, by increasing drug particle size, increasing wettability, and producing amorphous particles.

**KEYWORDS**:Poorly water-soluble drugs; hydrophilic carrier; solid dispersion; solubility enhancement; dissolution rate; bioavailability.

## I. INTRODUCTION:

Because of its simplicity and ease of use, the oral route is thought to be the most practical and preferred method for administering medications. When compared to other routes of administration, oral medications typically result in the best treatment outcomes and better patient compliance. However, some medications' poor water solubility frequently restricts their bioavailability, making oral administration difficult. Solubility and permeability are the two main factors that determine how much of a drug is absorbed orally. The Biopharmaceutical Classification System (BCS) divides drugs into four groups according to these two criteria. Drugs with low membrane permeability and low aqueous solubility are categorised as class IV drugs in the Biopharmaceutical Classification System (BCS). Solid dispersion techniques are therefore considered an effective strategy to enhance the oral absorption and bioavailability of drugs, particularly those in BCS Classes II and IV.

| BCS Class | Drug Solubility | Drug Permeability | Example of Drugs |
|---|---|---|---|
| Class I | High Solubility | High Permeability | Pregabalin, Dolasetron. |
| Class II | Low Solubility | High Permeability | Ribociclib, Aprepitant. |
| Class III | High Solubility | Low Permeability | Didanosine, Varnakalant. |
| Class IV | Low Solubility | Low Permeability | Amphotericin, Acyclovir. |

**TableNo. 1:BCS Classification system.**

The poor water solubility of nearly 40% of recently discovered drug candidates results in low dissolution, low bioavailability, and the requirement for higher doses that may be toxic.

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Enhancing solubility contributes to increased absorption, dissolution, and total bioavailability. pH adjustment, chemical modification, micronization, complexation, solid dispersion, hydrotropy, and cosolvency are some of the techniques that can improve the solubility of such medications.

**Solid dispersion:**

Solid dispersions are solid formulations where a hydrophobic drug is dispersed in a hydrophilic carrier, which can be crystalline or amorphous. Upon contact with water, the carrier dissolves, releasing fine drug particles and increasing surface area, dissolution rate, and bioavailability. This technique is widely used for enhancing solubility due to is simplicity, cost-effectiveness, and ability to improve drug absorption by reducing particle size.

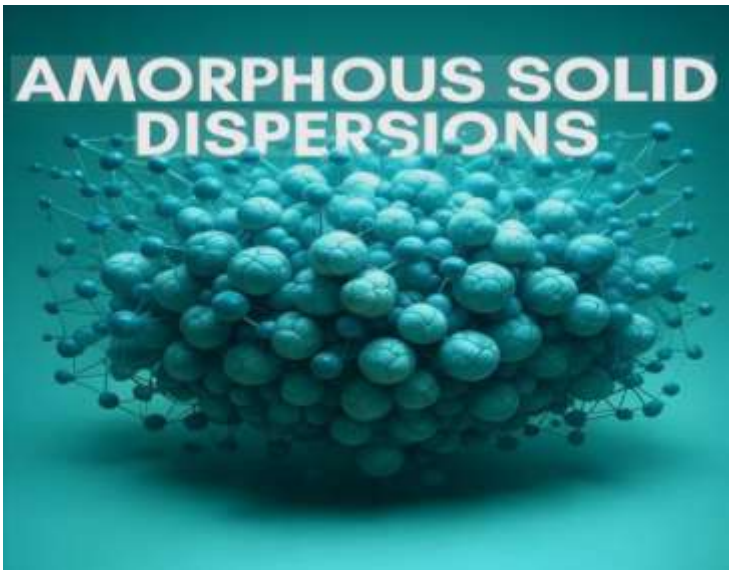


**Fig. No. 1:Amorphous solid dispersion.**

There are several ways to measure drug solubility. According to the united state pharmacopeia (USP), solubility is defined as the amount of solvent needed to dissolve one part of solute. It can also be expressed in molarity, molality, and is classified into seven categories.

| Descriptive term | Parts of solvent required per part of solute | Solubility range (mg/mL) |
|---|---|---|
| Very soluble | <1 | >1000 |
| Freely soluble | From 1 to 10 | 100-1000 |
| Soluble | From 10 to 30 | 33-100 |
| Sparingly soluble | From 30 to 100 | 10-33 |
| Slightly soluble | From 100 to 1000 | 1-10 |
| Very slightly soluble | From 1000 to 10,000 | 0.1-1 |
| Practically insoluble | >10,000 | <0.1 |

