

Thermo Scientific Pharma *mini* Implant Line

The complete solution for injectable drug delivery systems

Subcutaneous solid implants are an option for drug delivery systems and provide long-term drug release with the correct dosage. This pharmaceutical disease treatment can improve patient compliance because it is generally less burdensome than scheduled pills or injections. Typically the drug implants have the shape of a thin and flexible rod and are administered at specific locations where the drug is needed most. A majority of the commercially available implants deliver high-potency drugs e.g., hormones, very effectively and thus the necessary dose can be lowered, minimizing side effects.

For the development and production of solid drug implants a dedicated and fully automated system like the Thermo Scientific™ Pharma *mini* Implant Line can help reduce time to market and ensure that consistent, high-quality products are produced.

Integrating the Thermo Scientific™ Pharma *mini* HME micro compounder into an automated pharmaceutical process line provides precision and reliability with a hermetically sealed product flow, offering a complete solution that meets cGMP and FDA requirements.

Primary applications

- Implants for ophthalmology
- Hormone treatment of schizophrenia, prostate or breast cancer
- Extrusion of biocompatible polymers e.g. EVA, ethylene-vinyl acetate
- Extrusion of biodegradable polymers e.g. PLGA, poly(lactic-co-glycolic acid)



Pharma *mini* Implant Line

A hermetically sealed container filled with pre-blended material, consisting of polymer and API (active pharmaceutical ingredient), is connected with a containment valve to the Pharma *mini* Implant Line. After safe coupling the valve opens for product transfer directly into a gravimetric feeding unit. This containment solution ensures maximum operator safety and eliminates contamination of the starting material.

The high-accuracy dosing of the powder feeder together with the cooled inlet funnel of the extruder guarantee a uniform filling of the extruder screws, which is crucial for precise extrusion. This setup together with well-defined operating temperature and product residence time allows processing of starting materials that exhibit challenging properties such as easy segregation or thermal sensitivity. Therefore, the Pharma *mini* Implant Line is well suited for a wide range of possible polymer/API combinations without limiting the scope of your research.

Integrated QC of the implant

A range of die plates are available that produce filaments of 0.5 to 2.0 mm in diameter when leaving the extruder. Subsequent to the product discharge from the extruder, a closed-loop filament control system ensures that the specified diameter of the implant strand has minimal variability.

- A temperature-controlled guide plate avoids adhesion of the extruded strand during transportation. Deformation of the round strand is thus minimized.
- A bi-axial laser gauging system records diameter and roundness of the strand, assuring 100% quality at any time.
- A speed controlled, puller-wheel system does final corrections on the extruded filament diameter for a reproducible implant.

Based on the measurements of the control system, the continuously extruded filament will be cut into final implants meeting the required dimensions for diameter and length. Implants that are “out of specification” will automatically be collected in a separate collection tray within the process to ensure 100% quality of the end product.

The control system ensures an accurate feed stream of ingredients that leads to a stable extrusion process and facilitates the reproducible manufacturing of precise implants within small tolerances. During the entire manufacturing process the current system status, parameter values and the operation mode are monitored and displayed in detail on the Human Machine Interface (HMI) and recorded into an audit trail and batch report.

The Pharma *mini* Implant Line offers a unique solution for the complete process of developing and producing injectable drug delivery systems. High-quality components and precise automation with integrated QC and documentation help make your discovery and development process fast and efficient with these features:

- Hermetically sealed handling of material for maximum operator and product safety
- High-gravimetric feeding accuracy ($\pm 0.5\%$)
- Reproducible and stable extrusion process up to 100 g/h, even for challenging materials



Laser based take-off and cutting system

- Precise diameter control and adjustment in the range of 0.5 mm and 2.0 mm; accuracy of final product $\pm 0.005\%$ to 0.05% (depending on physical parameters of the compound used)
- Exact cutting of implant strand into specified lengths
- Automated sorting of in-spec and out-of-spec product for 100% quality assurance
- Integrated software control system for monitoring, documentation and displaying all system-relevant and process-relevant data



Final injectable drug implant

Technical specifications

Drive

Length / width / height (complete system)	1500 / 1600 / 2300 mm
Voltage / current / frequency	AC 400 V 3Ph + N + PE / 15 A / 50 Hz
Air pressure supply	outer diameter 10 mm
Weight	439 kg
Bypass	Pneumatic valve

Contact us today to learn more about our automated implant line, and how it can streamline your drug development projects.

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