

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 μ g/m³). 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

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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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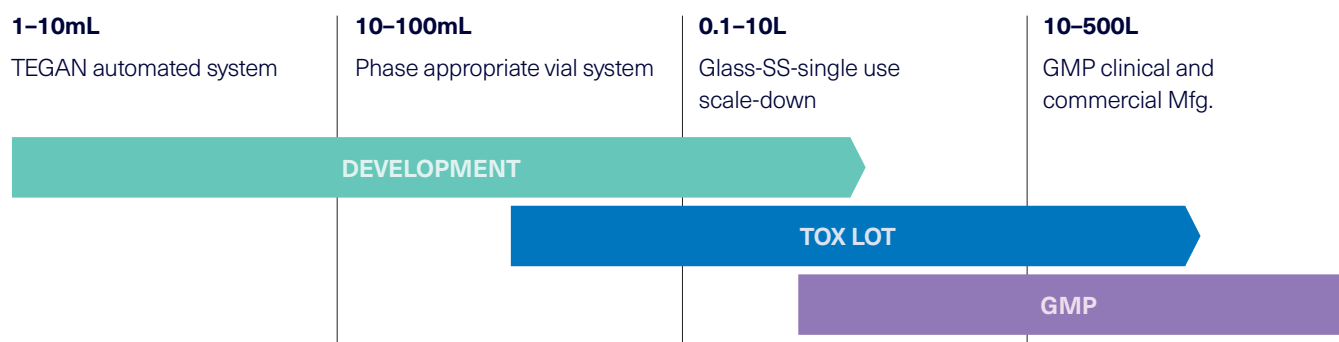
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Antibody Drug Conjugates (ADC)

When selecting AbbVie for your ADC, you gain an industry leading biopharmaceutical development partner. AbbVie's experienced scientific team and state-of-the-art facilities are unrivaled in biopharma and antibody drug conjugation. In addition to extensive ADC clinical experience, AbbVie can leverage its regulatory and commercial track record to deliver improved confidence leading to successful milestone achievement.

Your Conjugation Provider from Clinical to Commercial



Analytical development, release and stability

- Onsite quality and testing (Bio & ADC)
- UV/VIS
- MALS/IR
- CE, icIEF
- CE-SDS (Beckman), mCE-SDS (Perkins Elmer)
- HPLC, UPLC, LC/MS
- LAL, ELISA
- Environmental/bioburden testing
- HIC for DAR



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ABBVIE ADC MANUFACTURING NETWORK

EUROPE

1 Sligo, Ireland ●

USA

2 Chicago, Illinois ● ●

3 Worcester, Massachusetts ● ●

PUERTO RICO

4 Barceloneta ●

● **Antibody Intermediate**

- Dedicated mammalian technologies
- Full pharma development and manufacturing support
- Proven leader with two convenient North American sites
- 1,000L to 12,000L bioreactors
- Single use and fixed stainless steel options

● **Drug Linker — Payload**

- Segregated pilot facility capable of managing containment to <math><1\text{ ng/m}^3</math>
- 20+ years of high-containment GMP manufacturing
- Batches from 1–500g with option to increase capacity
- Scientific excellence to support a range of linker-payload chemistries

● **Conjugation**

- Primary site in Worcester, MA
- Integrated Biologics-ADC facility
- Highly engineered facility capable of containment <math><10\text{ ng/m}^3</math>
- Scale options up to 500L
- Single use and fixed stainless steel options
- Inline antibody remodeling and engineering options



One proven pharma partner, end-to-end solutions

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Aseptic Fill-Finish: Vial

AbbVie offers two convenient Aseptic Fill and Finish options for parenteral drug products: Vials & Prefilled Syringes. As a leading pharmaceutical partner, we can provide all necessary elements of delivering high quality parenteral products for both clinical and commercial requirements. AbbVie will leverage its know-how and proven quality, regulatory, and operational expertise to ensure you achieve your critical milestones as planned. Consistent and reliable pharmaceutical quality in every batch.