**Table No. 2**: **Expression for approximate solubility.**

**CLASSIFICATION OF SOLID DISPERSION**

- **Based on the carrier used**

1. **First Generation**: This generation uses crystalline carriers such as urea and sugars. These systems are highly stable but release the drug more slowly than amorphous dispersions.
2. **Second Generation:** These formulations employ amorphous polymer carriers, which

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enhance drug dissolution. They are divided into:

Natural polymers: Ethyl cellulose, HPMC, HPC, cyclodextrins. Synthetic polymers: PEG, polymethacrylates, PVP.

3. **Third Generation:** These dispersions use carriers with surfactant properties to improve dissolution and bioavailability of poorly water-soluble drugs. Examples include poloxamer, soluplus, compritol 888 ATO, sodium lauryl sulphate, tween 80, and castor oil.
4. **Fourth Generation:** Controlled release solid dispersion for poorly soluble drugs with short half-lives. Drug release occurs by diffusion or erosion. Polymers include ethyl cellulose, polyethylene oxide, and hydroxypropyl cellulose.

- **Based on the molecular arrangement**

1. **Eutectic Mixture:** Formed by rapid cooling of a melt of two components that mix completely in liquid form but have little solubility in solid form.Example: Paracetamol-urea
2. **Glass Solution and Suspension:** A glassy system where the drug dissolves in a glassy carrier, allowing faster dissolution.Example: Citric acid-PVP
3. **Solid Solution:** Solid solute dispersed in a solid solvent, usually prepared by solvent evaporation or co-precipitation, where both the drug and carrier are dissolved in volatile solvent such as alcohol.The solid solution can be of four types:

a) Continuous solid solution
b) Discontinuous solid solution
c) Substitutional solid solution
d) Interstitial solid solution

4. **Amorphous Precipitation in Crystalline Carrier:** Drug precipitates as an amorphous solid within a crystalline carrier.

Example: Sulphathiazide-urea.

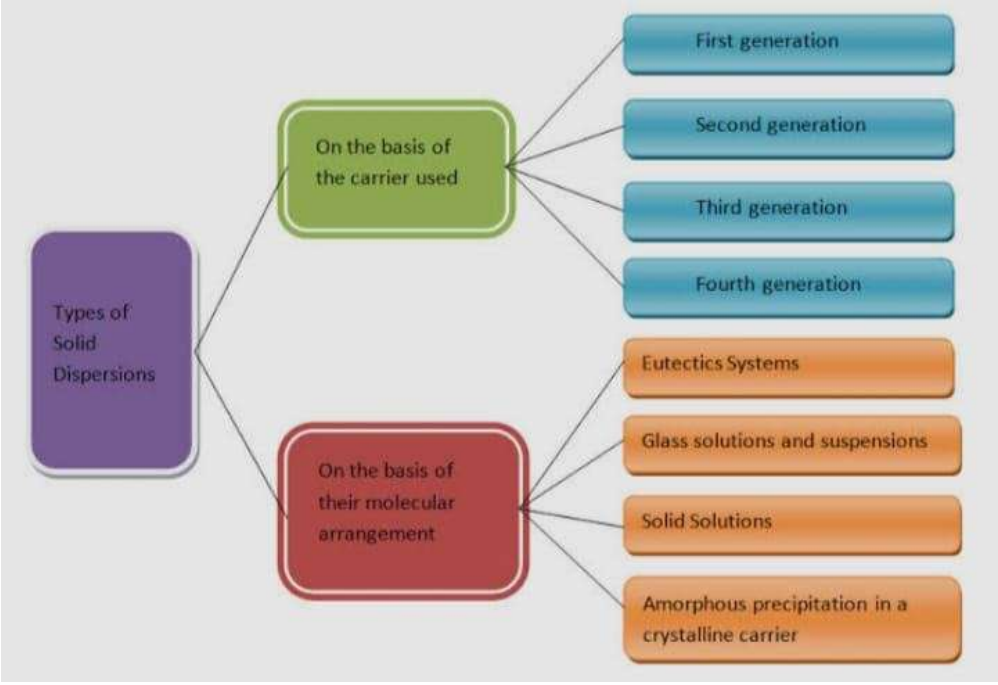


**Fig. No. 2:Classification of solid dispersion**

**MECHANISM OF SOLID DISPERSION**

Solid dispersions improve drug solubility and bioavailability through several mechanisms:

