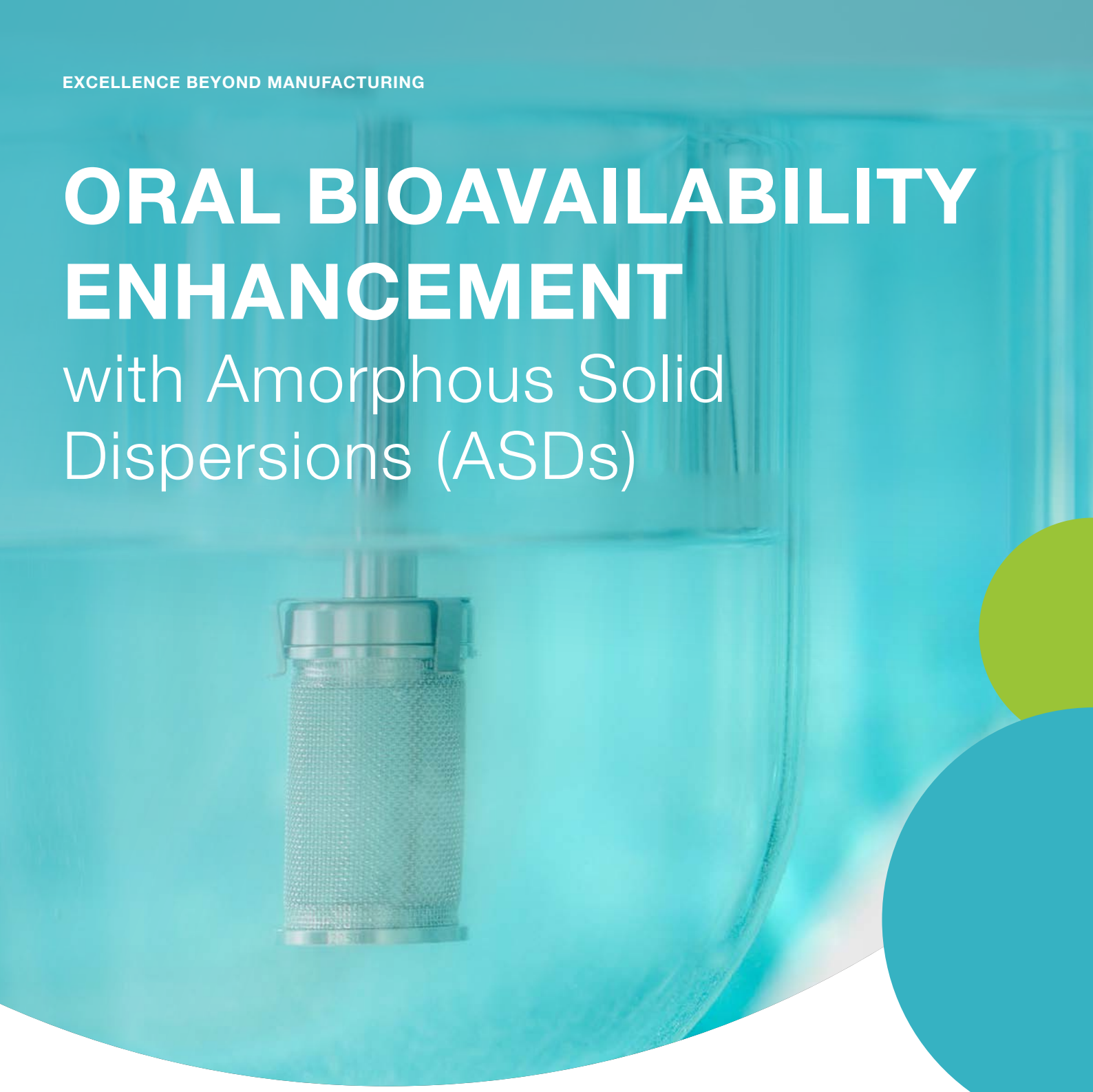
EXCELLENCE BEYOND MANUFACTURING

ORAL BIOAVAILABILITY ENHANCEMENT

with Amorphous Solid Dispersions (ASDs)



We improve API Bioavailability to Enable Therapeutic Breakthrough

The majority of modern drug candidates suffer from low solubility and permeability, limiting their bioavailability and withholding innovative therapeutic potential from patients. Aenova leverages science-based formulation strategies to enhance solubility and achieve the right efficacy for your drug.

