

Formulite®: the next-generation bioavailability enhancement technology



Enhanced bioavailability.
Optimized drug products.
For the benefit of patients.

A new standard beyond conventional solubility-enhancing technologies

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INTRODUCTION

Poor drug solubility and dissolution remain one of the greatest challenges in oral drug development, leading to low bioavailability, limited drug loading in finished products, and increased manufacturing complexity for many drugs. These limitations impact clinical performance, patient convenience, development timelines, manufacturing cost, and overall commercial potential.

OUTPERFORMING CONVENTIONAL SOLUBILITY-ENHANCING TECHNOLOGIES

Formulite® is a next-generation bioavailability enhancement technology designed to overcome these challenges through a scalable and commercially attractive solid oral dosage platform. Unlike conventional approaches, which often require trade-offs between dissolution performance, drug loading, and manufacturing simplicity, Formulite® combines high drug loading, rapid and efficient drug release, and straightforward manufacturing in a single platform. Enabling optimized bioavailability, cost-efficient manufacturing, patient-friendly dosage forms, and the opportunity for drug products to reach their full potential.

FORMULITE® BIOAVAILABILITY WITHOUT TRADE-OFFS

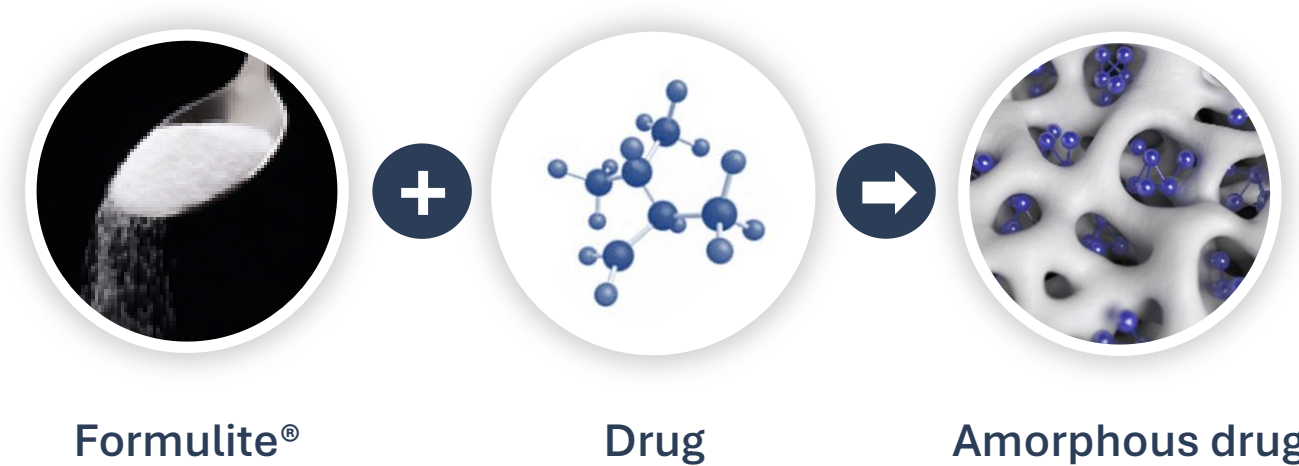
	Formulite®	Polymer-based ASDs		Micronization
		Spray Drying	Hot Melt Extrusion	
Bioavailability improvement	+	±	±	±
Patient-friendly tablet / capsule size	+	-	±	±
Overall processability and COGS	++	-	±	±

Legend: ++ Strongly positive, + Positive, ± Neutral, - Negative

FORMULITE® TECHNOLOGY PLATFORM

AMORPHIZATION THROUGH PHYSICAL ENTRAPMENT

Formulite® is made from mesoporous magnesium carbonate (MMC) and is a free-flowing powder. Amorphization is achieved by physically entrapping the drug within the nanoporous structure of Formulite®, stabilizing the drug in its amorphous state. Formulite® particles fully dissolve in the gastrointestinal tract, enabling rapid and complete drug release without residual carrier material.