- **Carrier-controlled release:** When the solid dispersion contacts gastric fluid, the polymer swells by absorbing water and forms a thick gel layer, from which the drug is slowly released.
- **Drug-controlled release**: In this mechanism, the polymer dissolves first, after which the amorphous drug dissolves at a regulated rate.
- **Dissolution-controlled release:** Her, the drug is released only after the polymeric coating dissolves. The release rate depends on the thickness and dissolution speed of the polymer membrane.

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## ADVANTAGES OF SOLID DISPERSION

1. Solid dispersion helps to increase the dissolution rate of drugs that are poorly soluble in water.
2. They reduce the drugs crystalline nature, converting it into a more soluble amorphous form.
3. They enhance the porosity of drug particles.
4. They improve the wettability of the drug, promoting faster dissolution.
5. They enable the formulation of tablets that integrate rapidly.
6. They can be designed for sustained or controlled drug release.
7. By improving drug absorption and reducing dosing frequency, solid dispersions can lead to better patient compliance.

## DISADVANTAGES OF SOLID DISPERSION

1. Their main drawback is their tendency to be physically and chemically unstable.
2. They can be difficult to handle due to stickiness.
3. Crystallinity may change over time, reducing dissolution rate.
4. Solid dispersions are sensitive to moisture and temperature, which can cause degradation.
5. May form hard lumps during large-scale formulation, making processing challenging.

## CARRIERS USED IN SOLID DISPERSION

Carriers are essential in solid dispersion formulations as they influence drug solubility and release. They can be hydrophilic, hydrophobic or water-swellable and may act as release enhancers or retardants depending on their properties. The choice of carrier directly affects the drugs dissolution behaviour.

**Criteria for selection of carrier**:

- Should be heat stable with a low melting point.
- Must be soluble in water and various solvents.
- Should be economical, non-toxic, and pharmacologically inert.
- Must be chemically compatible with the drug.
- Freely water-soluble carriers help to achieve rapid drug dissolution.

**Examples of carriers:**

**Sugars:** Dextrose, sucrose, lactose, mannitol, maltose, and starch.

**Acids:** Citric acid, tartaric acid, and succinic acid.

**Enteric Polymers:** HPMCP, Eudragit L100, Eudragit E100, Eudragit RL, and Eudragit RS.

**Polymers:** PVP, PEG, HPMC, methyl cellulose, hydroxypropyl cellulose. Cyclodextrin, xanthan gum, and sodium alginate.

**Surfactants:** Poloxamer 188, deoxycholic acid, spans, and polyoxyethylene stearate.

**Others:** Urea, urethane, pentaerythrityl derivatives, and hydroxyalkyl xanthine.

## METHODS FOR PREPARATION OF SOLID DISPERSION

Solid dispersion can be prepared using several modern techniques such as melting, direct powder extrusion, spray drying, supercritical fluid processing, and electrospinning method.

**•Melting Method:**

In 1961, Sekiguchi and Obi introduced the melting method, also known as the fusion method.

In this case, the drug and polymer carrier mixture is heated to create a homogenous molten mass, which is then quickly cooled in an ice bath while being vigorously stirred. To get the right particle size for the solid dispersion, the solidified mass is then crushed, ground, and sieved.

**▪Advantages:**

1. Simple and cost-effective process.
2. It produces uniform dispersions when mixed properly.
3. Suitable for thermally stable drugs.
4. Solvent-free process.

**▪Disadvantages:**

1. Not suitable for heat sensitive drugs or carriers.
2. Risk of phase separation or crystallization during cooling.
3. Difficult to scale up for industrial production due to viscosity challenges.

**•Direct Powder Extrusion Method:**

A contemporary method for creating solid dispersions intended to increase the solubility of medications that are poorly soluble in water is direct powder extrusion, which is frequently coupled with 3D printing. In this method, the drug and carrier powders are directly fed into an extruder or 3D printing system without prior melting or solvent processing. The mixture is then heated and mechanically processed to form a

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continuous filament or layer-by-layer structures, resulting in final dosage form such as tablets, films, or pellets.