- Ca. 80% of preclinical compounds face bioavailability challenges[1]
- Amorphous solid dispersions (ASDs) improve solubility and absorption
- Optimized formulation speeds up time to clinic and to patients

[1] Nikolakakis et al., Pharmaceutics 2017;9:50 and Ting et al., Bioconjug. Chem. 2018; 29:939-952

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FAST & EFFICIENT BIOAVAILABILITY ENHANCEMENT

Maximizing the Potential of Your Drug Candidate

Around 80% of preclinical compounds today are estimated to have bioavailability challenges[1]. Oral dosage forms of poorly water-soluble, slowly absorbed drugs tend to be most affected, often due to insufficient time for absorption in the gastrointestinal tract. As a result, considerable time and effort can be spent to overcome developability issues of a compound, which in turn can increase time to clinic and market.

[1] Nikolakakis et al., Pharmaceutics 2017;9:50 and Ting et al., Bioconjug. Chem. 2018; 29:939-952

Aenova speeds up development with economical use of your API

Our experts apply science-based rationales to select first-time-right formulation routes

We are passionate about delivering your drug candidate to patients with the utmost efficacy and care

AMORPHOUS SOLID DISPERSION (ASD)

Aenova's Bioavailability Technologies

As a leading Contract Development and Manufacturing Organization, Aenova offers a broad range of bioavailability enhancement technologies. Amorphous solid dispersion (ASD) is one of these highly successful formulation strategies.

- Drug is dispersed in a carrier or polymer matrix and converted to an amorphous state using solvent or melting technique
- Improved drug solubility and dissolution rate
- Drug release profile tailored to your specific requirements

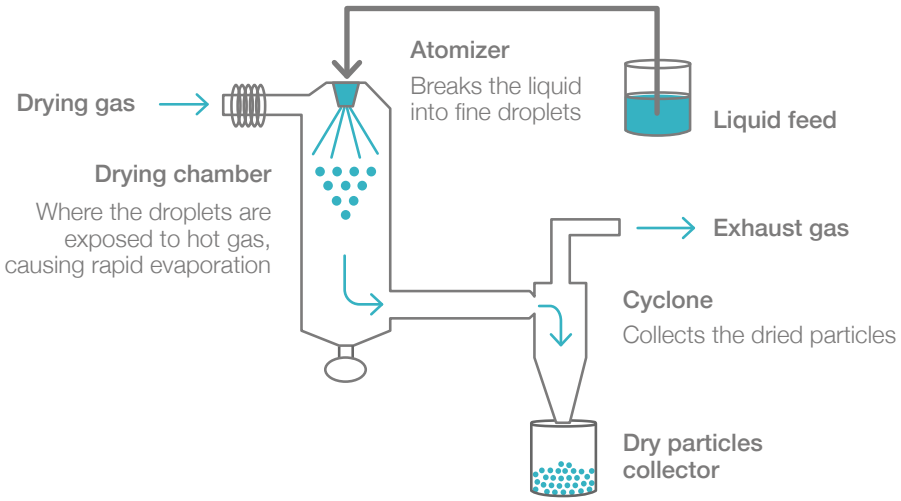
Common methods for preparing ASDs include **spray drying** and **hot melt extrusion**. Each technique has its advantages and is chosen based on the drug's properties and the desired characteristics of the final product.

ASD MANUFACTURING TECHNIQUES

Spray Drying

Spray Drying is one of Aenova's highly effective technology solutions for oral bioavailability enhancement. It involves converting a liquid or slurry into a dry powder by rapidly drying it with a hot gas.

Process Overview



Aenova Spray Drying Technology & Equipment

Aenova offers a state-of-the-art Spray Drying setup with laboratory and pilot scale equipment by renowned manufacturers Büchi and GEA in a dedicated area.
At our Killorglin site in Ireland, we combine the decades-long experience of our subject matter experts with top-notch equipment and research cooperations with leading universities in the field.

