

Pharma 11 Twin-Screw Extruder

Multifunctional pharmaceutical twin-screw extruder for development and small-scale commercial manufacturing

The Thermo Scientific™ Pharma 11 Twin-Screw Extruder is a multifunctional, small-scale extruder that easily converts from hot-melt extrusion (HME) to twin-screw granulation (TSG) and to wet extrusion. With its perfect size, this innovative product is the key instrument between the Thermo Scientific Pharma *mini* HME Micro-Compounder for feasibility trials and the more extensive production-scale Pharma 16 or Pharma 24 Twin-Screw Extruder.

With a throughput range starting at 20 g/h up to 2.5 kg/h, the Pharma 11 is designed to minimize early-stage project costs by supporting the use of small amounts of material, such as high-value API (active pharmaceutical ingredients). In addition, the Pharma 11 Twin-Screw Extruder design promotes straightforward process scale-up across the entire Thermo Fisher Scientific pharmaceutical extruder portfolio.

Small size provides big advantages

The small footprint of the Pharma 11 Twin-Screw Extruder makes it ideal for laboratory glove box applications such as when working with sensitive or hazardous materials requiring a controlled atmosphere. The Pharma 11's removable touchscreen can be placed outside of the glove box allowing for safe control of the extruder's process conditions. With the unique monocoque, fanless design, complete with fully integrated electronics and no additional cabinet required, the unit is simple to clean.



Hot-melt extrusion

HME offers a continuous and easy way to produce stable solid solutions or solid dispersions for poorly soluble APIs. The formulation will design the dissolution profile. This remarkable process is also valuable for immediate release and prolonged release over weeks or even months and can be achieved by changing the excipient. With the HME process, formulation scientists can design a vast range of drug release profiles.

Application diversity

Thermo Fisher Scientific pharmaceutical extruders span a wide range of human and animal health applications. In addition to HME, all instruments can be utilized for wet and melt granulation, film applications such as orally disintegrating films (ODF) and patches, implant production, and wet extrusion. Together with our customers, we expand these applications continuously.

Pharma 11 is a GMP-compliant extrusion solution

All product contact parts are made from pharma-grade stainless steel with relevant certification. Complete validation documentation including FAT and SAT protocols with IQ/OQ is available.

Improved software for best performance

The software supports 21 CFR Part 11 compliance, and the Windows® based, industry-standard control and operation software is comprehensively designed to enable integration into the customer's IT architecture. Moreover, Recipe / Batch Report and Audit Trail are available options.

Safeguards against cross-contamination

The product contact parts are easily removable and cleanable in a dishwasher. Replacement barrels and screws are available as individual options, ideal when dealing with numerous formulations and the risk of cross-contamination. This can save significant valuable time both in the lab and in the case of cleaning validation. Optional high-resolution torque and Process Analytical Technologies (PAT) measurements, such as FTIR, are easy-to-integrate options.



The unique modular design and easy-to-clean parts make the Pharma 11 Twin-Screw Extruder incredibly easy to use. The product contact parts are easily removable.

Customer benefits

The compact size, enhanced software, and wide range of downstream accessories support hot-melt extrusion and twin-screw granulation applications.

Multi-functional

- 3-in-1 machine: easily convertible from hot-melt extrusion (HME) to twin-screw granulation (TSG) and to wet extrusion
- Due to its compact size, it is suitable for R&D laboratory and pilot plant or small-scale commercial manufacturing
- Enhances process control, easy incorporation of PAT tools
- Industry-standard PLC allows integration into the customer's process control system via the ModBus TCP/IP and UPC UA interface

Cost and time efficient

- Fully scalable with the Thermo Fisher Scientific extruder product family
- Low minimum feed rate (down to 20 g/h depending on material) reduces the use of high-cost raw materials in the development stage

User friendly

- Fast, thorough cleaning validation due to high modularity— all parts that might contact product are easily removable
- Easy to operate with an intuitive, user-friendly interface
- Individualized online process tracking, via selection of parameters from a pre-defined list

Ideal size

- Maximizes lab space with a small footprint
- Perfect for the glove box or isolator applications due to its size and removable touchscreen

Compliance

- GMP-compliant, full validation with documentation including FAT and SAT protocols
- Recording of all process data with customizable options of data transfer and data reporting
- Supports 21 CFR Part 11 compliance

Improved software features for best performance

- Intuitive user interface combined with high-performance PLC for easy and automated operation
- Windows based—integration in the customer's IT architecture is possible
- User Management including the Windows function for password management / password restrictions
- Recipe / Batch Report and Audit Trail are optionally available
- Control of the feeder is already integrated
- Standard HMI languages include English and German— additional languages are available

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

Technical data

Speed	Variable speed drive system (10 to 1000 rpm)
Temperature	10 °C to 280 °C (with appropriate cooling device)
Heating zones	7 x 5 L/D heat/cool zones +1 heating zone for die
Feed zone	Permanent liquid cooled feeding port
Die	Rod die 2 mm (optional exchangeable die nozzles)
Torque	6 Nm per shaft, constant torque, and safety monitored
Pressure	100 bar, safety monitored
Power supply	230 V single phase, 16 Amps

Size (L x W x H)	90 x 50 x 41 cm
Weight	55 kg
Material	Pharma grade stainless steel



Pharma 11 Twin-Screw Extruder

Learn more at thermofisher.com/pharma11

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