Vial Fill-Finish Drug Product

Specialized formulation & development support North Chicago, Illinois and Ludwigshafen, Germany

- Extensive formulation and scale-up experience at all phases of development
- Lyophilization process optimization and scale-up transfer
- Method development and phase appropriate qualification

Clinical & Commercial GMP Manufacturing Sligo, Ireland

- Cutting-edge automated vial fill line with 6-head Bosch peristaltic technology
- Lyo and liquid fill options with 23m² auto-load lyophilizer
- Validated for 6R, 10R & 20R vials with capability to expand from 2R to 50R
- Fully automated isolator line with potent containment handling to <10ng/m³ OEL
- Single-use fluid path technology designed to minimize loss of drug substance
- 100% headspace analysis, manual and semi-automated visual inspection options
- Comprehensive pharmaceutical support including QC/QA and regulatory



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Aseptic Fill-Finish: PreFilled Syringe

AbbVie produces tens of millions of pre-filled syringes each year. Our extensive pharmaceutical network offers various manufacturing options for your biopharmaceutical, including aseptic pre-filled syringe manufacturing in North America. AbbVie is a leading commercialization partner with extensive scientific know-how to assist in drug delivery options and commercial readiness.

Prefilled Syringe Drug Product

Formulation & Development Services North Chicago, IL & Ludwigshafen, Germany

- Extensive formulation and scale-up experience at all phases of development
- Lab scale fillers for feasibility and development
- Method development and phase appropriate qualification

Clinical & Commercial GMP Manufacturing Barceloneta, Puerto Rico

- Biologics-focused Inova line with peristaltic technology
- Nested syringes in tubs with validated fill volumes from 0.4–2mL
- Non-destructive weight checks
- Experience with disposable and stainless equipment
- Manual and automated visual inspection
- Syringe blister pack options, with plunger and finger grips
- Full analytical capabilities including biologic, chemical, micro, stability and device functional testing



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Biologics: Development & Drug Substance Manufacturing

When selecting AbbVie, you gain more than a contract manufacturer. We are your pharmaceutical partner, focused on helping mitigate risk and accelerating your drug development timeline. Our site in Worcester, MA represents AbbVie's Biologics center of excellence, and one of the few sites that successfully manages drug complexities from development to commercial launch, and from antibody to ADC conjugation with one unified quality system and scientific team. We offer a simplified and dependable supply chain and better project continuity to give you greater confidence in the success of your biopharmaceutical program.

Commercial Success: 5 programs launched globally

Scientific Excellence: Clinical development for 70 projects in almost 40 years

Biologics Expertise: mAb, Fusion, Bi-Specific and ADC Conjugation expertise for DS & DP

Partnering Commitment: Consistent 3rd party focus and growth through facility investment

Development Manufacturing

- Cell bank development (MCB/WCB)
- Upstream and downstream process development
- Analytical method development
- Extended product characterization
- Viral clearance studies

Process scale-up labs feature single-use and stainless technologies, with scales ranging from 3L–500L

Commercial Manufacturing

- 38,000L of total capacity in the AbbVie Bioresearch Center in Worcester, MA
- Single use and fixed stainless-steel equipment in six manufacturing suite (1,000L to 6,000L)
- Each cell culture suite possesses dedicated DS purification
- Experienced process characterization and validation
- Second North American site for future commercial supply options (6,000L to 12,000L scale)