Technology & Equipment

- Laboratory scale for development
- GMP equipment (GEA), APIs up to OEB 4 (OEL > 1 µg /m^3)
- Organic solvents handling
- University collaborations for access to the latest developments and research specialists, enabling us to find innovative solutions for complex processes and formulations
- Full set of analytical methods in-house

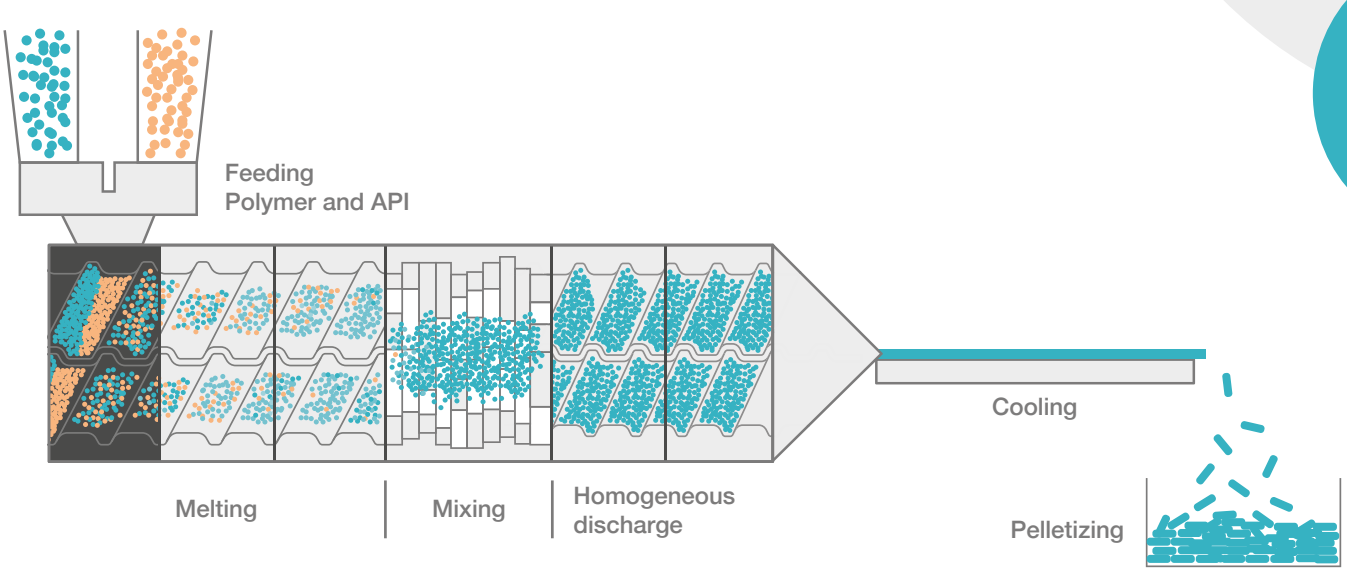
ASD MANUFACTURING TECHNIQUES

Hot Melt Extrusion

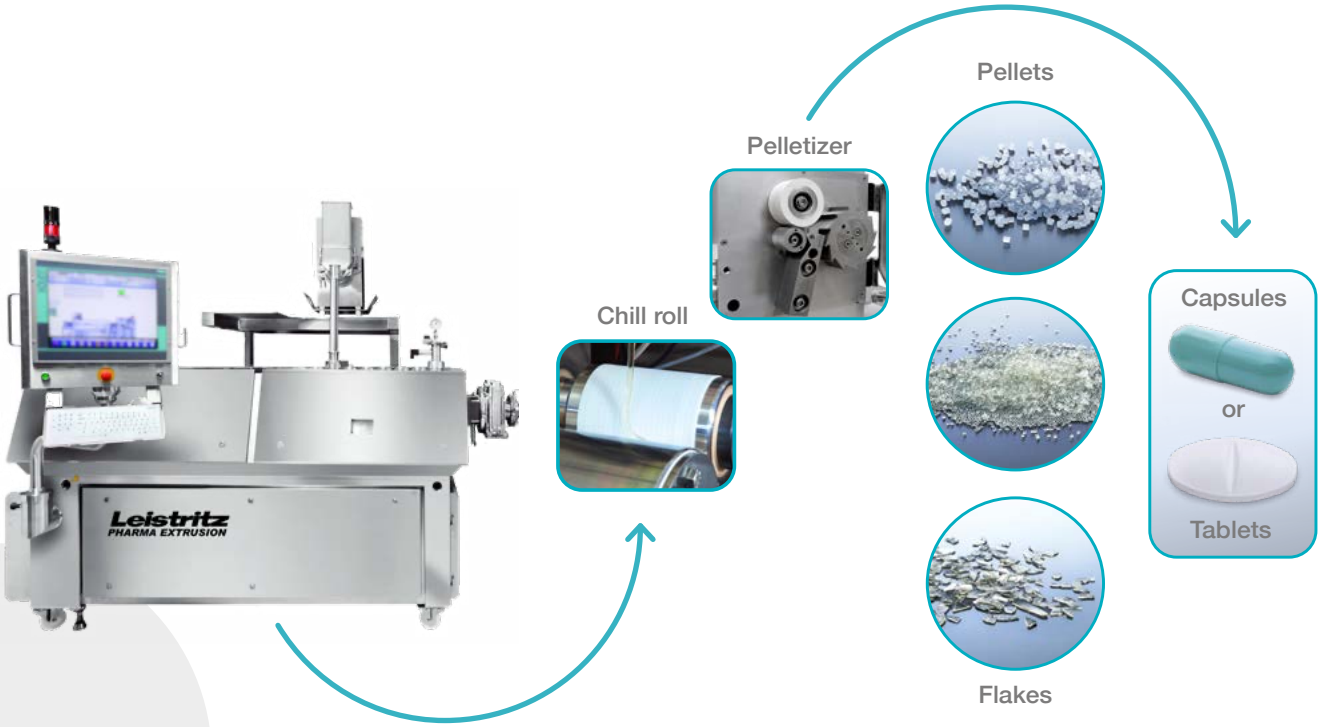
Hot Melt Extrusion (HME) is one of Aenova's highly effective technology solutions for enhancing an API's bioavailability and making it more effective for therapeutic use.

- Drug and polymer/excipients are intensely mixed at high shear rate, followed by melting and mixing which converts crystalline API into amorphous state (amorphous solid dispersion).
- The amorphous state of a drug shows enhanced solubility versus a crystalline state.
- The extrusion process can also produce particles with a larger surface area, which further improves the dissolution rate of the drug.

Process Overview



Aenova CDMO Hot Melt Extrusion Setup



Aenova Hot Melt Extrusion Technology & Equipment

Aenova offers cutting-edge equipment by leading manufacturer Leistritz, with the ability to scale seamlessly on the same type of equipment throughout the clinical phases.
To ensure the best possible effect and consistent product quality, the right choice of polymer and careful control of parameters such as temperature, screw speed, and pressure are crucial. With several hundred years of combined experienced between them, Aenova's formulation specialists at our hot melt extrusion Center of Excellence are sure to find a custom solution for your project.

Technology & Equipment

- Simulation with minimal API consumption
- Laboratory scale for development
- GMP equipment (Leistritz), APIs up to OEB 5 (OEL < 1 µg/m^3)
- Collaboration with equipment specialist Leistritz
- Full set of analytical methods in-house

Customized end-to-end development services, reliably delivered

Amorphous solid dispersions are a powerful tool in modern pharmaceutical development, enabling the formulation of high-quality, effective, and patient-centric medications. While their development and manufacturing can involve technical complexities, partnering with the right expert makes all the difference.

Aenova offers deep expertise and state-of-the-art capabilities in spray drying and hot melt extrusion to support your project at every stage. From early-phase development to pilot scale, we provide seamless, end-to-end contract services that accelerate your development journey and ensure a smooth, reliable process throughout.

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