



Particle Engineering

Particle Engineering Tool Box

Hovione offers a number of innovative Particle Engineering technologies, at all scales, to address recent challenges in drug delivery, including oral bio-availability, lung delivery, modified release and

taste masking. In each technology we can support you from proof of concept to commercial manufacturing.

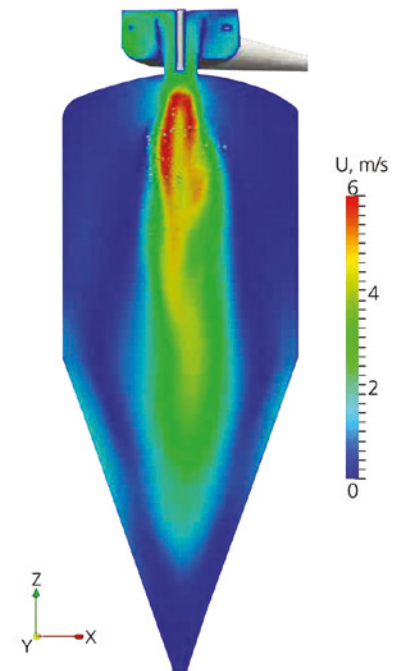
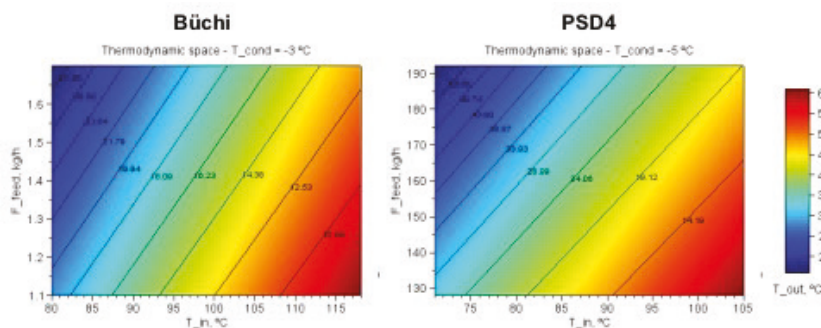
TECHNOLOGIES	SOLUTIONS				
	SOLUBILITY	ENHANCED DELIVERY*	PATIENT ACCEPTABILITY	MODIFIED RELEASE	PERMEABILITY
Spray Drying	☺	☺	☺	☺	☺
Hot Melt Extrusion	☺		☺	☺	☺
Wet Polishing	☺	☺	☺		☺
Jet Milling	☺	☺			
Co-precipitation	☺	☺		☺	
Spray Congealing	☺		☺	☺	☺

*Enhanced delivery by non-oral routes of administration including lung delivery.

Enhanced Process Understanding

Hovione Particle Engineering utilizes state-of-the-art modeling technologies to deliver industry-leading drug development solutions.

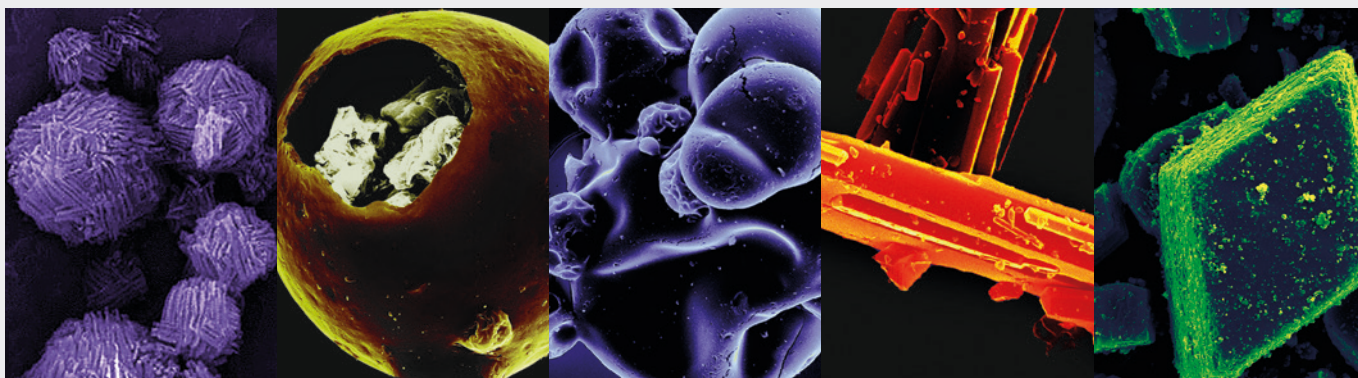
Modeling allows scale-up from small to commercial equipment.



