

Drug Substance

Mastering complexity with confidence

Hovione is home to challenging chemistries for over +65 years, combining complex molecule mastery with accelerated execution. Across every scale and stage, from substance to product, we make the difficult feel seamless.



Global API site network

Built-in backup capacity to secure supply



R&D global ecosystem

Shared know-how to de-risk scale-up



One-Site-Stop[®]

Drug Substance to Drug Product integration



40+ FDA inspections

Flawless regulatory track record over four decades



Contact our experts today to bring sustainability into your development journey from the very start

One partner to keep your molecule moving at pace

Accelerate your path to NDA/MAA submission

Ensure reliable scale up and faster market entry

Early stage

Process development and optimized regulatory support
Flexible infrastructure

Clinical supply

Process optimization and registration
Development mirror manufacturing capabilities
High potency capabilities (down to $1\mu\text{g}/\text{m}^3$)

API manufacturing

Expertise in small and large scale API manufacturing
Seamless transition from clinical to commercial
Technology transfer and life cycle management expertise

Differentiated API competences to unlock the potential of your project

Complex reaction capabilities

Organometallic and cryogenic (down to $-100\text{ }^\circ\text{C}$)
High pressure and hydrogenation (up to 85 bar)
Carbohydrate chemistry and amide bond formation

Advanced purification techniques

Membrane purification (UF, DiaF, NF)
Ion exchange purification
Metal catalyst remediation

Solid form and particle control

Controlled crystallization
Spray drying and particle engineering
Micronization

Special API

Corticosteroids (dedicated facilities)
High potent APIs (down to $1\mu\text{g}/\text{m}^3$)
Small, medium and large scale API production

World #1 global API network with downstream integration to offer supply chain security and operational continuity

New Jersey, USA

- Early stage and clinical supply
- Scale up | Small volume API
- Commercial supply: 4 - 3,000 L
- High potency API (down to $1\mu\text{g}/\text{m}^3$)
- Cryogenic, hydrogenation and organometallic capabilities
- **API, Particle Engineering***

Cork, Ireland

- Early stage and clinical supply
- Scale up | Large volume API
- Commercial supply: 2,500 - 16,000 L
- Cryogenic and organometallic capabilities
- **API, Particle Engineering***

Loures, Portugal

- Early stage and clinical supply
- Scale up | Small to large volume API
- Commercial supply: 30 - 12,500 L
- High potency API (down to $1\mu\text{g}/\text{m}^3$)
- Cryogenic, organometallic, hydrogenation, corticosteroids and carbohydrate capabilities
- **API, Particle Engineering* and Drug Product****

Macau, China

- Early stage and clinical supply
- Scale up | Small to medium volume API
- Commercial supply: 4 - 6,000 L
- Cryogenic, hydrogenation and specialized API
- **API, Particle Engineering***

* Spray drying, jet milling and crystallization
** Tableting, capsule filling

In the United States, call +1 609-918-2600
In Europe and the rest of the world, call +351 21 982 9000

hovione.com

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