

**REVIEW ON SOLID DISPERSION-BASED FAST DISSOLVING TABLETS
FORMULATION APPROACHES AND EVALUATION****Aakash Prajapati^{1*}, Priyanka Yadav², Amar Raval³, Jaini Patel⁴**

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ABSTRACT

Solid dispersion-based fast-dissolving tablets (SD–FDTs) are an emerging oral delivery platform designed to overcome the twin challenges of poor aqueous solubility and patient non-compliance. This technology integrates the solubility enhancement properties of solid dispersion (SD) systems with the rapid disintegration capability of fast-dissolving tablets (FDTs). This approach promotes molecular-level dispersion of hydrophobic drugs within hydrophilic matrices, improving wettability, surface area, and dissolution rate while minimizing crystallinity. Recent research emphasizes hot-melt extrusion, spray drying, and co-amorphous systems for stable SD formation and direct compression or lyophilization for tablet fabrication. Carriers such as PVP, HPMC, Soluplus®, and PEG have demonstrated improved dissolution and stability. The review outlines theoretical principles, preparation strategies, formulation design, physicochemical evaluation, and emerging technological advances, providing an in-depth analysis of how SD–FDTs can bridge the gap between formulation science and patient-centric drug delivery.

KEYWORDS: Solid dispersion, Fast dissolving tablet, Solubility enhancement, Hydrophilic carriers, Bioavailability, Disintegration.

1. INTRODUCTION

Fast-dissolving tablets (FDTs) are solid dosage forms that rapidly disintegrate in the oral cavity, typically within 30 seconds, releasing the drug for pre-gastric absorption. The oral cavity offers several physiological advantages—bypass of first-pass metabolism, rapid onset, and improved compliance for pediatric, geriatric, and dysphagic patients. However, the rate-limiting step for many lipophilic drugs remains dissolution rather than absorption.^[1]

Solid dispersion (SD) technology addresses this by incorporating poorly soluble drugs into hydrophilic polymer matrices, enhancing solubility through improved wettability, reduced particle size, and amorphization.^[2] The combination of SD with FDT technology creates a synergistic system that enables both enhanced dissolution and fast disintegration, making it particularly suitable for BCS Class II and IV drugs such as ketoprofen, duloxetine, and carbamazepine.^[3]

Recent studies have reported that SD–FDT systems enhance bioavailability by approximately 3–5-fold compared to conventional tablets. Advances in nanotechnology, amorphous polymer systems, and hot-melt extrusion have further optimized these formulations for scalability and stability.^[4]

2. CONCEPT OF SOLID DISPERSION

A solid dispersion is defined as a molecular or colloidal dispersion of one or more active pharmaceutical ingredients (APIs) within an inert carrier or matrix. It is a technique extensively used to increase the dissolution rate and bioavailability of poorly soluble drugs by modulating their physicochemical state.^[5]

Solid dispersions are classified into.^[6]

- Eutectic mixtures
- Amorphous precipitations
- Solid solutions
- Glass suspensions or co-amorphous systems

These systems alter the thermodynamic activity of the drug by converting the crystalline state into a metastable amorphous form, which exhibits higher Gibbs free energy and enhanced solubility.^[7]

2.1 Mechanisms of Solubility Enhancement

- Particle Size Reduction: Conversion of the crystalline drug to a molecularly dispersed or nanodomain form increases surface area.
- Improved Wettability: Hydrophilic polymers reduce the interfacial tension, enhancing drug–water interaction.
- Amorphization: Loss of crystallinity leads to an increase in free energy, improving dissolution rate.
- Enhanced Porosity: Porous matrices promote water uptake and faster wetting kinetics.
- Intermolecular Interactions: Hydrogen bonding between drug and carrier prevents recrystallization, improving stability.^[8]

3. FAST DISSOLVING TABLETS (FDTs): OVERVIEW

Fast-dissolving tablets are orally administered dosage forms designed to disintegrate rapidly on contact with saliva, generally within 10–30 seconds, releasing the active ingredient for absorption in the oral cavity or upper GI tract.^[9]

3.1 Advantages

- Elimination of swallowing difficulty and need for water.
- Improved bioavailability through partial pre-gastric absorption.
- Rapid onset of pharmacological action.
- Enhanced patient compliance, especially in geriatric, pediatric, and psychiatric populations.
- Potential for dose reduction due to bypassing first-pass metabolism.^[10]

4. RATIONALE FOR COMBINING SOLID DISPERSION WITH FDTs

The combination of SD and FDTs provides a dual mechanism of bioavailability enhancement:

- Solid dispersion increases solubility.
- FDT ensures fast release and absorption.

This is particularly beneficial for BCS Class II drugs, where dissolution is the rate-limiting step. For example, duloxetine hydrochloride SD–FDTs demonstrated a 2.8-fold increase in dissolution rate and a 1.9-fold increase in bioavailability compared to plain FDTs.^[11]

Integration of SD into FDTs ensures.

- Rapid disintegration in oral cavity.
- Molecularly dispersed API for immediate dissolution.
- Increased surface area for absorption.

5. METHODS OF PREPARATION OF SOLID DISPERSIONS^[12]

Table: Methods for Preparation of Solid Dispersions.

Method	Principle	Advantages
Melting (Fusion)	Drug and carrier are co-melted, then rapidly cooled to form a solid mass	Solvent-free, simple, cost-effective
Solvent Evaporation	Drug and carrier dissolved in volatile solvent; solvent evaporated	Suitable for heat-sensitive drugs
Melting–Solvent (Fusion–Solvent)	Combines solvent and fusion steps for enhanced dispersion	Good mixing and uniformity
Kneading Method	Drug and polymer mixed with solvent under pressure	Economical, scalable
Spray Drying	Solution atomized in hot air; solvent evaporates instantly	Produces porous, fine particles
Lyophilization	Freeze-drying after solvent removal	Highly porous product with fast dissolution
Hot Melt Extrusion (HME)	Drug–polymer mix extruded under controlled heat/shear	Continuous, solvent-free, scalable

6. CARRIERS USED IN SOLID DISPERSION^[13]

Table: Carriers Used in Solid Dispersions.

