Melt Extrusion Modeling and Formulation Information System (MemFis®)

Formulation and process development – delivered with speed and on track
Melt extrusion – a future technology

More than 90% of drugs in the current pharmaceutical company pipelines are identified as poorly soluble belonging to BCS classes II and IV.

Solid dispersions offer effective solutions to the challenge of formulating poorly soluble drugs. Crystalline drug molecules are converted to and stabilized in the amorphous state by a polymeric matrix.

Melt extrusion is a leading technology in preparing solid solutions. The process is well-known in the plastics and food industries. Interest in melt extrusion for pharmaceutical applications has grown significantly due to its economic and environmental advantages and the opportunity to create innovative formulations.
Melt extrusion can be used to prepare well-defined pellets with controlled particle size. The melt extrusion process combines several conventional operations (blending, granulation, sizing) in one compact unit operation. Sustained release, taste masking and final dosage formation are accomplished in one step. With appropriate process and formulation design melt extrusion can be performed at lower than 100°C to safely formulate temperature sensitive actives (e.g. ibuprofen/EUDRAGIT® E PO at <60°C).

Bioavailability enhancement
- Polymers dissolve drugs and stabilize solid solutions

Pellet technology
- Homogeneous particle size distribution
- Sustained release or taste masking

Masking of unpleasant tasting actives
- Interaction of complementary ionic groups (anionic/cationic) provide advanced taste masking

Low temperature melt extrusion
- Temperature-sensitive drug compounds

Melt extrusion at a glance
- Easy scale-up
- High mixing efficiency (excellent content uniformity)
- Short processing time
- Easily controlled process parameters
- Process analytical technology (PAT)
- Solvent-free manufacturing (avoids environmental hazards and costly drying steps)
- Low cost continuous process
Empirical trial and error methodologies have extensively been used to identify polymer-drug pairs and saturation concentrations in solid dispersion formulation development. Here, binary or ternary blends of API and polymers, possibly in combination with solubilizers, are mixed randomly at several drug loadings.

Systematic approaches to formulation development of solid dispersions can potentially reduce the number of experiments significantly. Rather than relying on random mixing of drug and polymers, the initial formulations in screening studies are selected based upon drug-polymer physicochemical properties, such as solubility parameters, hydrogen bonding and thermal properties.

MemFis® (Melt Extrusion Modeling & Formulation Information System) allows pharmaceutical formulators systematic screening of formulations and processing conditions at early stages of solid dispersion product development. It applies well-established solubility parameters and extensive melt extrusion knowledge gained over the last decade at Evonik Pharma Polymers & Services for determining first formulations and initial processing conditions.
MemFis® – a jump-start for your melt extrusion projects

MemFis® at a glance

- Implements proven solubility parameters and molecular interaction considerations
- Provides estimations for both extrusion and formulation processes
- Combines Evonik information technology and melt extrusion expertise
- Saves API as well as development time and cost
- Reduces the number of experiments
- Enables development to start with small amounts of API being of particular importance for NCE developments
- Supports the right choice of API for life cycle management (generics/originators)
- Applies to all solid dispersion process technologies including spray drying

MemFis® is not exclusively designed for EUDRAGIT® polymers; it includes all pharmaceutical polymers, e.g. (meth)acrylics, cellulosics (HPMC, HPMCAS, HPC, EC, MC, CAP), vinyl pyrrolidones, vinyl acetates, vinyl pyrrolidones-co-vinyl acetates, and Soluplus®.
Pre-screening and MemFis®

After the first problem analysis and a theoretical evaluation, take advantage of MemFis®, our unique set-up for in-silico formulation modeling and process adaption which includes screening for polymers, drug loading and process parameters. In only one week, MemFis® provides valuable results to help you decide on the next steps of your project.

Feasibility studies

It is better to carry out a feasibility trial than discuss a problem at length. Often, one trial already provides more than 80% of the answer. We can produce smaller batches at less than 20 g total batch size, providing enough sample material for initial assessment and analytics.

Formulation development

The feasibility study was successful – what’s next? Using our equipment or yours, we assist you in formulation development to reach your targets faster and more conveniently. According to your formula or our proposals, you select what you need – theoretical assessment, experimental design and manufacture of extrusion batches. We also offer analytical services.

Clinical batches

We offer the capabilities of manufacturing melt extrusion batches under cGMP conditions to supply your clinical studies.
Evonik Pharma Polymers & Services
global capabilities

As a pioneer in pharmaceutical melt extrusion, Evonik Pharma Polymers & Services has an intimate knowledge of the equipment and related process parameters. Our global team of formulation experts have long-term experience to support your development projects maximizing the success of your API and significantly speeding up your development process.

Evonik Pharma Polymers & Services offers on-site support using the customer’s equipment for process development and trouble shooting. Technical workshops on various topics, including training in melt extrusion, are available. As a special service we design in-house seminars and presentations tailored to the customer’s specific requirements.

Evonik technical centers – capabilities and equipment
All six technical centers offer:

• MemFis®
• Feasibility studies
• Formulation development

Birmingham, AL, USA
• Steer Engineering Omicron 12

Piscataway, NJ, USA
• Thermo Fisher Minilab
• Leistritz Nano 16
• Spray Dryer

Darmstadt, Germany
• Rondol Microlab 10 mm
• Leistritz Micro 18
• Downstreaming equipment including Leistritz Micro Pelletizer
• Spray Dryer

Mumbai, India
• Steer Engineering Omicron 12

Shanghai, China
• Thermo Fisher Minilab

Tsukuba, Japan
• Büchi Mini B-290 Spray Dryer
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MemFis® = reg. trademark of Evonik Röhm GmbH, Darmstadt, Germany

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