

BEYOND SOLVENTS: THE FUTURE OF SUSTAINABLE AMORPHOUS DISPERSION DEVELOPMENT

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Sustainability in pharmaceutical manufacturing is often positioned as an environmental objective, with emphasis on reducing solvent use and minimizing waste. While important, this does not fully capture what sustainability represents at a system level. For development and commercial leaders, sustainability is increasingly evaluated through its impact on cost, risk, and timelines, as these factors ultimately determine sustainable asset value. The most meaningful strategies are those that eliminate inefficiency within the manufacturing process, allowing resources to be directed into the product rather than lost in production.

The Hidden Cost of Complexity in ASD Manufacturing

Solvent-based amorphous solid dispersion (ASD) technologies have long enabled poorly soluble molecules, but they introduce operational complexity beyond formulation. These processes rely on large volumes of solvent, meaning a significant portion of material entering the system does not become product and instead must be removed, recovered, and managed. This creates a system where time, energy, and infrastructure are required but end up in waste stream. In simple terms, money is being put into the process that never becomes product. These inefficiencies increase the cost of both the product and the process used to make it. At the same time, added dependencies on materials, equipment, and processing steps increase the risk of variability, delay, and disruption. As programs scale, these issues compound, increasing material use, extending timelines, and elevating supply chain risk. The amorphous dispersion manufacturing technology therefore directly contributes to long term sustainability of the product.

A Simpler Model for ASD Manufacturing

KinetiSol™ Technology addresses this inefficiency by simplifying the system at its source. As a solvent-free, fusion-based process, KinetiSol eliminates solvent usage and the need for recovery, secondary drying, and supporting infrastructure (figure 1). Instead, what goes into the system comes out in the product. By reducing process steps, minimizing infrastructure, and removing unnecessary dependencies, KinetiSol creates a more direct and efficient manufacturing pathway.

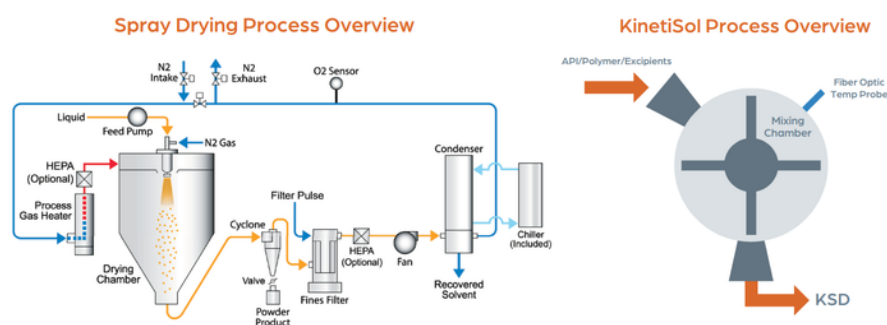


Figure 1: Equipment Processing Complexity of Spray Drying vs KinetiSol

Sustainability as a Driver of Cost, Time, and Risk Reduction

When inefficiency is removed, sustainability becomes a measurable driver of business performance. Based on an internal analysis of commercialized ASD products, KinetiSol can improve operational and environmental footprint by up to 87% while lowering commercial ASD manufacturing costs by

approximately 30% to 50%. These savings extend beyond cost. Simplified processes reduce variability, improve reliability, and accelerate development timelines. The result is a system that operates with flexible throughput and higher predictability, allowing both time and capital to be reinvested into advancing the product.

Scalable by Design, Not by Redevelopment

Traditional ASD processes often introduce additional complexity during scale-up, requiring changes in equipment, configuration, or formulation. These transitions extend timelines and introduce additional risk, as each stage demands further optimization and validation. KinetiSol avoids this by maintaining a consistent operating principle from early development through commercial manufacturing. Scale is achieved by adjusting throughput (up or down) rather than scaling across multiple sizes of equipment. This reduces scale-up burden, shortens timelines, and creates a more efficient path to commercialization and lifecycle management.

Supply Chain Resilience

Simplifying the manufacturing system also reduces reliance on energy-intensive steps and external supply chains. Eliminating solvent evaporation and recovery lowers energy demand, while removing solvent input reduces dependence on external materials and logistics. This creates a more resilient manufacturing model with fewer points of failure, improved operational control, and reduced exposure to disruption, supporting a more stable path to market.



Figure 2: Solvents represent risk to supply chain & environment

Sustainability as a Driver of Asset Value

Today, asset value is shaped by more than product performance alone. It is also influenced by how efficiently a product can be developed and manufactured. Sustainability creates value when it removes the waste, complexity, and inefficiency that add cost and risk to development and manufacturing. By eliminating solvents, simplifying the process train, reducing operational burden, and supporting a smoother path to scale, KinetiSol lowers cost, shortens timelines, and improves predictability.

Re-Imagining Sustainable Amorphous Dispersion Development

Sustainability in ASD development is not just about a greener footprint. It is about reimagining how amorphous dispersions are developed and manufactured. Imagine a process that eliminates solvents, simplifies manufacturing, eases scale-up, reduces operational burden, and creates a more predictable path to market. KinetiSol brings those advantages together in one platform, showing that sustainability can do more than reduce environmental impact. It can lower cost, reduce risk, strengthen supply resilience, and create greater long-term asset value.

See how AustinPx is helping teams reimagine ASD development: www.austinpdx.com/kinetisol

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