EXCELLENCE IN DRUG PRODUCT MANUFACTURING

Formulite® streamlines manufacturing compared with conventional ASD spray-drying approaches, by:

- reducing process steps from API to finished drug product by >30%
- using 50–100× less solvent

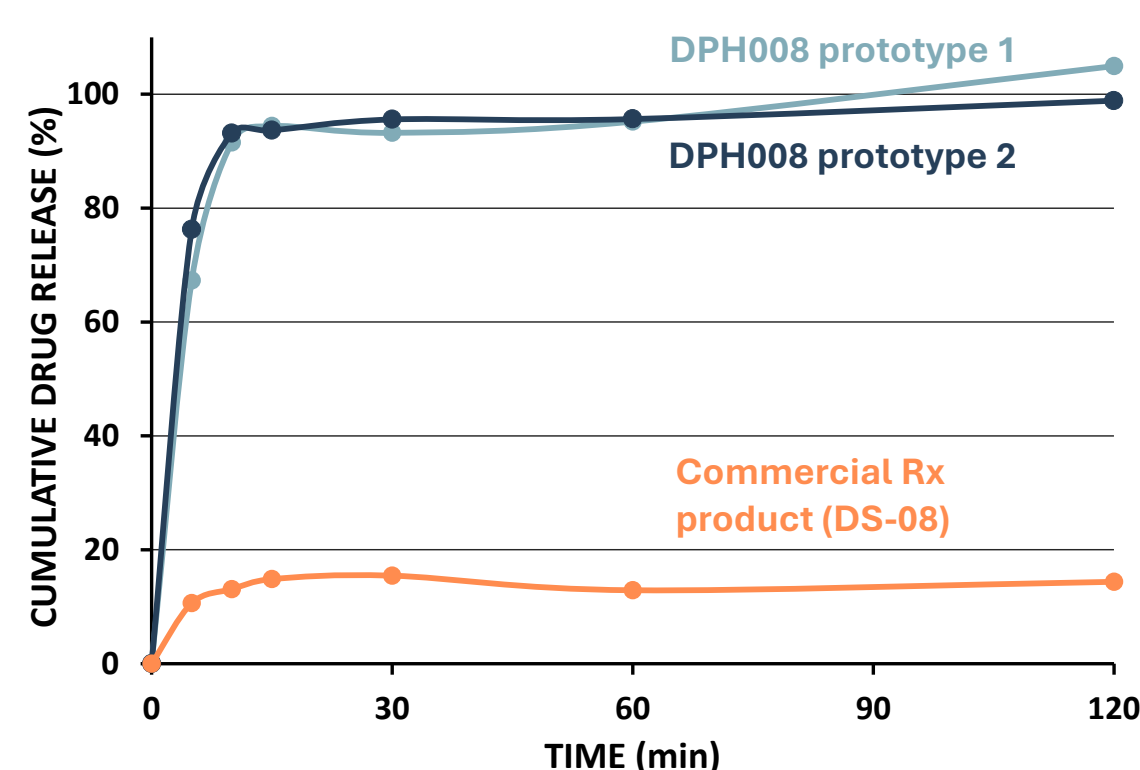
Fully compatible with standard OSD manufacturing

- Formulite® integrates seamlessly with established oral solid dosage manufacturing processes

TECHNICAL & CLINICAL VALIDATION

SIGNIFICANTLY ENHANCED DISSOLUTION PROFILE

DPH008 (Formulite® versions of DS-08) prototypes benchmarked against a marketed blockbuster formulation containing the same API



- DPH008 offers superior dissolution and complete drug release compared with commercial Rx product with DS-08

CONSISTENT BIOAVAILABILITY GAINS DEMONSTRATED IN RAT STUDIES

>30 different APIs successfully evaluated with Formulite®

API	Therapeutic area	PK: Formulite®-API vs Rx (% AUC increase)
Idelalisib	Oncology	159
Ibrutinib	Oncology	119
Rilpivirine	Antiviral	275
Sorafenib	Oncology	>200
Vismodegib	Oncology	267
DS-08	Oncology	167
DS-16	Oncology	162
DS-29	Autoimmunity	240

- Benchmarked against marketed blockbuster formulations
- Data on additional API examples within several therapeutic areas available upon CDA and open for partnering/co-development

HIGHER DRUG LOADING ENABLED IN FINISHED PRODUCT

Comparing XTANDI® with a Formulite®-based enzalutamide (ENZ) prototype

	XTANDI® Astellas/Pfizer	Formulite-ENZ Disruptive Pharma
Dose	40 mg	40 mg
Excipients	292 mg	70 mg
Tablet weight	332 mg	110 mg
Drug loading	12%	36%