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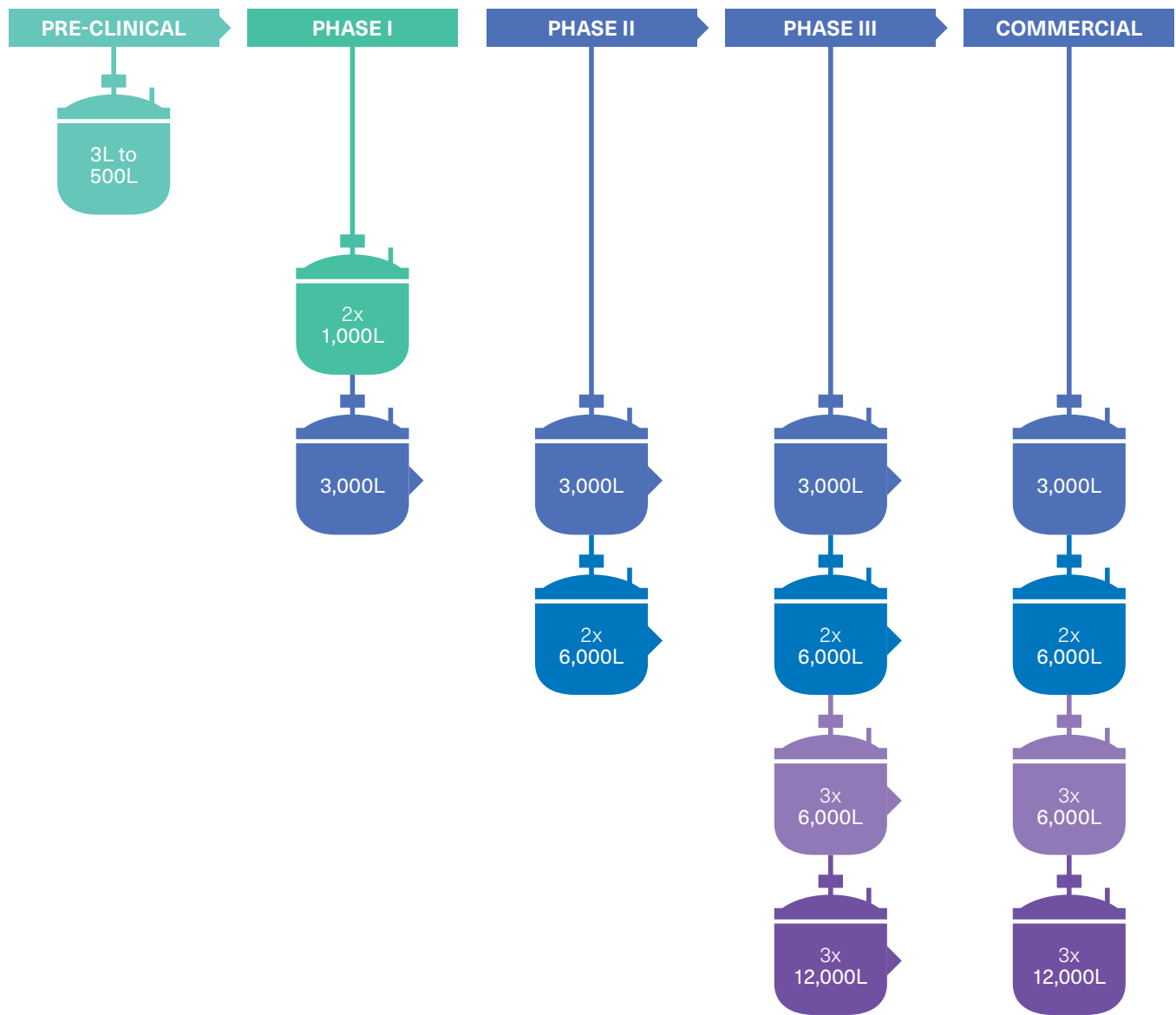
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Client Services

- Comprehensive clinical & commercial pharma support
- Global regulatory filing, approval and launch expertise
- Dedicated pharmaceutical planning and project management
- Capacity and scale options to accommodate multiple partner programs
- Dedicated capacity options with flexible contracting for strategic partners
- Exceptional track record of scale-up milestone achievement, BLA and ongoing supply
- History of facility expansion for internal and external commercial requirements



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Hot Melt Extrusion

AbbVie Contract Manufacturing offers proprietary hot melt extrusion (HME) technology in both the US and Europe. As the global leader and pioneer with more than thirty years of HME extrusion development experience, AbbVie has launched the most commercial products utilizing this technology. HME is widely recognized as an effective technology to transform poorly soluble APIs into amorphous solid dispersions.

