WHERE THE MONEY GOES: AMORPHOUS DISPERSION MANUFACTURING

As the number of molecules exhibiting solubility constraints has grown, so too has the utilization of amorphous solid dispersion (ASD) formulation strategies to improve the bioavailability of orally delivered small molecules. For more than two decades, spray drying has been the dominant platform for ASDs.

Pharmaceutical spray drying requires environmentally unfriendly solvents and vast amounts of nitrogen, large operational and physical footprints, and long production times. Additionally, as the product moves through the development stages and commercial demand increases, equipment scale changes are often needed. These drawbacks introduce scale-up and supply chain risk, as well as increased manufacturing costs.

KinetiSol™ Technology provides a better, faster and lower cost development and manufacturing path for many ASD molecules currently manufactured by spray drying. A solvent-free, fusion-based process, KinetiSol forms ASDs in seconds.

Its advantages compound across the development lifecycle. In early development, KinetiSol compresses prototyping timelines from months to weeks and enables a broader formulation design space that supports a wider range of polymers and excipients, as well as client IP generation. In clinical development, one equipment model supports Phase 2 through commercialization, minimizing or eliminating formulation drift and PK bridging studies due to consistent product properties. While these benefits accelerate early milestones, the true economic value of KinetiSol emerges at commercial scale, where efficiency, sustainability and commercial value drive competitive advantage.

To demonstrate the cost differences between KinetiSol and spray drying, in this case study, we compared the cost of manufacturing a commercially approved ASD drug made by spray drying and AustinPx's KinetiSol, then followed the money from prototype through commercial supply.

THE MODELED PRODUCT

PRODUCT

BCS Class IV oral small molecule (NNRTI), commercialized in 2008 as a spray-dried dispersion tablet (25, 100 and 200 mg tablets). Peak volume: ~5 metric tons ASD/year.

SPRAY-DRIED DISPERSION ASSUMPTIONS

Solvent: **Methylene chloride/ethanol**
Polymer: **Hypromellose (HPMC)**
Drug load: **~25% (1:3 drug to HPMC)**
ASD content in finished tablet: **50% w/w**
Solids load: **~5.4% w/w**
Liquid feed rate: **202 kg/hr**

KINETISOL DISPERSION RESULTS

Solvent: **None**
Polymer: **Hypromellose (HPMC)**
Drug load: **20% (1:4 drug to HPMC)**
ASD content in finished tablet: **75% w/w**
ASD production rate: **20 kg/hr**

Note: AustinPx successfully manufactured this product for Phase I clinical testing, PK bridging studies and multiple registration-scale batches (150 kg/batch). Additional details are available on request.

Modeled savings at commercial scale (US dollars)

$20M
annual cost of goods, spray drying

$12M
annual cost of goods, KinetiSol

30 to 40% lower cost of goods

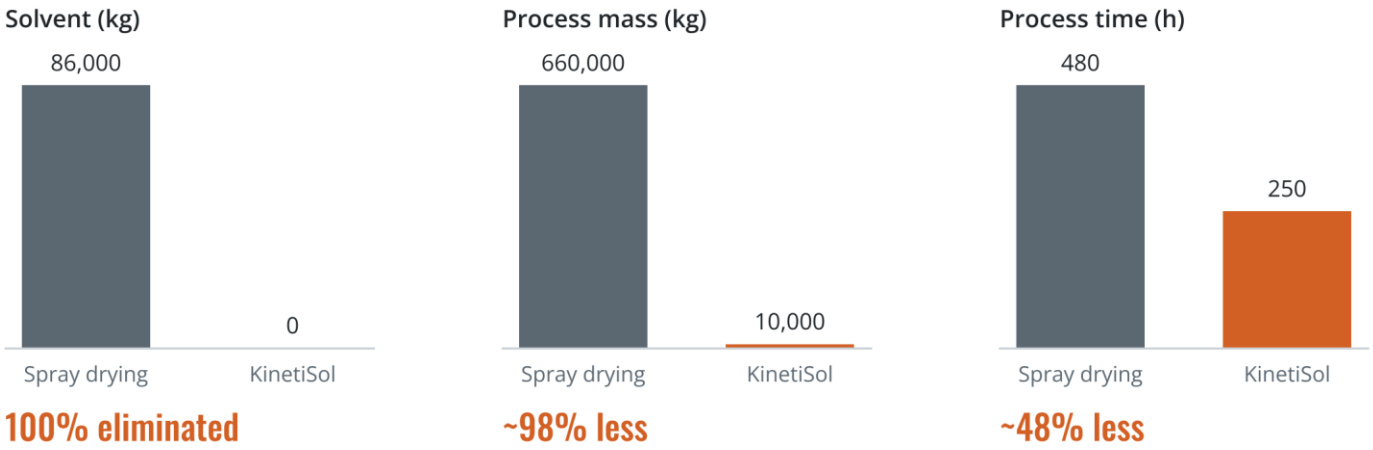
0 kg organic solvent, vs. 86,000 kg

8 months faster to market

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WHAT DRIVES THE DIFFERENCE

More than 85% of a spray-dryer feed is solvent. That solvent must be bought, stored, evaporated, condensed, and recovered. KinetiSol is solvent-free. What goes in, comes out and processing time is cut in half.



