AUSTINPx™

PHARMACEUTICS / MANUFACTURING

KinetiSol™ Technology: A Sustainable and Efficient Revolution in Bioavailability Enhancement

The pharmaceutical industry is pushing the chemical drug space boundaries in search of new and more effective compounds. Consequently, the number of poorly soluble drugs has grown. To meet the challenge of poor solubility, pharma has developed processing technologies for the next generation of amorphous solid dispersions (ASDs). However, several ASD technologies utilize organic solvents, namely spray drying. These solvents can have a significant environmental impact, as well as greater manufacturing complexity and costs. AustinPx's KinetiSol™ Technology has enabled the development of ASDs without the use of solvents, often with improved bioavailability facilitating lower doses compared to alternative ASD methods.

The pharmaceutical industry, responsible for life-saving innovations, faces growing scrutiny for its environmental impact. With emissions exceeding those of the automotive and aviation sectors, pressure to adopt sustainable practices is increasing. Yet, these demands often conflict with the need for speed, efficiency, and quality in drug development. AustinPx's KinetiSol™ Technology bridges this gap by offering a sustainable and highly efficient alternative for enhancing the bioavailability of poorly soluble drugs.

The Inefficiencies of Spray Drying

Pharmaceutical spray drying, the most common method for producing amorphous solid dispersions (ASDs), is rife with inefficiencies. The spray drying process relies on organic solvents, consuming an estimated 8,000 metric tons of solvent annually and generating millions of liters of hazardous waste. Additionally, due to the growing issue of poor solvent solubility, researchers are turning to more toxic organic solvents, such as tetrahydrofuran (THF) and dichloromethane (DCM), for many new chemical entities. Which only adds to the supply chain, safety and environmental risk of the drug's manufacturing process.

The environmental impact is further compounded by the need for multi-story facilities, secondary drying, and complex nitrogen, solvent, and waste management systems. These inefficiencies create operational bottlenecks, increase costs, and prolong development timelines, all while contributing to environmental degradation.

Figure 1: *Solvents represent risk to supply chain and environment*

KinetiSol: A Game–Changer in Efficiency and Sustainability

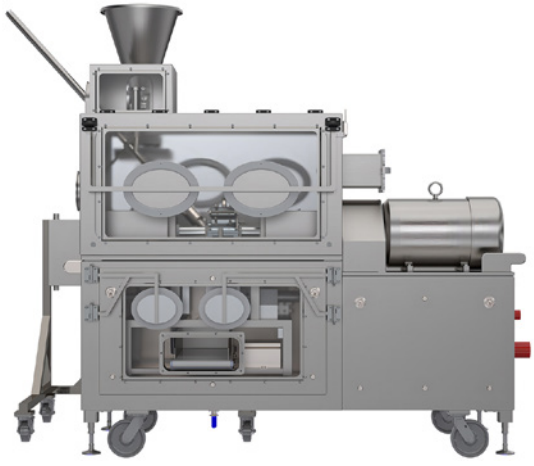

Figure 2: KinetiSol Commercial Scale Equipment

KinetiSol eliminates these inefficiencies through a solvent-free, fusion-based process that combines sustainability with operational and bioavailability advantages. By leveraging high-speed mixing (up to 7,000 RPM), KinetiSol achieves rapid, uniform blending of APIs and excipients in as little as 10 seconds.

Unlike spray drying, KinetiSol requires a compact operational footprint (Figure 2). At just 8' x 12', KinetiSol's large scale equipment integrates easily into pilot-scale manufacturing facilities. Additionally, due to the simple design of the equipment, it bypasses the need for nitrogen and secondary drying, significantly reducing the operational infrastructure required to support production (Figure 3 and 4). These features streamline manufacturing, simplify scale-up, and significantly cut costs, offering pharmaceutical companies a distinct edge in bringing drugs to market.

KinetiSol's efficiency supports the pharmaceutical industry's shift toward sustainability. By eliminating solvents and nitrogen requirements, KinetiSol reduces waste, waste, and emissions. The process's streamlined design further minimizes maintenance, operational support, and environmental impact.