Experience

- Unparalleled industry leader with >35+ years of formulation & manufacturing know-how
- Integrated formulation development, clinical & commercial manufacturing
- Most commercial products launched (>7), first product marketed in 2005
- Academic collaborations to drive innovation; highest rate of HME technical publications

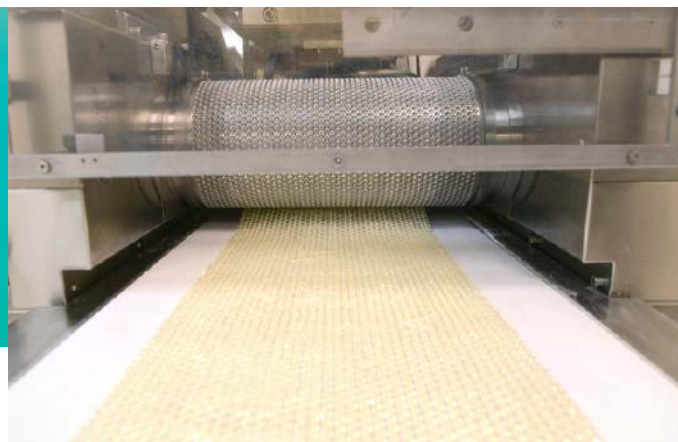
Capability

- 10+ extruders in network
- 18mm–70mm screw size
- Multiple OEMs (Liestritz, Coperion, Bosch)
- Potent capability (<1 μ g/m³)
- Expertise in scale-up & technical transfer between sites
- Several simulation & scale-up models available for fast development to minimize API usage

Advantages & Value

- Continuous manufacturing without the use of solvents
- Wide range of scale to grow with product needs
- Ability to qualify multiple sites
- End to End manufacturing from extrudate to packaged drug product production
- Technical support & consultative services available
- Recognized leader in quality assurance

One proven pharma partner offering unique solutions to enhance bioavailability



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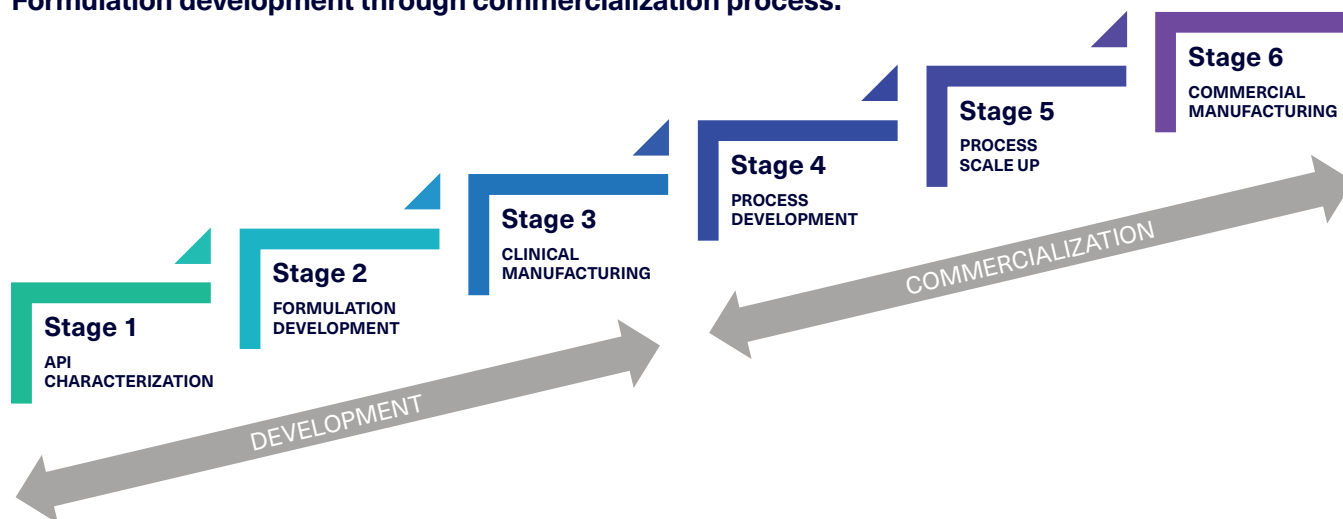
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Formulation development through commercialization process:



AbbVie employs a stage-based process with clearly defined success criteria to develop a robust and successful formulation.

