High Potency Manufacturing Capabilities

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An Industry Leader

Abbott's High Potency Manufacturing sites are licensed, state-of-the-art, multipurpose facilities for the design and manufacture of potent compounds that include high-containment capabilities.
Combined, these sites offer:

- Technical support functions: supporting chemical, process engineering, pharmaceutical and project management.
- Quality teams that provide method-transfer capability, product testing and GMP compliance through proven quality systems.
- Integrated supply chain teams to ensure the logistics of product transfer from raw material to finished good or drug product.
- Operational excellence teams that support projects with a range of Lean Six Sigma methodologies.
- Operator Exposure Bands (OEBs) from 1 to 5.

Wyandotte, Michigan	Sligo, Ireland
OEB 1 to OEB 3 (10–100 µg/m^3 to >100 µg/m^3)	OEB 3 to OEB 5 (10–100 µg/m^3 to <1 µg/m^3)
Active Pharmaceutical Ingredient	Active Pharmaceutical Ingredient
Process Development Lab	Finished Good/Drug Product
Analytical Capabilities	Analytical Capabilities
Highly Adaptive Process Design	Kilo Lab
Security Infrastructure for Controlled Drugs	Contained tabletting/ encapsulation suite
	Rapid New Product Introduction

High Potency Manufacturing Services

Small-Scale Production

Both Sligo and Wyandotte are designed to accommodate small-scale processing of potent active pharmaceutical ingredients, using lab scale equipment and the capability to complete a technical transfer to pilot scale processing skids.

- Gram-to-kilogram processing scales
- High-pressure reactors
- Pressure filter simulation
- Computerized data collection and control
- Contained glove-box technology
- Walk-in fume hood for processing
- Pilot scale production availability

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Active Pharmaceutical Ingredient (API) Commercial Production

In a combined fashion, these sites offer containment technology throughout the process, from glove-box dispensing capabilities and contained material transfers through split butterfly valve technology. All processes in the API facility are controlled using an Emerson DeltaV Distributed Control System with integrated recipe-driven process control.

- Dedicated hydrogenation suite (4000 L)
- Independent and configurable glass and stainless-steel equipment trains (400 L–4500 L)
- Identical process train configurations to facilitate scale-up activities
- Class 100,000 suites with Hastelloy and 316 stainless-steel filter dryers (typical range, 5 kg–250 kg)
- Process control temperatures (5–105 Celsius)

Finished Good/Drug Product

The Sligo Finished Good High Potency Manufacturing facility is equipped to process solid oral dosage forms. The equipment is highly automated with full recipe control and 21 CFR Part 11 compliance. An electronic manufacturing execution system is available to provide fully electronic control of the processes and electronic batch records.

- Contained dispensing and handling systems
- In-bin International Bulk Container (IBC) blending capabilities (50 L–420 L)
- Contained IBC-to-IBC transfer and milling stations
- High-shear wet granulation and drying single-pot processors
- Contained encapsulation suite with 100 percent weight checking
- Contained tabletting suite
- Tablet coating for potent cores/coating
- Full recipe control and Clean-In-Place (CIP) systems

Analytical Capabilities

Manufacturing is supported by quality control laboratories equipped with state-of-the-art instrumentation for chemical and microbiological analysis performed by trained and experienced staff. Each site offers unique, analytical controls to handle many laboratory tests:

- HPLC (reverse phase, normal phase, ion exchange, gradient and isocratic methods, pulsed amperometic detection, UV visible, diode-array, and MS detection)
- GC (FID and TCD detection, capillary and glass columns, headspace and residual solvents analysis)
- Spectrophotometry (FT-IR, UV visible)
- Atomic absorption, ICP, x-ray and particle size analysis
- Optical and electron microscopy
- Surface area and particle size distribution
- LC/MS
- Total organic carbon testing
- Thin-layer chromatography
- Wet chemistry (titrations, limit tests, LOD, color, flame, pH, heavy metals, USP, EP and JP methods)
- Microbiology lab for product testing and facility environmental testing
- Stability testing to ICH requirement

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