Type	Examples	Properties / Function
Hydrophilic Polymers	PVP K30, PEG 4000, HPMC, PVA, Soluplus®	Improve wettability, enhance solubility, stabilize amorphous form
Sugars & Polyols	Mannitol, Sorbitol, Lactose	Provide pleasant mouthfeel, act as fillers, improve dissolution
Surfactants	Poloxamer 188, Tween 80, Span 60	Reduce surface tension, aid solubilization
Cyclodextrins	β-CD, HP-β-CD, Methyl-β-CD	Form inclusion complexes, increase stability and taste masking
Novel Carriers	Kollidon® VA64, HPMCAS, Eudragit® EPO	Enhance glass transition temperature, inhibit recrystallization

7. FORMULATION OF SOLID DISPERSION-BASED FDTs

The formulation integrates pre-formed solid dispersions into a tablet matrix by direct compression, sublimation, or lyophilisation.^[14]

Critical formulation variables include carrier–drug ratio, type of superdisintegrant, and compression force.^[15] Direct compression is preferred due to its simplicity, cost-effectiveness, and product stability.^[16]

7.1 Essential Components^[17]

- **Drug:** Poorly soluble API (e.g., Duloxetine, Ketoprofen, Griseofulvin).

- **Superdisintegrants:** Croscarmellose sodium, Sodium starch glycolate.
- **Diluents:** Mannitol, Microcrystalline cellulose (Avicel PH 102).
- **Sweeteners & Flavors:** Aspartame, Sucralose, Mint, Orange.
- **Lubricants:** Magnesium stearate, Talc.

7.2 Manufacturing Techniques

- Direct compression.
- Lyophilization for highly porous tablets.
- Sublimation using camphor or menthol.
- Effervescent method for faster disintegration.
- Molding or spray-drying for heat-sensitive drugs.

8. EVALUATION PARAMETERS^[18]

Table: Evaluation Parameters of SD–FDTs.

Parameter	Method	Typical Limit	Significance
Weight variation	20 tablets	±5%	Uniformity of dosage
Hardness	Monsanto tester	2–4 kg/cm ²	Mechanical strength
Friability	Roche friabilator	< 1%	Resistance to abrasion
Disintegration	USP Apparatus	< 30 sec	Oral cavity suitability
Drug content	UV spectrophotometry	90–110%	Uniformity
Dispersion time	pH 6.8 buffer	15–30 sec	Rapid release
Dissolution	USP Type II	≥ 95% in 10 min	Rate of drug release
Stability	ICH Q1A	< 3% degradation	Shelf-life prediction

9. COMPARATIVE ADVANTAGES^[19]

Aspect	Conventional FDT	SD-Based FDT
Solubility	Limited	Significantly improved
Disintegration	Moderate	Rapid (≤10 sec)
Dissolution	Surface controlled	Molecular dispersion
Bioavailability	Moderate	Enhanced (1.5–3×)
Patient compliance	Good	Excellent
Stability	Moderate	Improved with polymer selection

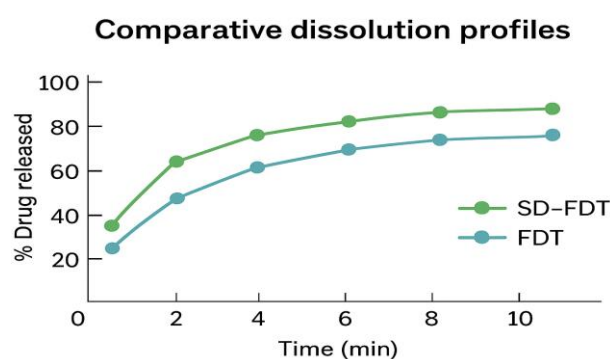


Figure: “Comparative dissolution profiles showing enhanced drug release of SD-FDTs compared to conventional FDTs.”

10. RECENT ADVANCES AND RESEARCH TRENDS^[20]

- ✓ **Amorphous solid dispersions** with Soluplus®, PVP VA64, and HPMCAS showing improved physical stability.
- ✓ **Hot-melt extrusion (HME)** allows solvent-free continuous production.
- ✓ **Nanofiber and nanosolid dispersion systems** increase dissolution rate via high surface area.
- ✓ **Co-amorphous systems** (drug–drug or drug–excipient) enhance stability.

- ✓ **3D printing** enables patient-personalized FDT–SD dosage forms.
- ✓ **Duloxetine and celecoxib SD–FDT formulations** show >90% drug release in 10 min.

11. APPLICATIONS^[21]

- Suitable for BCS Class II drugs (poorly soluble, highly permeable).
- Emergency therapy (e.g., antiemetics, antihistamines, analgesics).
- Pediatric and geriatric patient-friendly systems.
- Psychiatric medications like duloxetine for improved adherence.
- Quick onset analgesic and anti-allergic therapy.

12. CONCLUSION

Solid dispersion-based fast dissolving tablets offer a synergistic combination of solubility enhancement and rapid drug release, leading to improved bioavailability and patient acceptability. Selection of an appropriate carrier, optimization of preparation method, and stability control are crucial for successful formulation. With advancements in polymer science and process technologies like HME and spray drying, this approach holds great promise for future pharmaceutical development. Thus, SD–FDTs offer a hybrid platform combining rapid release and improved solubility, representing a practical approach to overcome bioavailability challenges in modern oral drug delivery.

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