

## Thermo Scientific Pharma 11

Unique, flexible twin-screw compounder for hot melt extrusion and twin-screw granulation

In the early development of a new drug, research and development formulation scientists face the challenge that only a small amount of expensive API (Active pharmaceutical ingredient) is available for experiments.

The Thermo Scientific Pharma 11 compounder provides cost-effective extrusion capabilities from a material and labor perspective requiring sample sizes of just 20 grams of material. Its parallel 11 mm twin-screws and compact design which is fully scalable with the Thermo Scientific standalone pharmaceutical compounding systems, enables researchers to obtain results relevant to the process and even perform small scale production.

### Primary Applications

- Drug delivery systems
- Implants
- Tablets
- Granules



### Pharma 11 mm Compounder

The Thermo Scientific Pharma 11 is a very small scale extruder perfect for a wide range of drug development applications. Achieving a minimum throughput of just 20 g/h, it is ideal for research and development applications especially when developing and testing recipes with expensive API and associated compounds. As a GMP-compliant unit, the Thermo Scientific Pharma 11 is also suitable for clinical trials and small scale production for throughputs up to 2.5 kg/h.

Designed to meet the toughest of challenges faced by customers and at the same time maximize the investment when progressing through the phases of the product development cycle, the screw and barrel designs are geometrically scalable across the whole Thermo Scientific portfolio of extruders from lab and pilot through to production scale.



## Key Benefits:

### Small

- Uses smaller material quantities for faster, cost-effective development
- Maximizes lab space with small footprint machine
- Perfect for glove box or isolator applications due to removable touch screen

### Simple

- Easy cleaning and validation: all material contact parts easily removable
- Easy to operate with user-friendly, intuitive touchscreen with integrated feeder control
- 2-in-1 machine: easily convertible from hot melt extrusion (HME) to twin-screw granulation (TSG) applications

### Scalable

- Minimizes scale up risks: Cost and time saving due to the full scalability of the Thermo Scientific extruder product family
- Provides process control: Documentation of extrusion parameters and suitable for PAT
- GMP-compliant, full validation available: FAT, SAT, IQ/OQ

## Minimized Project Risks

In early drug development, very small amounts of API are needed to produce a high variability of batches. The innovative Pharma 11 twin-screw extruder is the key instrument between the Thermo Scientific Pharma mini HME micro-compounder for feasibility trials and the bigger production twin-screw extruders.

Just one of the advantages of the Pharma 11 is that the screw elements and barrel design scale geometrically across the whole portfolio of Thermo Scientific Pharma extruders and thus allow easy process scale-up.

The parallel twin-screw extruder portfolio caters to each step of the drug development process from small scale formulation development with the 11 mm to pilot and production scale with the 16 mm and 24 mm extruders and beyond. Each machine is complemented by the necessary feeders and downstream equipment that integrate seamlessly to provide a true "lab to line" solution.

## High Modularity, High Convenience

The throughput range of the Pharma 11 is from 20 g/h up to 2.5 kg/h. Therefore it is useful for very small batch production in drug development and as a small continuous production machine, as in the case of implant production for example.

The product contact parts are very easy to remove and therefore easy to clean in a washing machine. Replacement barrels and screws are available as individual options, ideal when dealing with numerous recipes and needing to avoid any risk of cross-contamination. This can save significant valuable time both in the lab and when needing to achieve cleaning validation. Split barrel, split die and barrel clamps also help to simplify the cleaning process.

The barrel of the parallel co-rotating twin-screw extruder has an L/D ratio of 40:1. With the screw length adaption kit significant flexibility is provided in enabling the barrel length to be adjusted to suit the application.



Pharma 11 – 11 mm compounder for pharmaceutical applications

## Easy Handling

Testing of different formulations and associated validation documentation is quick and easy. High resolution torque measurement and PAT measurements such as FTIR are additional options easy to integrate.



Easily remove and replace the barrel of the Pharma 11

## Handling Highly Potent APIs

The small footprint of the Pharma 11 compounder makes it ideal for glove box applications when having to handle aggressive materials. For this purpose, the touchscreen can be removed and fixed at the outer side of the isolator.

With the unique monocoque, fanless design complete with electronics fully integrated into the unit itself, no additional cabinet is required and the unit can simply be rinsed with water (IP54) to avoid any dust formation.

