

Hot Melt Extrusion: A Proven Technology for Enhancing Drug Solubility and Bioavailability

Pharmaceutical science is evolving rapidly with innovative techniques aimed at improving drug solubility, stability, bioavailability and patient compliance. One such transformative technology is Hot Melt Extrusion (HME). It enables the manufacture of solid dispersions, controlled-release formulations, and novel drug delivery systems, making it a cornerstone of modern pharmaceutical development.

Hot Melt Extrusion is a clinically proven pharmaceutical technology, with several products successfully commercialized worldwide. Examples include Kaletra® (lopinavir/ritonavir), Norvir® (ritonavir), Noxafil® delayed-release tablets (posaconazole), and Onmel® (itraconazole), demonstrating its robustness, scalability, and regulatory acceptance.

HME is a solvent-free, continuous manufacturing process where active pharmaceutical ingredient is combined with polymers and heated through an extruder to produce uniform solid dispersions or granules. Granules are later compressed into Tablets Or encapsulated as per need.

Why Hot Melt Extrusion?

- Enhanced Solubility and Bioavailability:** HME disperses drugs at the molecular level within a polymer matrix, improving dissolution rates and absorption.
- Continuous and Scalable Process:** HME supports continuous manufacturing, reducing batch-to-batch variability and aligning with Quality by Design (QbD) principles.
- Solvent-Free and Environmentally Friendly:** HME is a green technology, eliminating the use of organic solvents and the associated regulatory concerns.
- Flexible Formulation Design:** The technique supports immediate-release, sustained-release, and taste-masked formulations, enabling innovative dosage forms.
- Improved Stability and Patient Compliance:** HME solid dispersions enhance chemical and physical stability, while enabling orally disintegrating films, tablets, or pellets for better patient adherence.

Applications in Pharmaceuticals

- Solubility enhancement of poorly soluble APIs
- Controlled or modified-release systems
- Taste masking for bitter drugs
- Multi-drug combination formulations
- Personalized medicine and small-batch patient-specific formulations

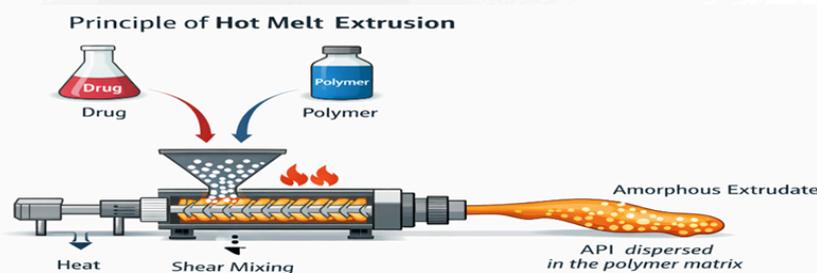
PharmSol Expertise in HME

At PharmSol, our team of subject matter experts (SMEs) has extensive experience in applying HME to:

- Develop amorphous solid dispersions
- Formulate sustained and modified-release tablets & pellets
- Optimize extrusion parameters for scalability
- Design multi-drug combination therapies

The Science Behind HME

HME combines heat, mechanical shear, and pressure to blend drugs with thermoplastic polymers. By controlling temperature, screw speed, and feed rate, consistent, high-quality extrudates are produced. This ensures reproducibility, scalability, and improved drug performance.



Through Hot Melt Extrusion technology, we deliver robust and clinically effective formulations, supporting our partners in streamlining development timelines and advancing products to market efficiently.

Get in touch with our experts. Send us an email
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