Extrusion and Material Characterization for Drug Development and Production

From laboratory to tablet, your partners for innovation in pharmaceutical processing

Get your drugs to the market faster

A leading life science and control technology company can offer you more than just single solutions! Thermo Fisher Scientific, the world leader in serving science, can help you make your discovery and development process faster and more efficient. That's because we are professionals in nearly every phase of the drug discovery and development process, from target discovery to manufacturing.
Our Thermo Scientific material characterization (MC) solutions offer features and benefits that can span the pharmaceutical market from formulation to manufacturing. We use continous processes to allow reliable, one-step scale-up from development to production.

If your company's projects involve the following:

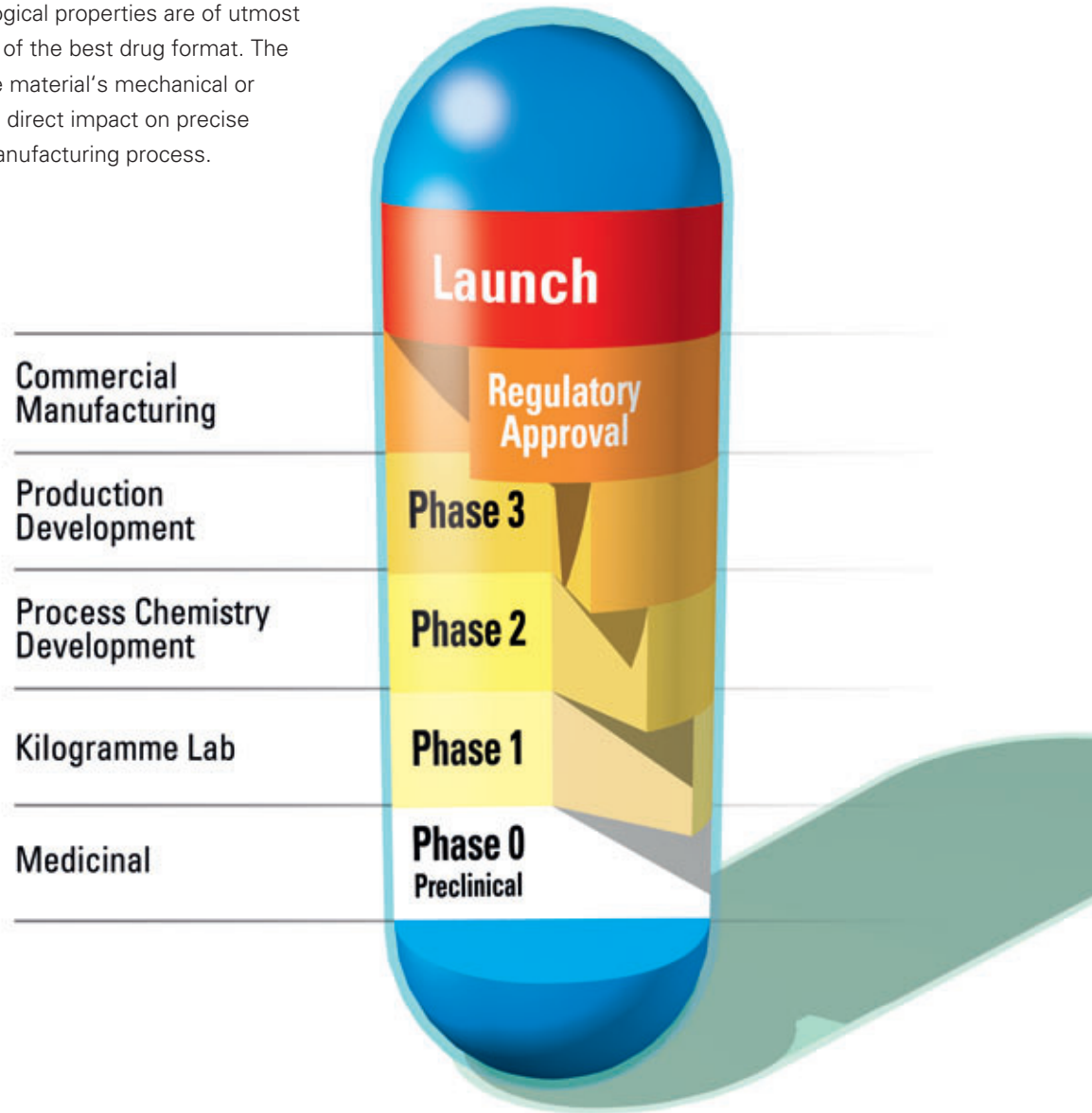
- **Hot melt extrusion**
- **Continuous granulation**
- **Dispersing or incorporating drug in liquids or solids**
- **GMP extrusion**
- **Online optical spectroscopy**
- **Analysis of rheological properties and microscopic structure**
- **Investigating viscoelastic or extensional flow behaviors**
- **Wettability of raw materials**

Thermo Scientific material characterization solutions assist you with your pharmaceutical challenges!