Analytical Services:

- HPLC (reverse phase, normal phase, ion exchange, gradient, and isocratic methods, pulsed amperemeter 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

Downstream Manufacturing Options:

(see Oral Solid Dose cutsheet for more details)

- Tablets (including multi-layer)
- Controlled Release
- Modified Release
- Capsules
- Milling

Packaging Options

- Blisters
- Bottles
- Sachets/Sticks
- Wallets

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Microbial Fermentation Services

AbbVie Contract Manufacturing offers world-class fermentation capabilities based on more than 60 years of leadership in fermentation. Your project will benefit from AbbVie's scientific expertise as a leading development and manufacturer of fermentation processes at our 180-acre facility in Chicago, Illinois. We bring the same degree of expertise and passion to your project as we do with our own, supporting you from cell bank development through large-scale manufacturing.

Types of Products

- Small molecule API's to be administered orally or as an injectable
- Large molecule API's to be administered orally
- Bulk food ingredients
- Agrochemical active ingredients
- Semi-synthetic products

Types of Organisms

- GMO & non-GMO manufactured under GLSP (good large scale practice)
- Experience with:
 - Actinomycetes
 - *E. coli*
 - Fungi
 - *Bacillus*
 - Yeast

Development Manufacturing (Non-GMP)

- Strain improvement via classical and recombinant methods
- Preparation of R&D, master and working cell banks
- Inoculum process development
- Fermentation and downstream process development and characterization including:
 - 55–500L fermenters in pilot plant
 - Track key parameters including pH, DO, temperature, agitation and off-gas
 - Recovery operations that are representative of commercial scale
- Method development and transfer for analytical, microbial and cleaning methods

Clinical and Commercial Manufacturing

- Over 3000 m³ fermentation capacity
- Fermenter working volumes from 10,000L–100,000L
- Batch and continuous sterilization of media
- Dedicated facility for cell bank preparation and storage with redundant equipment and controls
- Broad range of downstream capabilities including:

- Microfiltration	- Chromatography
- Centrifugation	- Crystallization
- Liquid / Liquid extraction	- Fluid bed drying
- Ultrafiltration	- Filter drying
- Evaporation	
- Packaging liquids into presterilized totes or tanker trucks and dried solids into drums

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Analytical Services

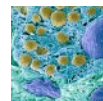
- High Performance Liquid Chromatography (HPLC) – reverse phase, normal phase, etc.
- ICP-OES and ICP-MS
- Gas Chromatography (GC) analysis
- GC-MS and LC-MS
- Reference standard & purity characterization
- Spectrophotometry (FT-IR, UV-Vis, GC Mass Spec)
- Wet chemistry (titrations, LOD, pH, heavy metals, etc.)
- Biopotency
- Turn-key stability testing service
- Cleaning method development via LC and TOC
- X-ray diffraction, TGA and DSC
- Optical and electron microscopy
- Surface area and particle size analysis on site
- Specific organism detection
- Microbial identification and limits testing
- Bioburden (AMC / Endotoxin – LAL)
- Environmental testing

Manufacturing Excellence

- Class-A certified operation, focused on efficient processing
- Key Performance Index (KPI) monitoring
- Environmental Health and Safety (EH&S) programs to ensure pollution prevention and resource conservation
- Process Analytical Technology (PAT) and process control systems
- Distributed Control Systems (DCS)
- Continuous improvement

Client Commitment

- Reliable supply through established supply and operations planning (S&OP) processes
- Dedicated project management
- New product introduction business process
- Global Chemical Manufacturing Control (CMC) filing support
- Information confidentiality and security via cyber and physical controls



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Ophthalmics

AbbVie Contract Manufacturing offers ophthalmic drug product manufacturing services in Waco, Texas. As a global pharmaceutical partner, we can provide high quality manufacturing of ophthalmic products for your late-stage clinical and commercial needs. Waco has decades of scale-up and tech transfers experience across multiple products. AbbVie will leverage its know-how and proven quality, regulatory and operational network to help you achieve your milestones through comprehensive manufacturing support.

