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## A Detailed Review on Novel Solubility Enhancement Techniques

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### ABSTRACT

Approximately 40% of the marketed drugs and 70 to 90% of the drugs in development are poorly water soluble. Solubility plays a crucial role in the absorption of the drugs ingested orally. As most of the drugs are poorly soluble the solubility enhancement is the prime requisite to enhance dissolution, bioavailability and therapeutic efficacy. Several approaches as physical modification, pH adjustment, Super critical fluid technology, liquisolid techniques and chemical modifications are to enhance the solubility. Physical methods include particle size reduction, solubility enhancement by carriers, by surfactants, by complexation chemical modifications include Hydrotrophy, co-solvency, nano technology, salt formation and co-crystallization. This review mainly focuses on novel techniques to enhance solubility includes liquisolid system, Spherical agglomeration, melt sonocrystallization, Hydrotrophy, Natural deep eutectic solvents nano technology-based methods, solid state engineering, advanced formulation strategies include self-emulsifying drug delivery systems, and supercritical fluid technology and other innovative techniques like and micro wave assisted techniques.

**Keywords:** Solubility Enhancement, Hydrotrophy, Co-solvency, Nano technology

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## INTRODUCTION

From decades solubility enhancement is the key challenge for a successful pharmaceutical formulation. Though there are several techniques to enhance the solubility still extensive research is held on in this area.

Solubility in quantitative terms is the concentration of solute in a saturated solution at a certain temperature and qualitatively spontaneous interaction of two or more substances to form a homogenous molecular dispersion<sup>1</sup>. The solubility of a drug can be given by different terms based on no of parts of solvent required to dissolve one part of solute and given in table no 1

**Table 1: Terms of approximate solubility as per USP<sup>1</sup>**

<b>Term</b>	<b>Parts of solvent required for one part of solute</b>
Very soluble	Less than 1part
Freely soluble	1 to 10 parts
Soluble	10 to 30 parts
Sparingly soluble	30 to 100 parts
Slightly soluble	100 to 1000 parts
Very Slightly soluble	1000 to 10,000 parts
Practically insoluble or insoluble	More than 10000 parts

The Biopharmaceutics classification system (BCS), remains cornerstone in drug formulation, offering a scientific basis for predicting oral absorption by categorizing drugs according to their solubility and intestinal serves as a guiding framework to understand and predict oral drug absorption by categorizing drugs based on their aqueous solubility and intestinal permeability<sup>2</sup>: The BCS classification along with suitable examples cited in table 2. The research data available on chemical methods has given in table no 4.

**Table 2: BCS classification of drugs<sup>3</sup>**

<b>BCS Class</b>	<b>Solubility</b>	<b>Permeability</b>	<b>Absorption pattern</b>	<b>Drug examples</b>
i	High	High	Well absorbed	Metoprolol, Propranolol, Verapamil
ii	Low	High	Variable	Carbamazepine, Ketoconazole, Danazol, Itraconazole
iii	High	Low	Variable	Cimetidine, Acyclovir, Atenolol
iv	low	Low	Poorly absorbed	Hydrochlorothiazide, Paclitaxel, Furosemide, Ritonavir

### Conventional solubility enhancement techniques

Physical Solubility Enhancement Techniques: The research data available on Physical methods has given in Table 3.

**Table 3: Solubility Enhancement by Physical methods**

Techniques	Mechanism	Drug	Polymers and carriers used	References
Particle size reduction	Increases surface area → faster dissolution (Noyes-Whitney equation)	Fenofibrate, Griseofulvin, Naproxen, Itraconazole	PEG, Gelucire	4
Solid dispersion technique	Drug dispersed in hydrophilic carriers → improved wet ability and reduce crystalline nature	Nimilodepine	PVP K30 Maltodextrin	5
Hot melt extrusion (HME)	Drug with polymer are melted together and extruded which leads to form amorphous particles	Piperine,	Eudragi Soluplus Kollidon	6
Supercritical fluid extraction (SCF)	Supercritical CO <sub>2</sub> precipitation leads to fine particles with narrow distribution	Paclitaxel, Ibuprofen	Poloxamers (pluronic F68, F127)	7

**Table 4: Solubility Enhancement by Chemical methods**

Techniques	Mechanism	Examples	Polymers and carriers used	Ref.
Salt formation	Conversion of weakly acidic or basic drugs into salt forms to improve ionization and aqueous solubility	Telmisartan	HCl, Acetone DMSO	8
Co-crystallization	Formation of multi component crystalline system (drug+ co-former) that enhances dissolution without altering pharmacological activity	Carvedilol	Hydrochlorothiazide (co-former)	9
Complexation	Formation of inclusion or non-inclusion complexes with carriers that enhances solubility	Fenofibrate	Hydroxy propyl βCyclodextrin)	10
Hydrotropy	Addition of large amounts of hydrotropic agents to increase solubility via weak interactions.	Paracetamol, Domperidone	sodium benzoate, sodium acetate, niacinamide, urea, sodium citrate	11
pH adjustment and buffering	Alteration of medium p <sup>H</sup> to enhance ionization and solubility of weak acids/ bases	P-Methoxycinnamic acid	Cyclodextrin	12

