

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

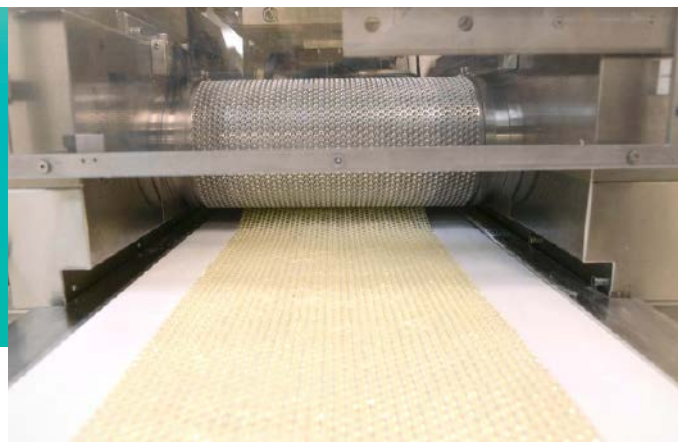
Capability

- 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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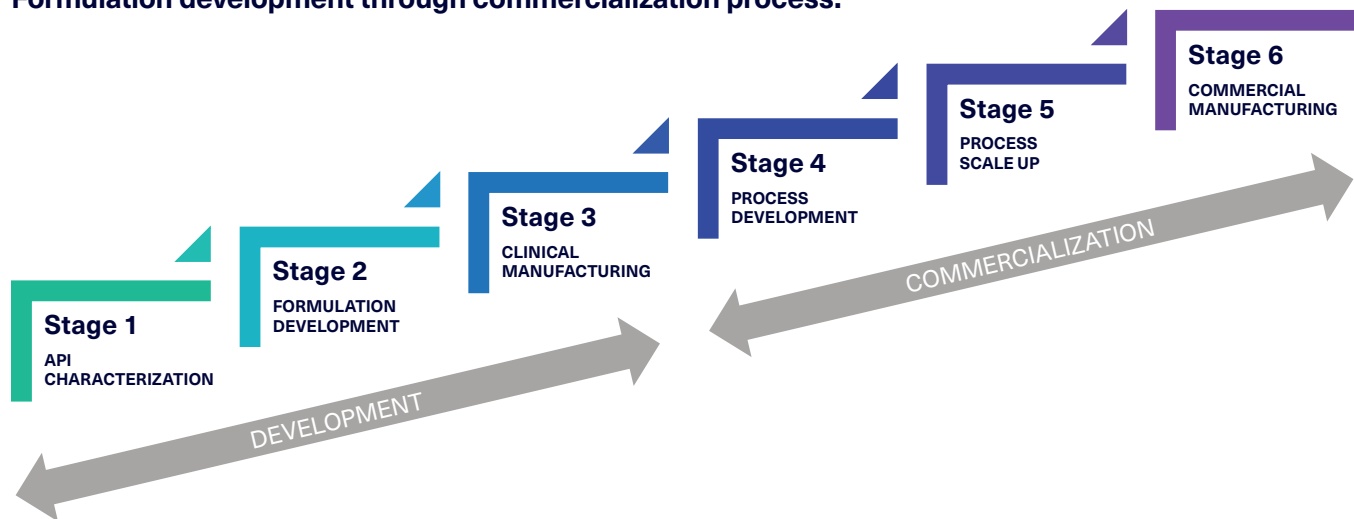
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Vision. Expertise. Success.

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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