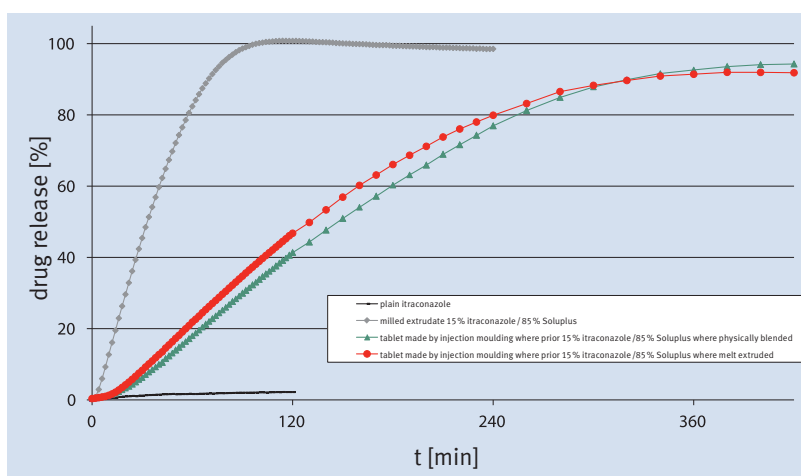


Thermo Scientific Pharma 11, the perfect fit for isolator applications

## Hot Melt Extrusion - A Versatile Process For Formulation

More and more poorly soluble APIs are reaching the drug formulation laboratories. Hot melt extrusion offers a continuous and easy way to produce stable solid solutions or solid dispersions with a fast and increased dissolution behavior.

Nevertheless, this outstanding process is also valuable for a prolonged release over weeks or even months and can be achieved by changing the excipient. With the HME process, formulation scientists have the opportunity to design a vast range of drug release profiles.



Release profiles of Itraconazole in different formulations:

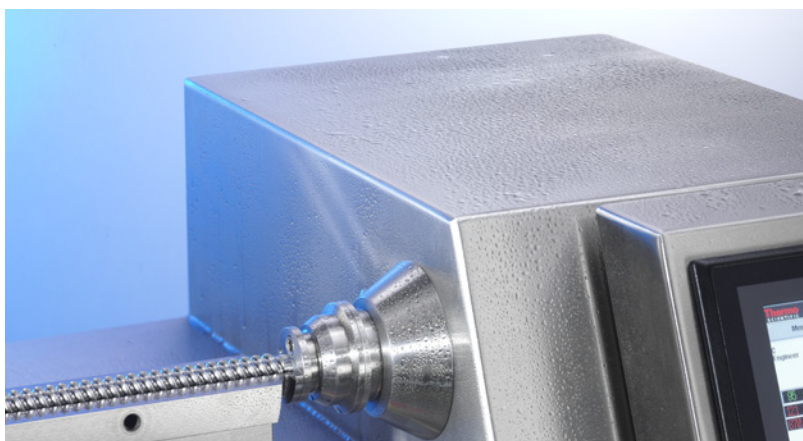
Black curve shows dissolution of pure API, blue curve shows dissolution of powder mixture after injection moulding, red curve shows release of the melt extruded mixture

Graph courtesy of BASF SE, Ludwigshafen/Germany

## GMP Compliant Extrusion Solution

To cater to a broad range of process requirements, the Thermo Scientific Pharma 11 can be combined with a variety of feeding solutions and downstream equipment. These include volumetric and gravimetric feeders for even the most challenging bulk materials. To produce granules from the melt an air-cooled conveyor belt can be used to cool the polymer strand and transport it neatly onto a pelletizer. With its variable rotating cutter, the pelletizer may be used to produce cylindrical pellets in different sizes for further processing.

All product contact parts are made from pharma-grade stainless steel with relevant validation documentation including FAT, SAT, IQ/OQ.



Easy cleaning and validation, spray-washable unit with easily removable contact parts

Technical Data	
<b>Speed</b>	Variable speed drive system (10 to 1000 rpm)
<b>Temperature</b>	10°C to 280°C (with appropriate cooling device)
<b>Heating zones</b>	7 x 5 L/D heat/cool zones, +1 heating zone for die
<b>Feed zone</b>	Permanent liquid cooled feeding port
<b>Die</b>	Rod die 2 mm, Optional exchangeable die nozzles
<b>Torque</b>	6 Nm per shaft, constant torque, safety monitored
<b>Pressure</b>	100 bar, safety monitored
<b>Power supply</b>	230 V single phase, 16 Amps
<b>Size (L x W x H)</b>	90 x 50 x 41 cm
<b>Weight</b>	55 kg
<b>Material</b>	Pharma grade stainless steel

In nearly every phase of the drug discovery and development process, we help you make your discovery and development process faster and more efficient. Find out more about our Thermo Scientific twin-screw extruder portfolio featuring micro-compounders, small-scale units or production extruders.

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### Material Characterization

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