

Experience Unrivaled

Potent API and Drug Product

AbbVie Contract Manufacturing offers potent capabilities for drug product and APIs covering development phases to commercial production. We are among few companies with potent-capable facilities in North America and Europe, reflecting an advantage of working with a global pharmaceutical developer and manufacturer. Our advantages include the depth of scientific expertise that applies to your project and our exceptional track record for compliance and safety. Our capabilities also encompass the highest Environmental Health and Safety (EHS) industry practices for handling potent compounds.

Overall Capabilities

Potency classification down to $<1\mu\text{g}/\text{m}^3$
 Potent active pharmaceutical ingredients (HPAPI)
 Dedicated hydrogenation suite (4,000 L)
 Process control temperature (-20 °C – 120 °C)

Unique Capabilities

Hot Melt Extrusion
 Single pot processing
 Split butterfly valve transfers
 Identical process train configuration to facilitate scale-up activities

Development Manufacturing (Non-GMP & GMP)

- Blending (3 L – 400 L)
- Dry granulation (Gerteis roller compactor)
- Wet granulation (10 L – 75 L)
- Single Pot Processing (10 L – 75 L)
- Milling
- Compression / encapsulation
- Coating

CONTRACT MANUFACTURING

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Commercial Manufacturing

- Independent and configurable glass and stainless steel equipment trains (440 L – 4,500 L)
- Dry granulation (Gerteis roller compactor)
- Wet granulation (120 L – 300 L)
- Single pot processing (100 L – 200 L)
- 3 Class 10,000 suites with Hastelloy and 316 stainless steel filter dryers (5 kg – 150 kg)
- Purified water system
- Small kilo scale reactors (including high pressure reactors)
- In-bin International Bulk Container (IBC) blending capabilities (50 L – 420 L)
 - IBC to IBC transfer and milling stations
- Clean-in-place (CIP) systems
- Containment suites
 - Encapsulation
 - Tableting suite with in-process automatic weight check and in-line metal detection
 - Tablet coating suite with adjustable tablet pan size

Analytical Services

- HPLC (reverse phase, normal phase, ion exchange, gradient and isocratic methods, pulsed amperometric detection, UV visible, diode array, and MS detection)
- LC / MS & GC / MS
- GC (FID and TCD detection, capillary and glass columns, headspace and residual solvents analysis)
- Spectrophotometry (FT- IR, UV visible)
- Atomic absorption, ICP and X- ray
- Optical and electron microscopy
- Surface area and particle size distribution
- Total organic carbon testing
- Microbiology lab for product testing and facility environmental testing
- Stability testing



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