

Thermo Scientific Pharma *mini* HME

Conical micro compounder for hot melt extrusion and implant production

Developing new drugs, shortening time-to-market, reducing waste of expensive API's, and minimizing overall development costs provide distinct advantages for pharmaceutical manufacturers. The Thermo Scientific™ Pharma *mini* HME Micro Compounder helps achieve these goals by allowing users to identify the right drug candidates for hot melt extrusion (HME) and design an R&D-to-production process, starting with as little as 3 grams of material. Using a small-scale compounder such as the Pharma *mini* HME extruder can be also ideal when developing and manufacturing injectable drug implants.

Materials

- Pharmaceutical ingredients (API's)
- Excipients
- Medical polymers
- Drug delivery systems
- Subcutaneous implants

Applications

- Hot melt extrusion
- Medical devices
- Injectable implants
- Controlled drug release
- Handling and processing of highly potent API's in a glovebox

The challenge

Hot melt extrusion and continuous processing can lead to fast formulation development and cost efficient production.



Final injectable drug implant



But when developing new drugs, users are still faced with several challenges. Finding API/excipient formulations that are good candidates for hot melt extrusion can be difficult especially when the API is expensive and in limited quantities. In this phase of development, the health effects of a new API are often not clear. Therefore, it can be necessary to run HME trials in a laminar flow or glovebox to ensure maximum operator safety. On the other hand, subcutaneous implants designed for controlled drug delivery are produced in such small dimensions that a manufacturing throughput of only a few grams per hour is sufficient to establish a micro production line.

The solution

With the Pharma *mini* HME compounder, we offer a micro twin-screw extruder that can identify HME drug candidates with as little as 3 grams of total material. This helps you efficiently screen API/excipient formulations to

- establish injectable implant production
- operate in a glove-box, ensuring operator safety

The compounder with conical co- or counter-rotating screws is designed to minimize waste and reduce downtime for cleaning. The product contact parts can be easily removed and cleaned using a washing machine and an autoclave.

Even washing the product contact parts by hand is simple due to rounded edges and minimal screw threads and crevices. To reduce the risk of cross-contamination and minimize cleaning downtime, additional sets of product contact parts are available.

All parts are designed and manufactured to allow easy handling as well as quick assembling and disassembling, even with gloves in containment solutions such as a laminar flow box or a glovebox. Containment is possible because of the very small footprint of the Pharma *mini* HME compounder, and the separate touchscreen control, which offers the same look and feel as the larger Thermo Scientific™ Pharma twin-screw extruders. The IP 54 rating and the fanless design allow the operator to spray wash the Pharma *mini* HME compounder to bind powdery excipients and API's.

The conical screw design offers the advantage of reducing total volume and extra pressure build-up at the screw tips to extrude a uniform material with constant output rates. In addition, the conical design offers the best mixing capability on such a small scale and allows the Pharma *mini* HME compounder to operate without the use of expensive and sensitive feeding devices.

In combination with the integrated, cooled feed funnel and a cooling option for the continuous force feeder, the Pharma *mini* HME compounder can be used as a continuous small-scale compounder to prepare samples for clinical trials or for micro production of medical devices and implants as drug delivery systems. The shape of the extruded material can be controlled by using various die plates.

Ancillary equipment

Several feeding accessories are available, from a manual piston feeder for small quantities of material up to a force feeder for continuous feeding.

The modular design of the Pharma *mini* HME compounder allows an easy exchange of the product contact parts. Spare barrel components and screws are available. A batch conversion kit, which includes a barrel with backflow channel and a manual bypass valve is also an option. This allows the Pharma *mini* HME compounder to be converted from a continuous compounder to a small batch mixer with adjustable residence time. This enables the unit to evaluate the mixing behavior and thermal stability of the drug/excipient formulation. With the Thermo Scientific™ HAAKE™ MiniJet Pro Piston Injection Molding System, the Pharma *mini* HME compounder offers a complementary workflow solution to create a test specimen for formulation development and to characterize melt extrudate, solid dosage forms.



Cooled feed funnel

Features and benefits

- Requires only 3 g (4 ml) of material for compounding
- Small footprint, fanless design with separate touchscreen control for operation in fume cabinet or glovebox applications
- Removable and exchangeable product contact parts for quick and easy cleaning
- IP 54 for protection against dust and water allows the Pharma *mini* HME compounder to be spray washed
- Useable as small-scale production (e.g. for subcutaneous implants) unit for throughputs of 100g/h
- Touchscreen control with user levels and password protection
- Data logging software is an option to record temperatures, torque, and screw speed
- Optional batch conversion kit to use the Pharma *mini* HME compounder as a small batch mixer
- Complementary workflow solution when coupled with the HAAKE MiniJet Pro injection molder

Technical specifications

Motor power	400W
Speed range	10...360 min ⁻¹
Max. torque	5Nm/shaft
Power supply	230V ± 10%, 50/60 Hz 115V ± 10%, 60 Hz
Temperature	max. 280 °C with 2 set points
Heating time	<10 min
Volume	3g (4 ml)
Screw design	Co- or counter-rotating, pharma grade stainless steel 1.4112 (440 B)
Barrel	High performance / pharma grade stainless steel M340

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