**▪Advantages:**

1. It is the solvent-free process, minimizing toxicity and environmental impact.
2. It can be adapted for heat sensitive drugs by using lower temperatures.
3. Improves the solubility of poorly water-soluble drugs through better dispersion.
4. It is well suitable for quickly developing new formulations.
5. Enables accurate control over dosage, shape, and the distribution of drug within the product.

**▪Disadvantages:**

1. It requires specialized extrusion or 3D printing equipment.
2. Precise temperature regulation is essential to prevent degradation of the drug.
3. Scaling up for large-volume industrial production can be difficult.

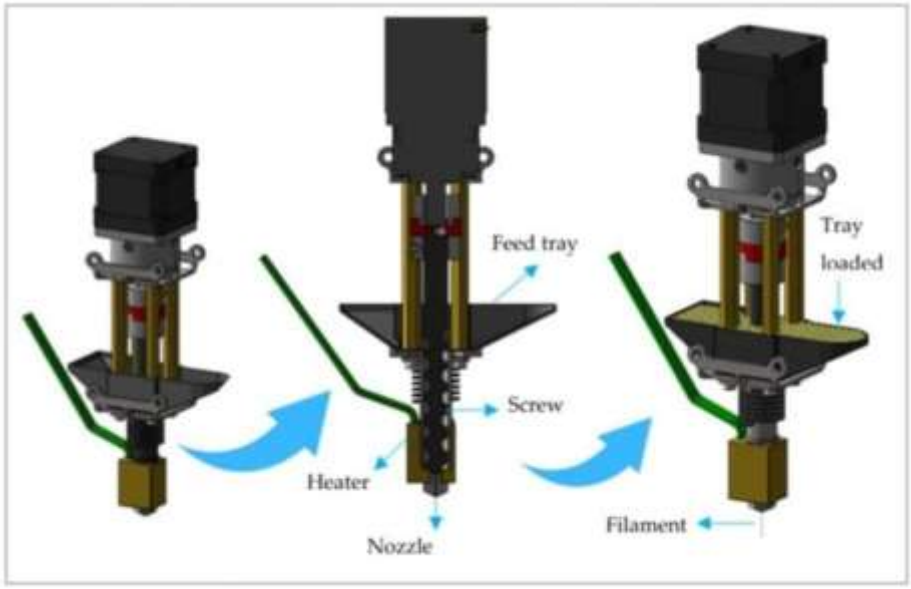


**Fig. No. 3:Single-screw direct powder extruder**

**•Spray Drying Method:**

One of the most popular and effective methods for creating solid dispersions is spray drying. In this procedure, a suitable solvent is used to dissolve or disperse the drug and carrier. Because of the large surface area of the droplets, the solvent evaporates nearly instantly when the mixture is sprayed into a stream of heated air. Solid dispersion particles consequently form in a matter of seconds, frequently quickly enough to prevent phase separation. The droplet size, which is easily controlled by adjusting the atomiser, is what primarily determines the particle size obtained.

**▪Advantages:**

1. It produces uniform and amorphous solid dispersions.
2. Enables rapid processing, making it suitable for heat-sensitive pharmaceuticals.
3. It can be readily scaled up for industrial production.
4. It has high reproducibility and suitable for continuous manufacturing setups.

**▪Disadvantages:**

1. Use of volatile organic solvents may cause toxicity and environmental concerns.
2. It requires expensive and sophisticated equipment.
3. Some degree of thermal degradation may still occur during drying.