### Novel Solubility Enhancement Techniques

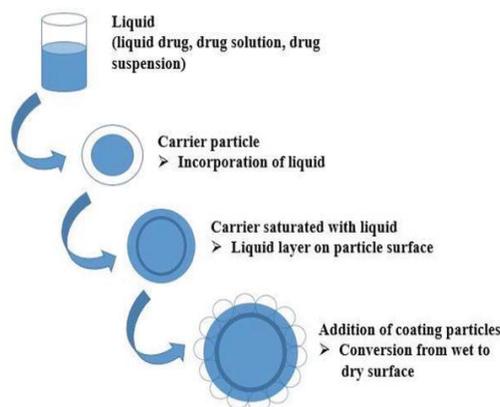
#### Liquisolid compacts<sup>13</sup>:

The liquisolid formulation was obtained by mixing the drug with non-volatile solvent, and then the drug solution was mixed with carrier excipients, where coating of the drug molecule with thin film

is formed. The resulting liquid medication carrier system was adsorbed on coating agent to obtain dry, free-flowing and non adherent powder that can be easily compacted into tablets so, screening of non-volatile solvents, carrier, and coating material was essential.

### **Spherical agglomeration (spherical crystallization)<sup>14</sup>:**

Spherical agglomeration is a particle engineering technique used to improve the solubility, flow ability, compressibility, and dissolution rate of poorly soluble drugs. It involves the transformation of fine drug particles into spherical agglomerates by agglomerating them in a liquid medium.



**Figure 1: Spherical agglomeration technique**

### **MELT SONO CRYSTALLIZATION<sup>15</sup>:**

The use of ultrasound waves to produce small sized drug particles with improved physicochemical properties such as nucleation of crystallization. The energy of ultrasound leads to compression as well as expansion. After completion of some cycles, it forms bubbles and grows, it collapses. This collapse of formed gives the energy to enhance the nucleation process which leads to highly repeatable as well as a predictable crystallization process, significance to apply ultrasound to crystallization is as follows,

1. Narrowing of met stable zone width,
2. Narrowing of particle size distribution,
3. Minimizes level of cooling process for getting crystals,
4. Highly repeatable process, predictable.
5. Controls the polymorphs.

### **Pro-drug approach<sup>16</sup>:**

The pro-drug approach is a chemical modification technique used to increase the solubility and bioavailability of poorly soluble drugs. A pro-drug is an inactive derivative of a drug that undergoes enzymatic or chemical transformation in the body to release the active drug. By

modifying chemical structure of the drug, its solubility, permeability, and stability can be improved without altering the drugs pharmacological activity

### **Hydrotropy<sup>17</sup>:**

Hydrotropes such as sodium benzoate, sodium citrate, and nicotinamide, increase the solubility of hydrotropic substances in water. Hydrotropy is a technique that improves aqueous solubility of poorly soluble drugs by adding a large amount of second solute, known as hydrotrope. This method is advantageous because it does not require chemical modifications of the drug, the use of organic solvents or the preparation of emulsion system.

### **Natural deep eutectic solvents (NADES)<sup>18</sup>:**

NADES are formed by mixing hydrogen bond donors (HBA) with hydrogen bond acceptors (HBA). Strong hydrogen bonding and ionic interactions between HBA and HBA result in eutectic mixture with a melting point lower than its individual components. These are solubilization of poorly soluble drugs, by enhancing bioavailability of natural products and synthetic drugs. These are also act as permeation enhancers; Biocompatibility and low toxicity; Environment friendly and biodegradable.

### **Nanotechnology<sup>19</sup>:**

Nanotechnology in solubility enhancement involves reducing drug particle sizes to the nanometer range (1-1000 nm), which increases the surface area and improves the dissolution rate and bioavailability of poorly soluble drugs. The resulting nanoparticles can be pre owned various formulations, as nanosuspensions, nanocrystals, lipid-based nanoparticles. The nanoparticles can be used in various formulations such as nanosuspensions, nanocrystals, and lipid-based nanoparticles.

### **Solid state engineering<sup>20</sup>**

Crystal engineering has emerged as a powerful and versatile approach to address the solubility issue by rationally designing API crystal structures through precise control of intermolecular interactions, thereby enhancing solubility, dissolution rates, and ultimately bioavailability.

### **Polymorphism**

“polymorph” refers to crystalline compounds that have identical chemical structures and molecular compositions while explicitly excluding the enantiomeric and tautomeric forms. Different drug polymorphs usually exhibit distinct physicochemical properties (e.g., melting point, density, solubility, and stability) due to variations in molecular stacking or conformations. These differences can further affect the manufacturing processing, bioavailability and clinical efficacy of the drug.

