SCALABLE SOLUTIONS FOR HIGH POTENT OSD MANUFACTURING

Manufacturing oral solid dose (OSD) drug products with high potent active pharmaceutical ingredients demands strict containment, advanced facilities, and expert handling.

At Recipharm, every high potent project begins with a comprehensive risk assessment, covering sampling, dispensing, manufacturing, packaging, and analysis, to ensure safety for patients, workers, and the environment.

How Recipharm supports your success

- Seamless tech-transfers to keep timelines on track
- Proven processes for managing potent and sensitive compounds
- Flexible batch sizes to fit development and supply needs
- Advanced containment facilities for maximum safety
- Compliance with the latest global regulatory standards

Containment & compliance

We combine infrastructure, expertise, and robust quality systems to safely manufacture your high potent OSD products from clinical to commercial scale.

- Closed systems, isolators, ventilated enclosures, split butterfly valves, local exhaust ventilation
- Pressurised zones, single-pass air, high air change rates, safe-change filters, airlocks, misting showers
- Segregated QC rooms with independent HVAC (H13 filtered, no recirculation)
- Laminar flow cabins for product exposure (e.g. sampling)
- Strict PPE: chemical suits, hoods, PAPRs, gloves; restricted and health-monitored access
- QA systems ensuring compliance across facilities, equipment, and procedures
- Hazardous waste managed under special containment
- Cleaning validation based on API characteristics under containment

Small-scale high potent capabilities

Supporting early phase development with secure, reproducible processes and smooth scale-up to commercial manufacturing.

- Rapid and secure technology transfer
- GMP compliant operations
- Robust analytical methods
- Scalable solutions for efficient development
- Expert regulatory support

Our advanced dry granulation system ensures enhanced safety and containment for highly potent APIs. Dust-tight valves and Wash-In-Place functionality prevents operator exposure and cross-contamination, while the closed system design maintains consistent containment throughout the process.

Our technology supports low minimum batch sizes, making it ideal for early development when API is limited. With precise control over granule size, density and flowability, it reduces waste and enables safer, predictable scale-up.

- **Dispensing:** Two dedicated rooms with isolators
- **Dry granulation:** Premium brand roller compactor (max 100 kg/h) with Wash-In-Place (WIP) functionality
- **Dry mixing:** Minimum 20 kg batch size
- **Tableting:** Force-feeding tableting machine with full containment and WIP capability
- **Coating:** Premium brand coater (20–175 kg, assumption 0.8 density) designed for high potent products, equipped with WIP

Commercial high potent capabilities

Recipharm have the ability to manufacture high potent drugs and facilities equipped with dust containment capabilities to handle APIs with low OEL. We also offer state-of-the-art manufacturing and packaging equipment, with a high level of automation and control in production.

- **Dispensing:** Two dispensing rooms (equipped with isolators)
- **High shear & fluid bed drying**
- **Dry mixing:** Rotating mixer using 1200 litre IBC with split valves
- **Tableting:** Centrifugal feeding machine with full containment and Wash-In-Place (WIP) measures
- **Coating:** 500 litre coater with containment controls and WIP functionality for high potent tablet handling
- **Visual Inspection:** Fully automatic system
- **Packaging:** Blister line (Aluminium/PVC and PVDC) and bottle line (plastic or glass) with full high potent containment compliance
- **Quality control:** Fully compliant QC area for high potent compounds, including SAS-equipped rooms; capabilities for dissolution, disintegration, friability, hardness, weight, laser diffraction, flowability, density, melt point, and sieving tests
- **Capacity:** ~250 tons/year (assumptions: 500 batches, 500 kg per batch, 8 h/batch; OEL < 1 µg/m^3

Your partner in high potent OSD manufacturing

From clinical development to full scale commercial supply, Recipharm provides the facilities, expertise, and scalability to deliver high potent OSD projects safely, efficiently, and in full compliance with global standards. We are ready to deliver your next project, contact our experts today.

About us

Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden and the US and are continuing to grow and expand our offering for our customers. We are supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 30 years, we have partnered with our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. We conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do.

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