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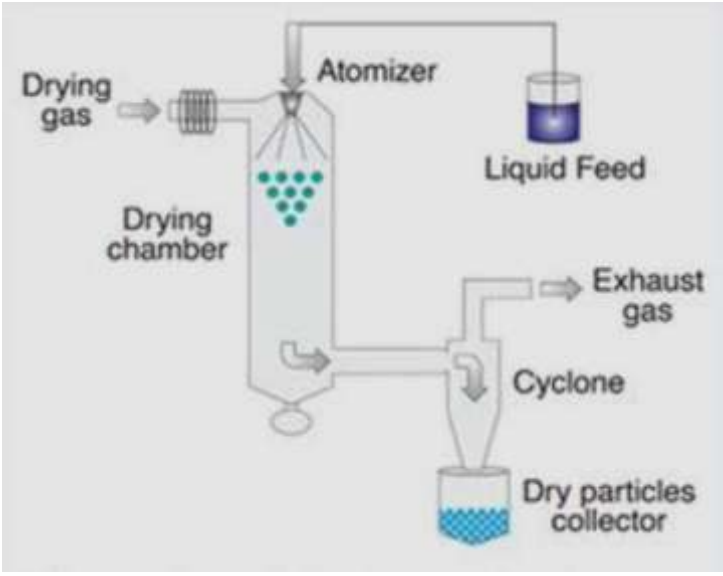


**Fig. No. 4:Spray drying process**

**•Supercritical Fluid Method:**

Supercritical carbon dioxide is frequently used in the supercritical fluid technique as an antisolvent or as a solvent to dissolve drug-carrier mixtures. The drug-carrier system dissolves when CO2 serves as the solvent, and it is then quickly expanded through a nozzle into a chamber with lower pressure. As a result, CO2 expands and cools abruptly, creating incredibly fine particles.

This approach, called Rapid Expansion of Supercritical Solutions, can generate nanoparticles ranging from 5 to 2000 nm. Since organic solvents are not required and any residual CO2 is harmless to patient. Hence, this method is considered as environmentally safe.

**▪Advantages:**

1. It produces fine, amorphous, and uniform particles.
2. No residual solvent remains in the product.
3. Suitable for heat sensitive drugs.
4. Allows precise control of particle size and shape.
5. It is solvent free process.

**▪Disadvantages:**

1. High cost and operational complexity.
2. It requires high-pressure specialized equipment.
3. Optimization of parameters is critical.
4. Some drugs have limited solubility in supercritical fluids.

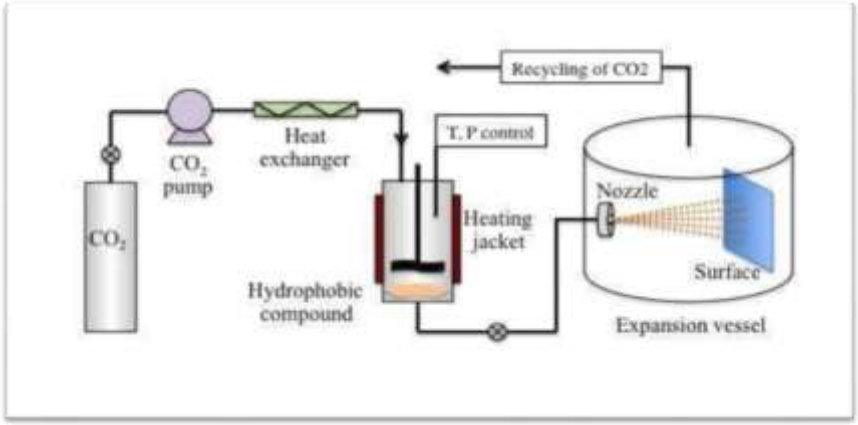


**Fig. No. 5:Supercritical fluid method**

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**•Electrospinning Method:**

Solid dispersion preparation and nanotechnology concepts are combined in electrospinning. This process involves extruding a polymer solution or melt through a narrow nozzle to create solid fibres. A high voltage, usually between 5 and 30 kV, is applied to a drug-polymer mixture. These fibres are collected on a collector screen to create a nonwoven mat or onto a rotating mandrel to create aligned structures as the solvent quickly evaporates. Because electrospinning is easy and very economical, it is a promising method for creating nanofibers and attaining controlled drug release. It could also be used in the future to prepare solid dispersions.

**▪Advantages:**

1. Simple, economical, and low-cost technique.
2. Rapid solvent evaporation produces amorphous fibers with very high dissolution rates.