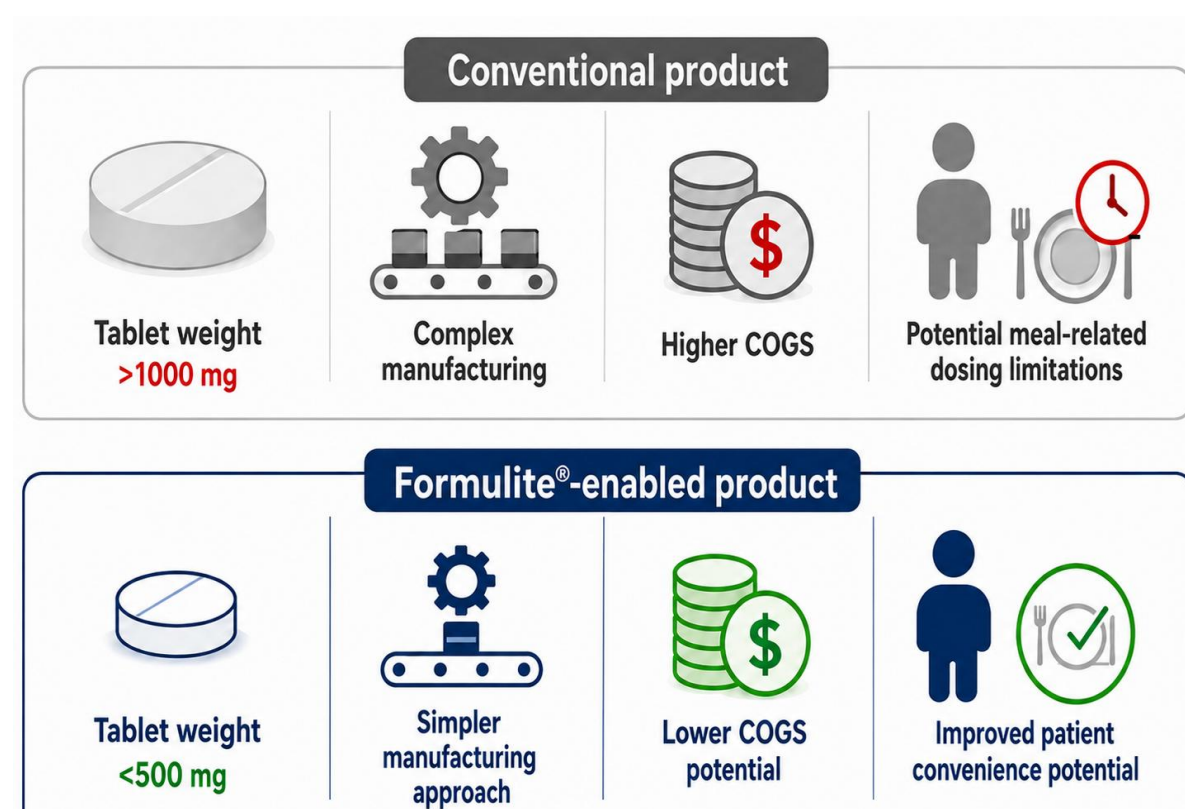
- Formulite-ENZ has higher drug loading compared with XTANDI® (a polymer-based ASD)
- Enables smaller tablets at equivalent dose
- Supports fixed-dose combination development

FORMULITE® CASE STUDIES

POSITIONED TO CREATE BLOCKBUSTER-SCALE VALUE

Formulite® is being evaluated by an international pharmaceutical company to optimize late-stage assets by reducing dose, simplifying manufacturing, and improving product performance, unlocking both clinical and economic value at scale.

Potential clinical and economic advantages of a Formulite®-enabled product



Addressing product limitations that drive cost, complexity, and patient burden for late-stage assets

- Overcoming insufficient bioavailability and poor dissolution
- Reducing tablet burden through higher drug loading in final product
- Lowering manufacturing complexity and cost
- Creating opportunities for dose optimization and lifecycle extension

FORMULITE® OFFERS MAJOR SOLVENT AND COST SAVINGS COMPARED WITH SPRAY DRYING

Case assumptions: 100 mg BCS II/IV compound, 100,000 units for pivotal study