Benefit from our extrusion and material characterization process solutions to develop your next generation drug! Benefit from our **IQ/OQ support**.

Extrusion Technology and Material Characterization for your next generation of drugs

In material characterization rheological properties are of utmost importance for the determination of the best drug format. The ability to analyze and describe the material's mechanical or formulation properties can have a direct impact on precise dosing and optimization of the manufacturing process.



Extrusion Technology

Molding small proof-of-concept samples with a limited amount of material, for solid drug form and implant development.

Hot melt extrusion for drugs with poor solubility, or taste masking, for controlled release application.

Twin screw granulation for controlled continuous processing, without scale-up problems.

Proof-of-Concept Studies

Thermo Scientific HAAKE MiniLab (Pharma GMP)
This micro-compounder offers the ability to start formulation development with a limited amount of the new drug compound (only 5g or 7 cm^3). By using the optional force feeder, continuous hot melt extrusion with very small volumes is possible.

Thermo Scientific HAAKE MiniJet
The HAAKE MiniJet injection molding system produces test specimens for mechanical and rheological analysis and simulates simple tablet molding and features easy handling. The system is an ideal tool for sample preparation, especially when used in combination with the HAAKE MiniLab micro-compounder.

The HAAKE MiniLab and HAAKE MiniJet offer a system solution that ideally complements the Thermo Scientific HAAKE MARS and Thermo Scientific HAAKE RheoStress 6000 rheometers for the physical and rheological determination of your preliminary samples.

Extrusion Technology

Thermo Scientific HAAKE PolyLab OS System
The modular HAAKE PolyLab OS offers the ability to easily change the process set-up via the "plug and measure" principle. The Open System (OS) design allows you to connect a variety of different systems and sensors. The system can grow to meet future needs – e.g. twin screw, single screw or mixer, standardized sensors to determine viscosity, distribution, etc. Even optical tests can be done online using spectroscopy probes. Easy handling is ensured via the plug and measure concept which is based on an integrated recognition system.

Thermo Scientific HAAKE PolyLab QC
A dedicated, single-screw extruder or mixer based on the HAAKE PolyLab QC System technology but focused specifically on mixing and kneading applications.

Ancillary equipment
A broad range of ancillary equipment is available, including pre-mixers, chill rolls, strand pelletizing lines, air cooled face-cut systems, injection molding systems, and cast sheet or blown film lines. Additional non-standard ancillaries and dies for special applications are offered on request.

From formulation development to production, we are committed to supporting your rheological, compounding and extrusion needs.

Formulation Development – Clinical Sample Production – Production

Thermo Scientific PharmaLab

This reliable twin-screw extruder with co-rotating screws provides easy track recording and handling. The PharmaLab includes PLC control with data logging and recipe storage to ensure reliable and repeatable results. The clamshell barrel, with simple-to-remove liners, allows easy and thorough cleaning of contact parts, remote from the process area, without the need to completely disconnect the barrel. The stainless steel compounders are built to GMP standards with a focus on clean, streamlined GMP design.

Thermo Scientific Pharma GMP Extrusion

These reliable, co-rotating twin-screw extruders include PLC control with data logging and recipe storage to ensure reliable and repeatable results. The clamshell barrel, with simple-to-remove liners, allows easy and thorough cleaning of contact parts.

For pharmaceutical hot melt extrusion, the Thermo Scientific Pharma HME lines can be used for product and process development through to production, delivering product in pellet or flake form.

For continuous pharmaceutical granulation, the Thermo Scientific Pharma TSG offers a more reliable product than a batch process. Multiple samples can be produced from small amounts of API, with minimal scale-up problems.

Material Characterization

Determination of viscoelastic and elongational properties

Wettability analysis of your raw material

Synchronous analysis of rheological properties and microscopic structure

Thermo Scientific material characterization solutions that allow you to optimize your drug or production process!

Development and Quality Control

Thermo Scientific HAAKE MARS

The HAAKE MARS rheometer has been designed for flexible use in daily R&D and can be adjusted quickly and easily to new requirements. Different temperature control units ensure reliable operations at a wide temperature range. Special measurement tools and systems can be integrated, including pressure cells up to 400 bar, an optical module for the synchronous analysis of the rheological properties and the microscopic structure of a sample and a wide range of measurement geometries.