**▪Disadvantages:**

1. Difficult to scale up for industrial production.
2. Amorphous products may suffer from stability issues.

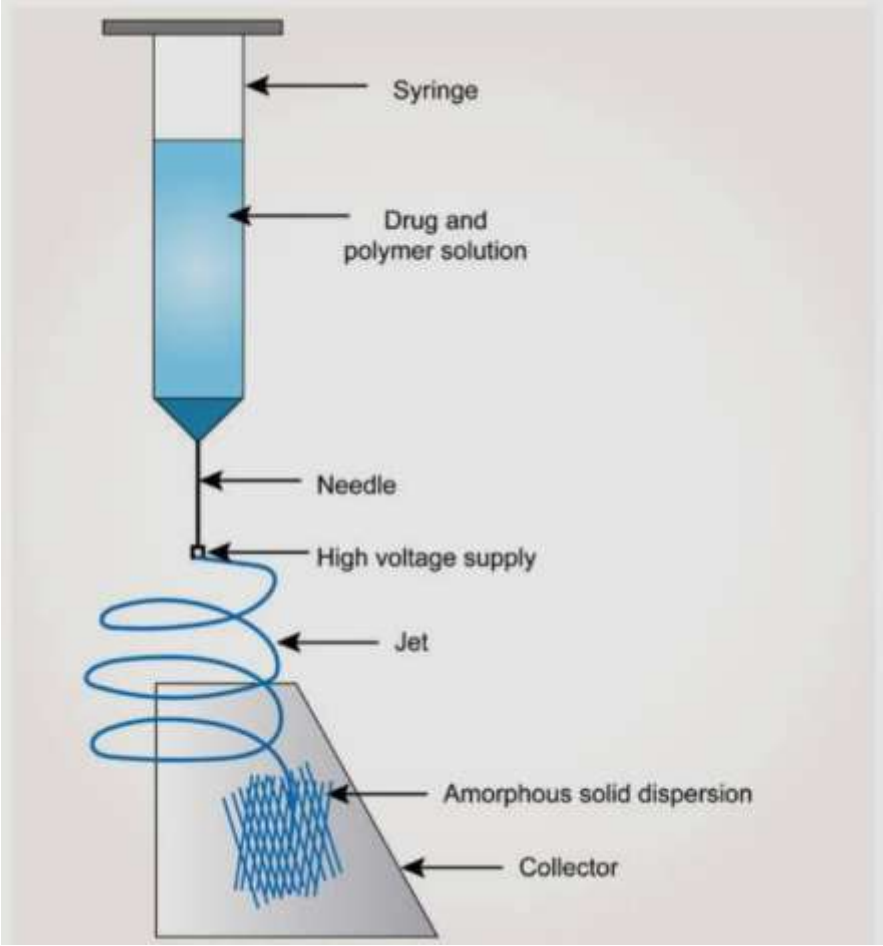


**Fig. No. 6: Electrospinning method.**

**APPLICATIONS OF SOLID DISPERSION**

1. It increases the rate at which poorly water-solublemedications dissolve, improving their absorption and bioavailability.
2. Reduces negative side effects of certain drugs.
3. Improves drug release from topical formulations like ointments, creams, and gels.
4. Allows incorporation of liquid or gaseous compounds into solid dosage forms.
5. Stabilizes drugs against degradation, including Hydrolysis and oxidation.
6. Minimizes incompatibilities that could cause undesirable effects.

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7. Decrease first-pass metabolism of drugs such as morphine and progesterone.
8. Provides rapid release of an initial dose in sustained-release formulations.
9. Ensures uniform distribution of small amounts of drug in solid dosage forms.
10. Unpleasant taste or odour of pharmaceuticals.

## II. FUTURE PROSPECTS

1.Although solid dispersions offer multiple benefits, their commercial use for poorly water-soluble drugs has been limited due to challenges in preparation, reproducibility, formulation, scale-up, and stability.

2.Current developments, particularly the development of surface active and self-emulsifying carriers with low melting points, have improved the feasibility of solid dispersions in preclinical, clinical and commercial application.

## III. CONCLUSION

Drug solubility is a major factor for influencing the absorption of orally administered medication. Therefore, one of the main challenges for formulation scientists in the development of drug products is improving the solubility of water-insoluble drugs to increase their bioavailability. A number of different technologies have been developed for the purpose of improving the solubility as well as dissolution of drugs. So, solid dispersion is one of the very useful techniques to improve solubility of water insoluble drugs compared to other methods.However, resolving some potential problems with the drug's stability and flow characteristics is still a work in progress. In order to improve the rate of drug release and, consequently, the oral bioavailability of water-insoluble medications, careful selection of the polymer and solid dispersion method can also be helpful.

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