Rely on Hovione Particle Engineering to Deliver Optimal Solutions

Hovione has more than a decade of accumulated experience and knowledge in Particle Engineering process development and scale-up.

Our multidisciplinary development teams combine science and management to reduce risk and time-to-market.



Broad set of solutions

We deliver improved solubility, bioavailability, patient acceptability, modified release and enhanced delivery by way of a broad range of technologies. Having access to a comprehensive range of technologies maximizes your probability of success.

From grams to tons

Reduce the risk and time with access to technologies from development to commercial scale. Having been involved in over 100 scale-up projects, Hovione has successfully supported numerous process validations and regulatory submissions with subsequent marketing authorizations. Our Particle Engineering manufacturing assets are spread over three sites (Cork, Loures, New Jersey) and range from pilot to very large scale equipment. We can also handle highly potent compounds.

Strong technical capabilities

Hovione's team of scientific and engineering experts brings a unique set of skills and experience for solving drug delivery problems.

From Drug Substance to Drug Product Intermediate to Drug Product

Our integrated services provide the opportunity for backward and forward integration, from clinical development to small commercial scales, within a single supplier.

Commercial supply

Our extensive manufacturing capacity provides the ability to dual source within the organization. There's the added assurance of our company's legacy of more than 55 years as a privately held organization with an impeccable quality and compliance track record, stable management and solid financials. All of our sites are FDA inspected and we have no warning letters.

Efficient time-to-market

Proven development methodologies and in depth engineering principles - including QbD, DoE, process modeling and more - enable efficient problem solving.

The Leader in Spray Drying

Combining the largest capacity, the best scale-up science and the most experienced team, you can trust Hovione to take your project from development to market.

Spray Drying is a continuous process that can be used for multiple applications. Over the last decade, the technology has been used for the production of solid dispersions to overcome the solubility issues related to oral drugs. It is also relevant to inhalable particles, specialty excipients and for the isolation of thermally labile products.



Development by Design™

Development by Design is a systematic methodology that involves the use of predictive tools, scale independent correlations and prior knowledge. Hovione can achieve a great balance between cost and risks and reduce the experimental burden of multiple scale-up stages by focusing resources where and when they are really needed. As a result, the time and material needed to establish an effective commercial scale spray drying process are significantly reduced.

Today we can have a commercial scale process within six months and thus deliver novel medicines to the market faster.

Impact of Hovione's Development by Design approach to spray drying process development	QbD APPROACH 2007-2013	TODAY UNDER DbD
# Runs at full scale	~ 60	~ 9
Material needed	~ 200Kg	~ 40Kg
Days at full scale	~ 4 weeks	~ 4 days

Integrated Offering

Drug substance

Hovione focuses on developing processes and GMP compliant manufacturing of active pharmaceutical ingredients. With a greater than 55-year track record of demonstrated performance, our technical staff has the know-how required not only to develop robust, efficient processes but also the ability to clearly prioritize the work flows throughout any phase of development for the NCEs. Hovione Drug Substance manufacturing capacity spans over four FDA-inspected sites on three continents. With over 1 000m³ of vessel capacity, we have the flexibility to accommodate our customers' products, whether they are low volume orphan drugs or the next large volume blockbusters.



Drug product

Hovione's expertise used to develop complex API synthesis and world-leading particle engineering approaches is now also applied to inhalation and oral dosage form drug product manufacturing.

Hovione offers a fully integrated service for clinical and small commercial scale complex drug product development and manufacturing. Customers can benefit from compressed timelines and seamless project management by having all activities performed by the same partner at the same site.

Inhalation capabilities:

- Highly potent products handling
- Low dosage/High yield capsule filling
- MultiNett 100% net weight verification

Oral dosage capabilities:

- Roller Compaction
- Tableting
- Tablet Film Coating
- Highly potent products handling





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