

Custom Active Pharmaceutical Ingredient

AbbVie Contract Manufacturing offers world-class custom active pharmaceutical ingredient (API) services based on more than 70 years of manufacturing excellence with facilities located in Chicago, Illinois and Campoverde, Italy. With a broad range of technical capabilities and experience in complex chemistries, we can bring the same degree of expertise and passion to your project as we do with our own.

AbbVie's API sites have the flexibility to run multiple chemical processes simultaneously to support late development phase to commercial products including highly potent drug containment up to OEL 3A ($1\mu\text{g}/\text{m}^3$). State of the art QC laboratories integrated across a highly experienced team focused on commercial readiness and manufacturing expertise are available to support technical transfer and life cycle management activities. AbbVie also offers our partners extensive CMC, QA and regulatory know-how with a proven track record resulting in a seamless technology transfer and assured success in validation and ongoing commercial supply.

Reliable High Quality Manufacturing

Capabilities

We support most general chemistry including, but not limited to:

- Organometallic (Grignard)
- Gaseous HCl
- Acetylene Chemistry
- Friedel-Crafts Chemistry
- Cyanation
- Hydride
- DIBAL reductions
- Chlorinated Solvents
- Chromatography

Commercial Scale

- 100–700kg/batch depending on process complexity
- Total site annual capacity of ~20–30 metric tons
- Several 10,000L–12,500L tanks (stainless steel and glass lined)
- Large scale stainless steel and Hastelloy filter dryers
- Reaction monitoring via OSI-PI software for web-based access
- Multipurpose facility with CAPEX options

Contract Manufacturing

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Vision. Expertise. Success.

Process Analytical Technology (PAT)

- Mass spectrum analysis for distillations and drying profiling
- FTIR for reaction completion
- FBRM/PVM for crystallization
- Raman for drying endpoint
- Online particle size measurement
- Conductivity for phase separations
- Refractive index for cake wash solvent displacement



Analytical and Microbiological Testing

Full support for method development, validation, and transfer services, as well as submission, audit and manufacturing support including:

- HPLC (reverse/normal phase and ion exchange, with UV/Vis, RI, fluorescence, ECD and ELS detection)
- GC (direct injection and headspace analysis with FID and TCD detection)
- ICP-OES, ICP-MS, GC-MS and LC-MS
- Spectroscopy (FT-IR, UV/Vis and AA)
- Powder X-Ray Diffraction, DSC Optical Electron Microscopy Surface Area and Particle Size Analysis
- Dissolution USP Apparatus 1, 2 and 3
- Cleaning Methods (LC and TOC)
- Microbiology Testing
- ICH Stability Storage and Testing



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