Corden Pharma

Drug Product

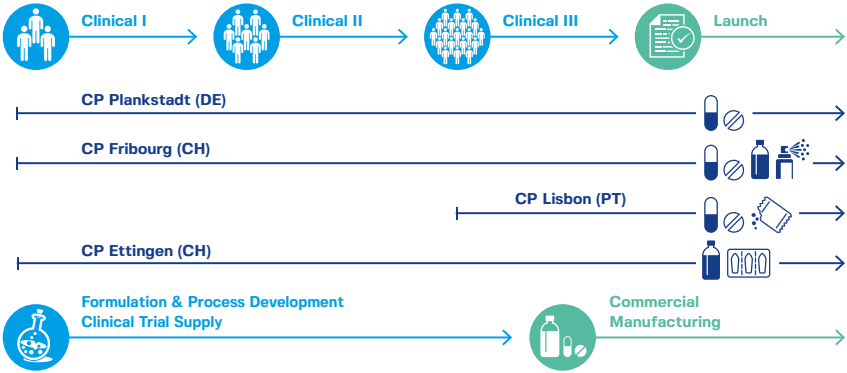
Small Molecules & Highly Potent

Your Expert Partner

for Drug Product Development & Manufacturing

With deep technical expertise, proven capabilities, and a strong track record in small molecule drug product manufacturing, we provide **development and manufacturing services** for a **broad range of non-sterile dosage forms** - including **solids, liquids and semi-solids for oral, nasal, dermal and rectal application** - across all clinical phases through to commercialization.

This broad spectrum of capabilities also allows formulations of **highly potent and oncological compounds.**



We guide you ...

... along your drug product supply journey.

Your One Partner Benefits

Proven Track Record & Scientific Excellence

Leverage deep technical expertise and a strong track record to develop robust, phase-appropriate processes and methods tailored to your specific challenges.

Broad Development & Manufacturing Capabilities

Benefit from versatile capabilities for a wide range of molecule classes, from early development to commercial scale, including highly potent and oncology compounds.

Integrated Supply

Access fully-integrated solutions, from API development to finished drug product, within a global facility network.

Regulatory Support & More

Gain end-to-end guidance across regulatory strategy, industrial scale-up, GMP readiness, and filing support - so you can confidently advance through every stage of development.

Trusted Quality & Compliance

Rely on our commitment to seek the highest standards of quality & compliance as the foundation of all our activities and projects.

End-to-End Partnership Made Easy

Benefit from a single point of contact throughout your project for both APIs and drug products, streamlined process collaboration and aligned project management across our network.

Dosage Form

Development & Manufacturing

We offer comprehensive dosage form development and manufacturing services for small molecules, highly potent APIs and peptides - **from early formulation and process development through to commercial production.** Our capabilities include a **wide range of oral solid dosage forms** such as tablets, capsules, minitablets, granules, and pellets, as well as oral liquids, syrups, suspensions, and rectal dosage forms.

Tablet packaging at CordenPharma.

Technology Transfers & Analytical Services

Implementing Your Product Successfully

For technology transfers, we follow a science driven, risk-based approach aligned with **Quality by Design (QbD)** principles, including risk assessment, gap analysis, and risk acceptance. Mitigation activities are carried out as needed - from small to full scale - using modelling, **Design of Experiments (DoE),** and building on comprehensive analytical and MSAT support.

Analytical services:

- → Comprehensive capabilities, technologies, and methodologies for compendial and specific compound testing
- → Phase appropriate method development and validation, including method optimizations and transfers
- → QC release testing for GMP batches
- → In-house and on-site ICH-condition stability chambers and programs as well as compendial microbial testing
- → Discriminating dissolution method development to support prototype selection and providing justification for regulatory documents

Small-scale spray dryer at CordenPharma.

Bioavailability

Our drug product innovation Centre of Excellence can formulate new molecular entities with challenging properties – such as peptides and small molecules with limited solubility, permeability, very low drug load, high potency, and limited stability – into Oral Solid Dose (OSD) drug products. **Our enabling technologies** such as spray drying, hot melt extrusion, nanomilling, and micronization **solve solubility-induced absorption issues.**

Read more about our bioavailability enhancement

Packaging

Our drug product facilities provide **end-to-end primary and secondary packaging solutions for oral solids, non-sterile liquids, and semi-solid dosage forms.** We support a **wide range of packaging formats** from standard commercial packs to specialized presentations such as sachets, unit-dose and multi-product blisters. With flexible infrastructure and agile workflows, we are equipped to handle both **large-scale production and small series packaging** to support clinical study supplies, market launches, and commercial distribution.

Key capabilities:

- → High-speed blister, bottle, sachet, and liquid filling lines
- → Contained packaging for highly potent drug products
- → Cold chain packaging (2–8°C) with validated logistics
- → Child-resistant and senior-friendly formats
- → Serialization & aggregation (EU FMD, US DSCSA)

Enema production at CordenPharma.

HIPO Range Potency

We specialize in the **development and cGMP manufacturing of highly potent APIs,** with proven expertise in handling compounds requiring containment for OEL values ≤ 0.05 µg/m³. Our capabilities include **formulation development and production of a variety of oral solid dosage forms,** such as tablets, capsules, minitablets, powders, granules, and pellets.

Formulation Development at CordenPharma.

Your Solution - No Matter the Potency

	Regular Potency			Potent	Highly Potent		
Criteria	**OEB1**	**OEB2**	**OEB3**	**OEB4**	**OEB5**	**OEB6a**	**OEB6b**
	Low Hazard	Moderately Hazardous	Hazardous	Highly Hazardous	Very Highly Hazardous	Extremely Hazardous	
OEL Range	> 1000 - 10 µg/m³			< 10 - 1 µg/m³	From 1 to < 0.05 µg/m³		

Fully-Integrated Services

for All Your Product Needs

Products	Services	Manufacturing Sites
APIs	→ Process development → Technology transfer → Clinical manufacture → Commercial manufacture	CP Bergamo, IT CP Chenove, FR CP Colorado, US CP Liestal, CH
Drug products	→ Formulation development → Clinical trial supply → Process development → Technology transfer → Commercial manufacture → CoE Innovative oral drug products → Bioavailability enhancement → Oral peptide delivery	CP Plankstadt, DE CP Fribourg, CH CP Lisbon, PT CP Ettingen, CH

* **Our cGMP facilities** are fully compliant with current regulatory requirements and applicable standards, while undergoing frequent regulatory inspections and customer audits.


24.52
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Peptides

Oligonucleotides

Lipids & LNPs

Injectables

Highly Potent
& Oncology

Small Molecules

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Get in touch
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