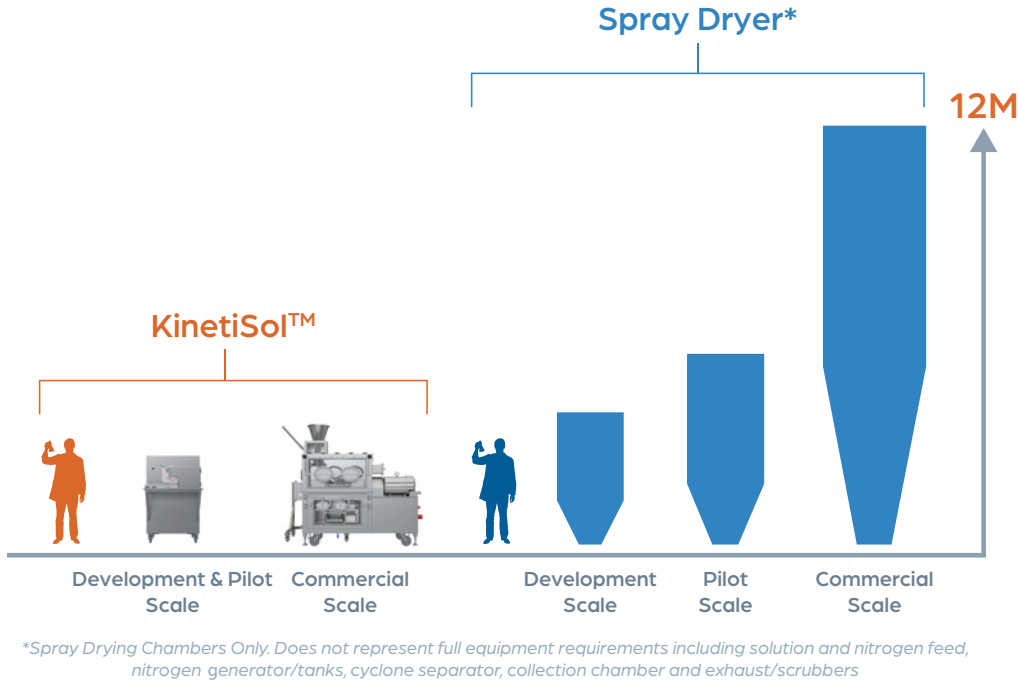

Figure 3: Equipment Footprint Comparison of KinetiSol to Spray Drying

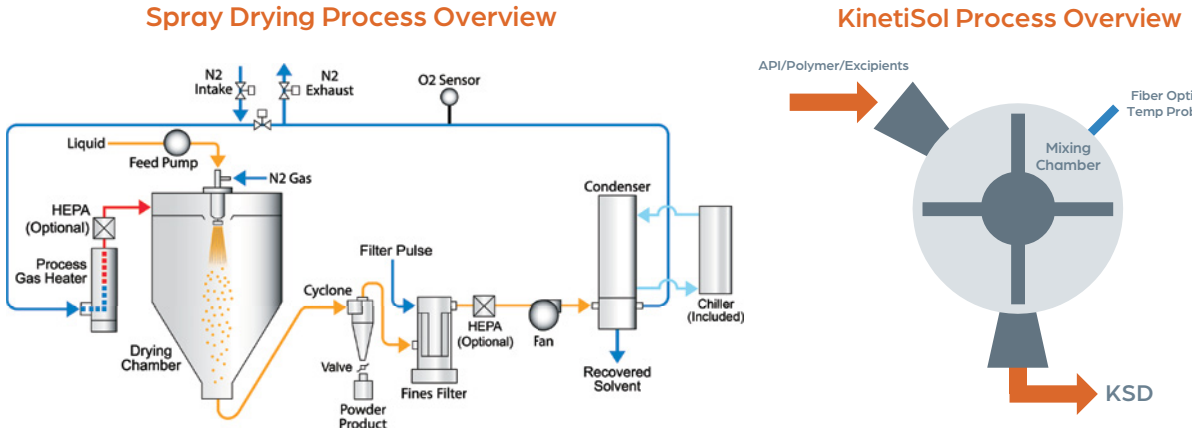

Figure 4: Equipment Processing Complexity of KinetiSol to Spray Drying

Performance–Driven Innovation

KinetiSol's fusion-based process is not only efficient but also versatile, accommodating a wide range of APIs, including those with high melting points or sensitivity to heat. Its high-energy mixing mechanism minimizes thermal stress, ensuring stability even for high melting point compounds.