Sterile Eye Ointments

- Fully automated aseptic filling line
- ~3.5 gram laminate tubes
- Full CIP/SIP
- Scale-up and tech transfer services
- Globally approved
- Analytical services include: on-site micro, QC laboratories & stability testing
- Commercial packaging with full serialization and aggregation

Aseptic Bottle Filling

- Preservative-free multidose bottle filling
- Preserved multidose bottle filling
- Bottle sizes of 5, 10 & 15mL
- Large batch capacity
- Globally approved
- Analytical services include: on-site micro, QC laboratories & stability testing
- Commercial packaging with full serialization and aggregation



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Oral Solid Dose

AbbVie Contract Manufacturing delivers advantages beyond a typical CMO to the drug product market. As a leading pharmaceutical developer and manufacturer, we have a large and diverse scientific team who bring extensive depth of knowledge and expertise to offer solutions to our clients' most difficult manufacturing challenges. With manufacturing flexibility across six facilities in the US and Europe, we offer one of the most effective global networks to accommodate oral solid production needs coupled with the most trusted reputation in the industry for quality, reliability, and on-time delivery.

AbbVie's Experience

- Flexible scales from boutique to large scale
- Production network delivers broad flexibility in scale and location
- Solution and consultative partnerships from development through commercial term
- Established wide network of commercial assets to accelerate speed to market

Unique Capabilities

- Potent (<1 µg/m³) manufacturing and storage
- Offer End to End manufacturing from API to bulk oral solid dose to finished Drug Product packaging
- Extensive controlled temperature warehousing capability (2–8°C API and Drug Product)
- Hot melt extrusion for difficult to formulate compounds/ bioavailability enhancement (see Hot melt extrusion cutsheet for more details)

Pharma partner offering technical expertise to successfully commercialize your product



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Oral Solid Dose Manufacturing

Blending

- V-blenders (2ft³–150ft³ scale)
- Bin blenders

Granulation & Drying Capabilities

- Roller Compaction
- High Shear granulation (75L, 300L and 1,200L)
- Spray granulation (400L–1,100L)
- Melt granulation (18mm–70mm screw size)
- Fluid Bed Drying
- Tray Drying

Milling capabilities

- Impact milling
- Screen milling
- Separation

Compression Capabilities

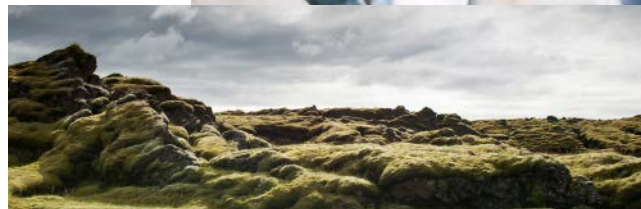
- Single layer
- Multi-layer
- Mini tab

Coating Capabilities

- Tablet coating
- Particle coating
- Active coating

Encapsulation Capabilities

- Granule filled
- Liquid filled (hard gelatin)
- Mini tab filled
- Over encapsulation



Packaging Capabilities

- Blisters
- Bottles
- Sachets/Sticks
- Wallets

Oral Liquid Manufacturing & Finishing

- Formulation
- Syrups/Suspensions/Solutions
- Bottle filling (15mL–500mL)

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Topical

AbbVie Contract Manufacturing offers topical filling services in Waco, Texas. As a global pharmaceutical partner, we can provide high quality manufacturing of topical products for your clinical and commercial needs. AbbVie will leverage its know-how and proven quality, regulatory and operational network to help you achieve your milestones through comprehensive manufacturing support for your topical formulations.

Non-Sterile Filling of Creams and Gels:

- Fully automated filling line
- Aluminum and laminate tubes
- Fill weights from 3 to 100 grams
- 600–1200kg batch size
- Globally approved
- Analytical services include: on-site micro, QC laboratories & stability testing
- Commercial packaging with full serialization and aggregation



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