Thermo Scientific HAAKE CaBER 1

The HAAKE CaBER 1 enables you to quantify extensional properties of semi-solids and liquids during development and advances development and dosage design. It is the first tool to easily analyze elongation properties.

Material Characterization

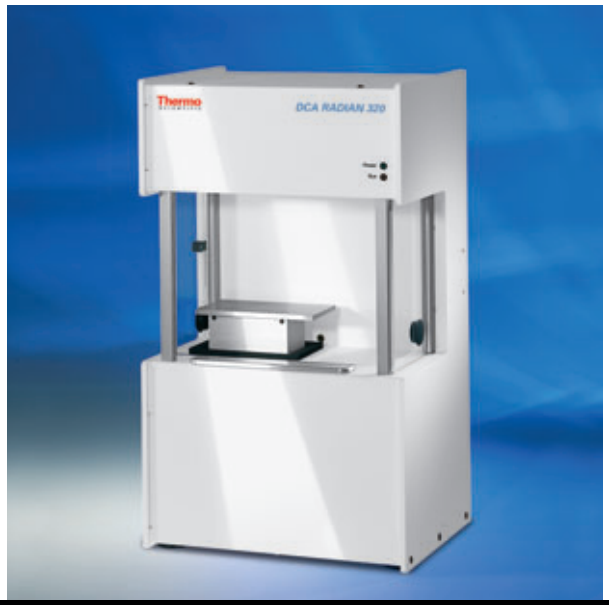
Thermo Scientific HAAKE Viscotester 7 plus
The quality control of the viscosity of fluids is supported by the HAAKE Viscotester 7 plus according to ISO 2555. The instrument complies with the "Brookfield method."
The small sample adaptor makes the unit ideal for use with expensive samples because it minimizes material consumption.

Whatever your challenges may be today or in the future – our family of products for the pharmaceutical market will enable you to be more successful!

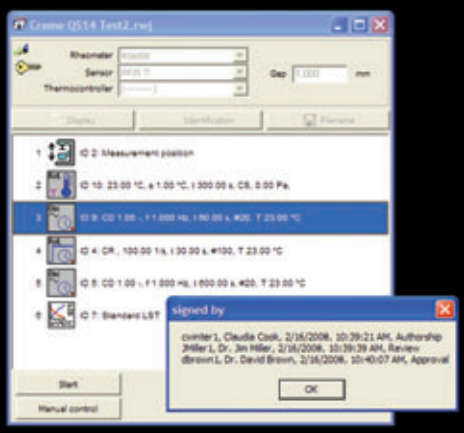
Formulation Development – Clinical Sample Production – Production

Thermo Scientific DCA Radian
Used to determine the wettability of your raw materials for dispersing, blending or mixing purposes, the DCA Radian is a user-friendly instrument with high precision and repeatability. The instrument can determine contact angle, surface tension, interfacial tension, wicking, fibre diameter, solid/liquid densities, CMC and solid volume.

Thermo Scientific rheometers and DCA units allow a comprehensive understanding of material characteristics.



Thermo Scientific HAAKE RheoStress 6000
The HAAKE RheoStress 6000 is a rotational rheometer for dedicated jobs in quality control and its modular design accommodates different temperature control units and measurement geometries.



Thermo Scientific HAAKE RheoWin 3
The HAAKE RheoWin 3 Software is the standard software for Thermo Scientific rheometers and viscometers and enables user-friendly data analysis. The HAAKE RheoWin 3 software can be extended with 21 CFR Part 11 tools for use with HAAKE MARS, RheoStress 6000 and Viscotester models. These tools have been developed to comply with the stringent regulations of the pharmaceutical industry. The tools provide a user management system, file integrity, an audit trail and electronic signature to ensure that the integrity of electronic records is always maintained.

Process Instruments

Benelux
Tel. +31 (0) 76 579 55 55
info.mc.nl@thermofisher.com

China
Tel. +86 (21) 68 65 45 88
info.mc.china@thermofisher.com

France
Tel. +33 (0) 1 60 92 48 00
info.mc.fr@thermofisher.com

India
Tel. +91 (22) 27 78 11 06
info.mc.in@thermofisher.com

United Kingdom
Tel. +44 (0) 1785 82 52 00
info.mc.uk@thermofisher.com

USA
Tel. 603 436 9444
info.mc.us@thermofisher.com

International/Germany
Dieselstr. 4
76227 Karlsruhe
Tel. +49 (0) 721 4 09 44 44
info.mc.de@thermofisher.com

www.thermo.com/mc

Thermo SCIENTIFIC