Additionally, the resultant KinetiSol solid dispersion (KSD) offers superior performance:

- **Improved bioavailability:** KSDs consistently outperform spray-dried dispersions (SDDs) in enhancing solubility and drug exposure (Figure 5).
- **Optimized manufacturability:** The high-density, low-surface-area particles (Figure 6) created by KinetiSol improve stability, reduce water ingress, and simplify downstream processes like tablet compression.
- **Patient-centric dosage forms:** Due to the characteristics of the resulting particles, KSD offers higher ASD loading into the final dosage form leading to pill burden reduction.

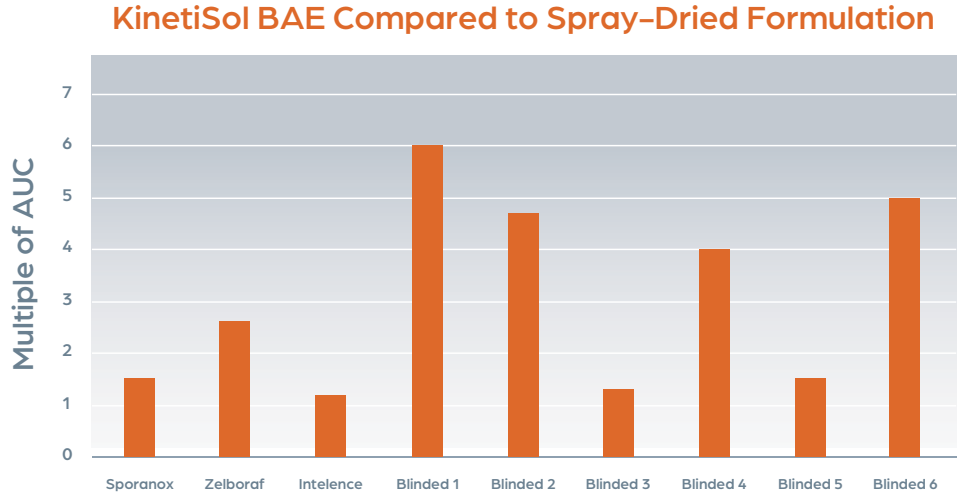

Figure 5: Oral bioavailability enhancement (BAE) achieved by KinetiSol over SDD formulations

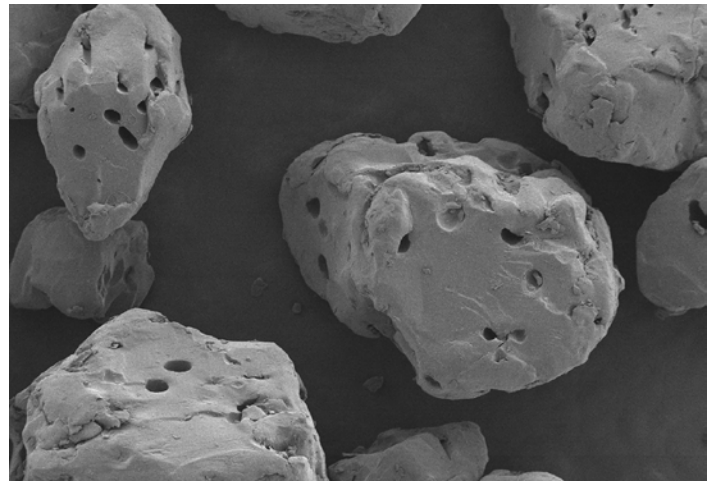

Figure 6: SEM of KinetiSol Particles

Accelerating Sustainability Goals

KinetiSol proves that efficiency and sustainability can go hand-in-hand, ensuring that pharmaceutical innovation continues to advance without compromising the product's performance, the planet or development timelines.

Since its launch, KinetiSol has been applied to over 60 molecules, enabling partners to align with carbon footprint-reduction goals, while maintaining competitive timelines and lower cost structures. Its ability to combine environmental responsibility with development efficiency makes it an invaluable tool for today's pharmaceutical landscape. As the pharmaceutical industry grapples with growing environmental challenges and rising efficiency demands, KinetiSol Technology offers a proven path forward.

For more information about KinetiSol visit austinpx.com/KinetiSol