



## Hot Melt Extrusion for Drug Delivery

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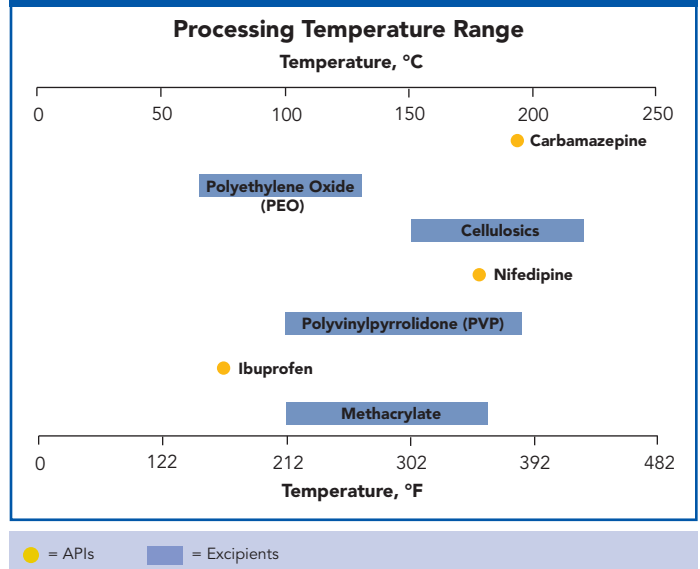
Foster Corporation's Delivery Science business unit has over 20 years of experience in hot melt extrusion for life science applications. Our cGMP facilities are equipped with state-of-the-art melt extrusion equipment to support pharmaceutical clients from small scale formulation development through clinical supplies. A range of post extrusion processing equipment is available for solid oral dosage forms.



## FORMULATION DEVELOPMENT

At Foster Delivery Science, our multidisciplinary team works closely with clients to focus on the physical and chemical properties of the drug substance and the dosage form requirements. Each formulation is unique, just as each drug substance is unique. We can quickly screen your active pharmaceutical ingredients (API) with a series of polymers and excipients to achieve improved kinetic dissolution rates, site specific delivery and controlled release.

### MATCHING TEMPERATURE PROFILES OF DRUGS AND POLYMERS: CRITICAL FOR A SUCCESSFUL BLEND



Each project starts with a strategic formulation and processing plan. This strategic plan is the result of a thorough analysis of:

- Pre-formulation data
- Intended dosage and pharmacokinetic requirements
- Route and site of administration
- Desired manufacturing and processing conditions
- Drug and dosage form stability
- Safety
- Patient compliance and convenience
- Scale-up from lab to pilot to commercial

Our expertise lies in utilizing a uniquely broad range of capabilities to select the best approaches that meet your needs.



## GMP MANUFACTURING

Foster's current Good Manufacturing Practices (cGMP) capabilities are a critical link in advancing promising compounds from R&D to commercialization. Our manufacturing team efficiently manages small proof of concept batches, clinical trial supplies and commercial manufacturing. We manufacture products to specification and quality standards with on time delivery. The added benefits such as no hassle scheduling, rapid batch record release and reporting, efficiency in technology and methods transfer all contribute to our high client satisfaction in manufacturing projects.



Our GMP manufacturing services are designed to support compounds with a wide range of safety classifications and can be scaled from milligram to kilogram quantities. Process optimization and validation ensure reliable and repeatable dose forms from development through clinical supply.

Our 60,000ft<sup>2</sup> (5,575m<sup>2</sup>) facility in Putnam, CT is ISO 13485 and 9001 certified, registered with the United States Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA, Schedule II-V).

## QUALITY

At Foster, we believe that drug product development and manufacturing begins with a total commitment to quality. Our quality and regulatory systems represent our commitment to every phase of our business. Quality Assurance is a key element but is only part of the commitment. This commitment is a foundation in our corporate culture and demands quality in every service we offer and every system our business is built on.

## HOT MELT EXTRUSION LEADERSHIP

Foster offers over 20 years of processing expertise from highly regulated life science applications to pharmaceutical clients seeking to leverage hot melt extrusion for novel drug delivery applications. Our unparalleled experience and commitment in the field of hot melt extrusion supports a range of drug delivery applications that include solid oral dose, implantables, and films. Our staff, facilities and equipment are dedicated to the support clients from formulation development through clinical supplies.





**Foster Corporation**

*a PolyMedex Discovery Group® company*

**45 Ridge Road  
Putnam, CT 06260  
PH: 860-928-4102  
FX: 860-928-4226  
[info@fostercomp.com](mailto:info@fostercomp.com)  
[www.fostercomp.com](http://www.fostercomp.com)**

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