### **Co-crystals**

A pharmaceutical cocrystal is generally defined as a single-crystalline phase that contains two or more different neutral molecules assembled by noncovalent interactions, such as hydrogen bonding, halogen bonding, charge transfer or  $\pi$ - $\pi$  stacking, in a specific stoichiometric ratio. At least one component is the target active pharmaceutical ingredient (API), and the co-former is either generally recognized as safe by the U.S. FDA or is another approved drug/pharmaceutical agent. Unlike salt formation, co-crystallization is applicable to any API—whether acidic, basic, or neutral when paired with a suitable co-former. This approach enhances the physicochemical properties of APIs through crystal structure modification alone, without altering the drug's chemical structure.

### **Solvates/hydrates**

**Solvates/hydrates** Solvates are crystalline solids that incorporate solvent molecules into their crystal lattice. When the trapped solvent molecules are water molecules, termed hydrates. The formation of solvates, particularly hydrates, is prevalent, in which approximately one-third of organic molecules can form hydrates. The formation of hydrates or solvates is governed by specific intermolecular interactions between APIs and solvent species.

### **Nano crystals**

**Nanocrystals** Pharmaceutical nanocrystals are typically defined as crystals with a particle size of less than 1  $\mu\text{m}$  that can be administered via various routes (e.g., oral, parenteral, transdermal, ocular, intranasal, and pulmonary). Owing to their small particle size, pharmaceutical nanocrystals exhibit increased saturation solubility, an enhanced dissolution rate, and improved adhesiveness to physiological barriers. Moreover, pharmaceutical nanocrystals offer higher drug-loading capacity, lower manufacturing costs, and enhanced scalability compared to other nanoparticle-based carriers.

### **Organic frame work solids:**

The incorporation of low water solubility drugs into porous materials has emerged as an innovative strategy to enhance drug stability and dissolution properties. In recent decades, the rapid advancement of organic frameworks (OFs) has introduced a fascinating array of porous materials. OFs are a category of porous crystalline materials composed of organic molecules and/or ions/clusters interconnected through covalent or noncovalent bonds, featuring high surface areas and adjustable porosity. These frameworks can be categorized into two main types: covalently bonded frameworks, including metal-organic frameworks (MOFs) and covalent organic

frameworks (COFs), and noncovalently bonded frameworks, such as hydrogen bonded frameworks and halogen bonded organic frameworks among others.

### Self-emulsifying drug delivery system<sup>21</sup>:

Self-Emulsifying Drug Delivery System (SEDDS) owns a promising future in enhancing solubility and bioavailability properties of sparingly water-soluble drugs. These are mixtures of drug, lipid, surfactants and oils. SEDDS are liquid to semisolid in nature, but it has some drawbacks like formulation development, quality control, stability etc. To overcome this, liquid SEDDS can be converted into solid SEDDS such as pellets, tablets, capsules, microspheres, nanoparticles, microbeads, suppositories etc. without affecting drug release property.

**Table 5: Novel Solubility Enhancement Techniques**

Techniques	Examples	Polymers and Excipients Used	Ref.
Liquisolid compacts	Carbamazepine, Naproxen	Micro crystalline cellulose, Aerosil, PEG, Crospovidone	22-24
Spherical agglomeration (spherical crystallization)	Cilostazol, Ibuprofen, Itraconazole, Mebendazole	HPMC, PVP, PEG	25-27
Melt sono crystallization	Ibuprofen, Celecoxib, Fenofibrate	Poloxamers, PEGs, Surfactants	28-30
Pro-drug approach	Paclitaxel, Oridonin, Etoposide, Acyclovir	PEGylation, esters, amides	31
Hydrotropy	Ketoprofen, Ibuprofen, Naproxen	Sodium benzoate, urea, nicotinamide, sodium citrate	32
Natural deep eutectic solvents (NADES)	Curcumin, Resveratrol	Choline chloride, organic acids, sugars	33
Nanotechnology	Atrovastatin	Poloxomers, PVP, HPMC, Tween 80	34
Polymorphism	Flufenamic acid	PEG	35
Co Crystals	Etodolac	p-hydroxybenzoic acid and glutaric acid	36
Solvates/Hydrates	sorafenib tosylate	methanol, ethanol and n-methyl-2-pyrrolidone (NMP)	37
Nano crystals	Lercanidipine	Methanol, PVPK30, PVA	38
Organic framework solids	Zinc nitrate hexahydrate	sodium dodecyl sulfate, ammonia, and methanol	39
Self-Emulsifying drug delivery systems	Ibuprofen	Tween 80, PG, PEG 400, glycerol, ethyl oleate	40

### CONCLUSION:

Solubility plays a crucial role in therapeutic efficacy of the drug given through oral route. As it influences dissolution and bio availability. Solubility can be enhanced by various techniques the selection of technique depends on physicochemical characters of the drug, Pharmacokinetic profile of the drug, melting point absorption site and type of dosage form. Proper selection of the method is the key to ensure the good oral bio availability, reducing the dosing frequency. The regulatory

requirements for the excipient concentration and therapeutic activity of the excipients should also be considered for biological safety purpose.

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