AUSTINPx™

CHOOSING THE BEST AMORPHOUS DISPERSION PATH BEFORE IT COSTS YOU

Avoid timeline delays, wasted API, contracting and vendor management headaches, and added development costs by screening multiple technologies in parallel with a single expert team.

Executive Summary

A growing number of oral small molecules require amorphous solid dispersions (ASDs) to address poor solubility, low exposure, food effect risk, or dose form challenges. The leading ASD technologies, including spray drying, hot melt extrusion, and KinetiSol™ Technology, each have a place in development, but sponsors often evaluate them sequentially or separately, across different vendors. This fragmented approach causes costly delays and makes formulation development more expensive and challenging than working with a single provider to screen all technologies in parallel.

AustinPx offers a more efficient path. As the only CDMO able to screen and develop all three leading ASD technologies under one roof, AustinPx gives sponsors a faster, more practical approach to choosing a formulation strategy that supports performance, manufacturability, and long-term product value.

Comprehensive ASD Screening Prevents Costly Rework

Modern small molecule pipelines increasingly demonstrate solubility, food effect, and stability challenges. These challenges can affect *in vivo* performance, dose design, pill burden, manufacturability, and scalability.

When a molecule is challenging to formulate, choosing a path based on one technology screen can be risky. A single prototype may appear acceptable during *in vitro* and initial animal PK testing, but present challenges later with human exposure, stability, dose form design, and scale-up. Once advanced through early clinical trials, changing direction to evaluate alternative strategies means more API, increased analytical testing, vendor transfer costs, and lost time.

Why One May Not Be Enough

Your ASD screening study should help determine whether your chosen formulation strategy is developable over the long-term. Can it maintain performance while accelerating timelines, and enabling dose form design, patient requirements, long-term stability, scale-up, and supply chain demands? When only one ASD technology is evaluated, sponsors may get a minimally viable result without knowing if another approach offers a stronger balance of performance, manufacturability, cost, and reduced risk.

Each molecule is unique and responds differently to each ASD technology. For example, a molecule may be limited by solvent solubility in one approach, thermal sensitivity or drug loading in another, or stability and downstream processing challenges that only emerge during scale-up and later phase testing. The available formulation space also varies. And some molecules may require a wider range of polymers and excipients to construct a viable and optimal formulation.

Comparing all three ASD technologies together functions as an efficient and cost-effective path forward,

establishing early the pros and cons of each technology against the sponsor, molecule and patient population's specific needs. Without that broader view, sponsors may commit time and money to a formulation strategy that creates downstream vulnerabilities in performance, stability, manufacturability, and long-term asset value.

The Value of Parallel Screening with One Expert Team

Screening multiple ASD technologies in parallel with one provider gives sponsors more than operational simplicity. It creates a stronger technical foundation for decision making because the same team builds institutional knowledge around the molecule, its liabilities, and how it responds across formulation approaches.

ASD development requires a deep understanding of how solid-state properties, dissolution behavior, stability, excipient selection, particle characteristics, and manufacturing conditions can affect clinical performance, GMP readiness, downstream scale-up, cost, and long-term asset value. Equitable *in vitro* and *in vivo* performance comparisons across the technologies and data analysis improves when performed by the same project team with a comprehensive ASD knowledge base. The goal is not to force every molecule into one technology, but to identify the best amorphous dispersion strategy before time and money have been spent on a less viable strategy.

Additionally, a single provider streamlines outsourcing management, simplifying contracting, project communication, and vendor management, while also eliminating facility-to-facility technology transfer costs.

Conclusion

AustinPx's amorphous dispersion experience spans more than 100 molecules, supported by a clinically experience team with a broad set of analytical tools and hands-on manufacturing expertise. Comprehensive and parallel ASD screening with AustinPx helps sponsors make smarter formulation decisions earlier before the program becomes harder, slower, and more expensive to change after clinical testing. Together, this translates into accelerated timelines and reduced development costs.