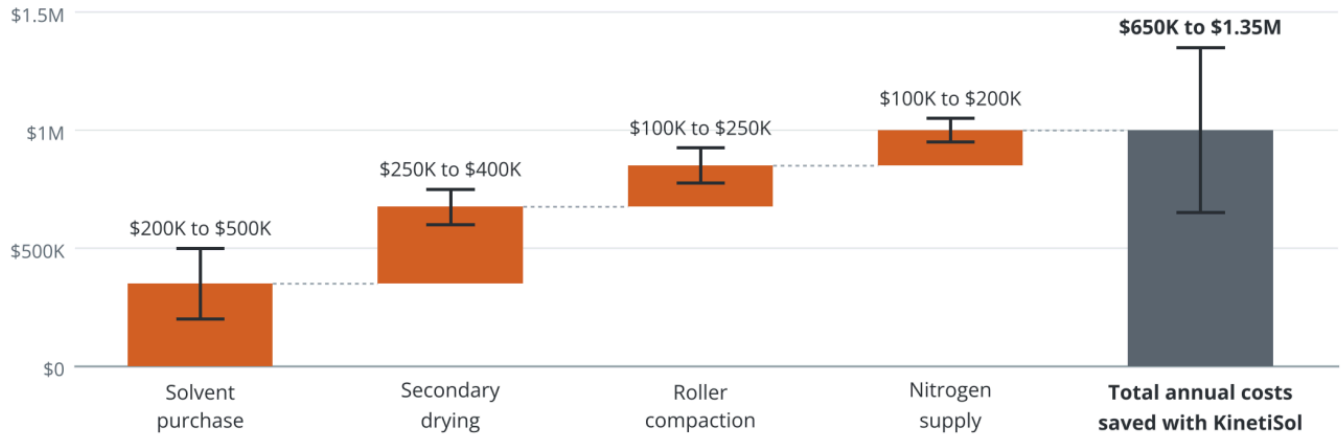
THREE SPRAY DRYING STEPS ELIMINATED

Due to KinetiSol's solvent-free process and dense and flowable particle properties, resulting KinetiSol ASDs move straight to milling and blending prior to compression, reducing processing steps, time, and risk, compared to spray dried dispersions, which required secondary drying and dry granulation.



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ANNUAL COSTS ELIMINATED BY KINETISOL



Each bar shows the midpoint of its estimated range, and the lines show the low and high estimates.

30 to 50% lower energy cost

KinetiSol forms ASDs with no solvent to evaporate, condense and recycle and no nitrogen to generate, store, and recover, removing the energy and cost of both.

Standard GMP Suite

KinetiSol is compact, mobile and requires only chilled water and power, allowing it to be rolled into a pilot scale manufacturing suite.

BEFORE COMMERCIAL: FEWER TRANSFERS, FEWER SURPRISES

As the product scales, a spray dried dispersion typically moves to a larger spray dryer between clinical phases, and each move can shift particle morphology and performance. KinetiSol scales with continuous run time or parallel unit configuration instead, minimizing scale up events from preclinical to commercial launch.

Metric	Spray drying	KinetiSol	Why it matters
Time to tablet prototype	6 to 8 weeks	**4 weeks**	Earlier first-in-human start
CTM manufacturing	Weeks/batch	**Days/batch**	Faster clinical supply
Tech transfer events	2 to 3	**1**	Hundreds of thousands to millions avoided in development and validation events
PK bridging studies	Likely	**Rare**	Fewer added clinical studies
Time to market	30 months	**22 months**	~8 months sooner to revenue

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THE BIGGER LEVER: LIFETIME VALUE

A broader formulation design space can support drug product patents that extend exclusivity.

Modeled lifetime value advantage (US dollars)

~$500M	+	$50M to $100M	=	$550M to $600M+
IP-extended revenue, 5 years past API loss of exclusivity		Lifetime operating savings		Total lifetime value advantage

THE TAKEAWAY

> **The ASD route chosen at feasibility sets the cost of goods for the life of the product. In this model, KinetiSol cut annual cost of goods from $20M to $12M, removed three processing steps and reached market 8 months sooner. Evaluating it early, before a spray drying process is locked in, keeps those savings on the table.**

Compare routes for your molecule

AustinPx develops ASDs by KinetiSol, spray drying and hot melt extrusion. Bring us your molecule at feasibility, and one team can evaluate the options side by side before your process is locked in.

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ABOUT AUSTINPX

AustinPx is a contract development and manufacturing organization (CDMO) providing analytical and formulation development services and cGMP manufacturing for small molecule drugs. The Company specializes in phase-appropriate development strategies, speed to clinic and market strategies, and bioavailability enhancement of poorly soluble molecules, including its next generation, fee-for-service, amorphous dispersion platform, KinetiSol™. For more information, visit **AustinPx.com**.

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