Foster Delivery Science

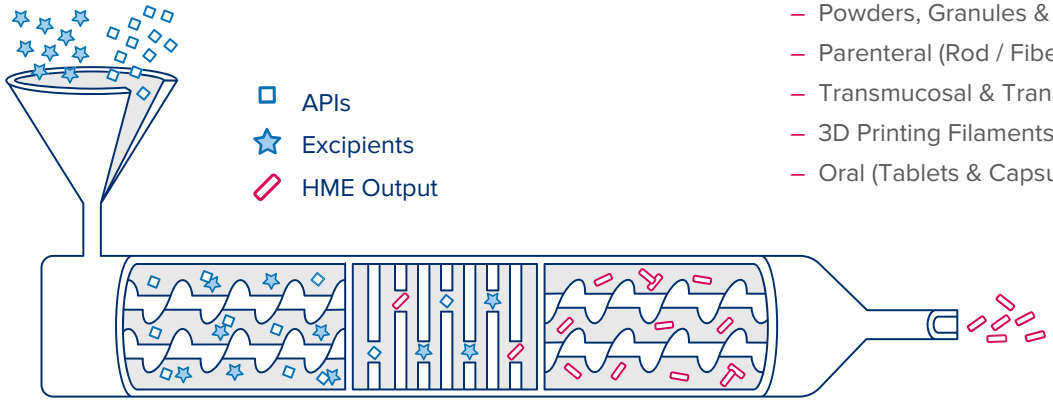
Contract Development and Manufacturing Organization
Delivering World Class Pharmaceutical Hot Melt Extrusion
Services, Compliantly

FOSTER
DELIVERY SCIENCE

Hot Melt Extrusion

Hot Melt Extrusion (HME) is the process of melt blending active pharmaceutical ingredients (APIs), polymers, and excipients in an extruder. Within the extrusion process, mechanical energy influences the degree of mixing achieved and thermal energy determines the amount of heat the formulation experiences in the process.

Several variables are used in the extrusion process to optimize a given formulation, including but not limited to barrel and screw designs and temperature. Extruder screws are individually constructed with components that assist in melting (via shear forces) and convey the formulation through the barrel, while mixing and homogenizing the material.



HME is a suitable and proven solution to provide long acting, modified, and targeted drug delivery. Novel dosage forms may require innovative and customized pharmaceutical product shaping. Foster Delivery Science's (FDS's) inventory of downstream processing equipment is available to manufacture traditional and customized dosage forms including:

- Powders, Granules & Pellets
- Parenteral (Rod / Fiber / Tube Type Implants)
- Transmucosal & Transdermal (Films)
- 3D Printing Filaments
- Oral (Tablets & Capsules)

Benefits of HME

Melt Extrusion offers several cost and performance advantages over traditional processing techniques.

- Improved Bioavailability
- Improved Solubility
- Improved Stability
- Controlled Morphology
- Promotes Miscibility
- Easily Scalable
- Accommodates Powders, Granules, Pellets, Liquids & Gases
- Economical, Less Capital Intensive
- Non-Solvent Process

HME Applications

Oral Delivery - Solid Solutions / Dispersions

Enhances bioavailability of poorly soluble APIs and may be used as an alternative to solvent processes for solid dispersions.

Resorbable Implant Delivery

Drug/device combination products with tailored and controlled release of APIs when the implant is intended to degrade at a desired rate.

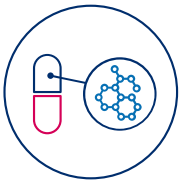
Non-Resorbable Implant Delivery

Local or systemic drug delivery of API's using non-absorbing polymers that can be removed at the conclusion of therapy.

Quality Management System

Foster Delivery Science's Quality Management System (QMS) is to ensure facility, equipment, procedures, records, the analytical methods used are designed and implemented to meet current 21CFR Parts 210 and 211, EU cGMP, ICH Q10, Pharmaceutical Quality Systems, cGMP 21CFR820 and 21CFR Part 11. FDS has a compliance-oriented mindset throughout the organization. Our QMS demonstrates the company's capability to conduct manufacturing processing and development activities which assure patient safety, conform to regulatory requirements, and meet international guidelines.

Formulation and Process Development



Foster Delivery Science offers rapid screening studies to provide proof-of-concept and feasibility information, used to identify stable lead formulations and drive pre-clinical and Phase I decisions.

- Pre-Formulation Studies- Excipient compatibility studies
- Solubility Screening- Solid Dispersions; Surfactant and co-solvent screenings; Analytical characterization of solid dispersions (kinetic solubility, dissolution rate)
- Proof of Concept Studies- Identification of lead binary polymer / drug formulations; Characterization and generation of stability information

Process Development and Scale-Up

To facilitate in process formulation development, FDS can characterize each formulation for thermodynamic and rheological properties. If necessary, the data can be leveraged for initial computer simulation of screw and barrel designs, and initial process conditions' definition. Processes are evaluated, optimized, and scaled on one of several extruders in the development suites or clean room facility.

Foster Delivery Science offers a range of equipment to support scale-up of formulations from laboratory to clinical and commercial manufacturing.

cGMP Manufacturing

Clinical Trial Material and Commercial Manufacturing

Foster Delivery Science has the equipment, facilities, and personnel to support pre-clinical and clinical trials. Its clean rooms and equipment are qualified to industry standards. FDS has manufactured materials for preclinical, Phase I, Phase II and Phase III.

Contract Development and Manufacturing

Foster Delivery Science's pharmaceutical melt extrusion is performed in a GMP facility using industry standard twin-screw and single screw extruders. FDS will support your commercial supply and clinical programs. Our inventory of equipment allows for proof- of-concept and early formulation development with as little as 20 grams of material and process optimization and scale-up.

Analytical Testing

Foster Delivery Science offers comprehensive in-house analytical testing including method development and qualification/validation.

The capabilities include:

- Liquid & Gas Chromatography
- Thermal Analysis
- Spectroscopy
- Dissolution Testing
- Optical Microscopy / Image Analysis
- Particle Size Analysis
- Inherent Viscosity
- General Wet Chemistry
- Total Organic Carbon (TOC)
- Disintegration Testing
- Stability

End-to-End CDMO Solution for Hot Melt Extrusion Services.

Mission Statement

Foster Delivery Science's mission is to develop and provide quality cGMP compliant manufacturing and products that meet or exceed the quality expectations of regulatory agencies and our customers with the goal of improving the lives of patients.

Quality Policy

Foster Delivery Science's Quality Policy is to implement and maintain a robust Quality Management System which delivers the highest level of quality products and customer service in a safe, efficient, and reliable manner. We sustain a culture of compliance that meets and exceeds the industry-accepted standards of FDS's stakeholders including patients, customers, and government regulators.

Certifications

– ISO 13485:2016

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Doc I – Rev 052021