

High Potency API and Drug Product Services



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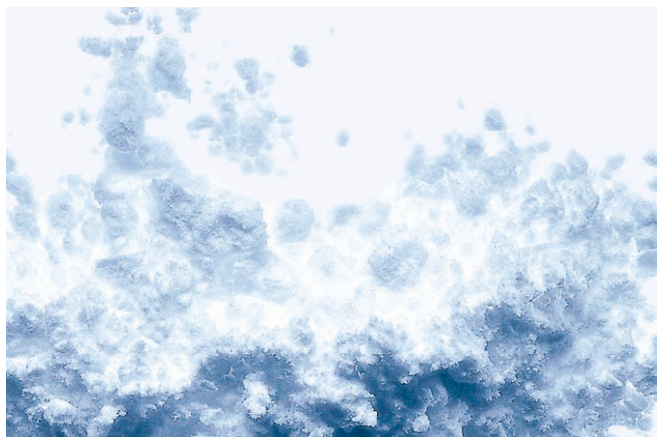
Siegfried offers the capability for early stage development, scale-up & commercial manufacture of both high potency drug substance and high potency oral solid dosage forms, with occupational exposure limits (OEL) ranging down to 1 µg/m³.

With continual investment in its containment technology, controls & the capability for safe handling of such materials and a breadth of operating experience since 2004, you can expect more with Siegfried as your preferred partner for high potency material needs.

For drug substances Siegfried offers in Zofingen, Switzerland a state of the art development & analytical building (opened 2009), using specific separate controlled areas for synthesis, process development & analysis. API scale-up and cGMP manufacturing is provided in its segregated production facilities for high potency materials.

Drug product formulation development and small scale cGMP manufacture is also provided at Zofingen in Siegfried's purpose built containment facility opened in 2012. Coupled with existing high potency commercial manufacturing facilities at its Malta site, seamless scale up of your drug product from early development through to regular production is available.

The combination of both drug substance & drug product services when working with Siegfried means you can expect more value & synergies, offering you complete integration and continuity of supply for your high potency products throughout their lifecycle. Contact us for an informed and open discussion regarding how we can meet your requirements.



Drug Substance

Overview

Zofingen (OEL to 1 µg/m³)

- Modern state of art development & analytical building (opened 2009), with specific separate controlled areas for synthesis, process & analytical development.
- Segregated cGMP production facility for high potency material process scale-up & API manufacture.
- Commercial scale cGMP production facility.

Development

Purpose built labs for handling high potency materials, both for synthetic chemistry and analytical services.

- Synthetic route investigation
- Process optimization
- Process implementation
- Determining critical process parameters
- Salt screening / crystallization program
- Design of Experiment (DoE) approaches
- Developing 2nd generation processes

Small / Pilot Scale

Production scale

Reactor configuration: 2 x 60 L glass lined
60 L Hastelloy
100 L glass lined

Operating Range: –60°C to 220°C

Pressure Range: up to 16 bar

Product Isolation: 80 L Hastelloy Filter-dryer (incl. Glove box)

Batch Sizes: 1–20 kg

Pilot scale

Reactor configuration: 250 L glass lined
400 L glass lined
250 L stainless steel

Operating Range: –60°C to 220°C

Pressure Range: up to 2 bar

Product Isolation: 40 L Hastelloy centrifuge

Drying: 200 L Hastelloy spherical dryer

Batch Sizes: 10–80 kg

Production

Production scale

Reactor configuration: 1 x 1000 L stainless steel
2 x 2500 L stainless steel
2 x 2500 L glass-lined
2 x 4000 L (stainless steel & glass-lined)
1 x 5000 L stainless steel

Operating Range: –20°C to 160°C

Pressure Range: Up to 40 bar

Product Isolation: Centrifuge (Halar/hastelloy)

Drying: Spherical dryer

Batch Sizes: 100 kg

Other capabilities

Milling facilities

Hammer mill Micronisation (planned)

Drug Product

Overview

Zofingen (OEL to 1 µg/m³)

- Segregated cGMP high containment development area for formulation development & small-scale sample manufacture.
- Separate controlled area for analytical development and quality control.

Malta (OEL to 1 µg/m³)

- Segregated cGMP production areas for high potency material handling.
- 4 separate suites for granulation, tableting, coating & blister production.

Development

Wide range of pre-formulation and dosage form development services, including analytical development and stability studies.

Operations: Blending
mixing
granulation
compression
coating
encapsulation
bottle filling

Small scale

Site: Zofingen

Scale: Up to 3 kg

Products: granules, tablets, film-coated tablets, capsules

Equipment: Isolator, V-processor, sieve, tablet press, coater, capsule machine

Service: Initial formulation process development & cGMP clinical trial quantities

Siegfried substance classifications & handling

OEL*	Exposure category	Hazard risk potential	Available at Siegfried
< 1.0 µg/m ³	4	Very High	No
10 – 1.0 µg/m ³	3	High	Yes
50 – 10 µg/m ³	2B	Substantial	Yes
500 – 50 µg/m ³	2A	Enhanced	Yes
> 500 µg/m ³	1	Small	Yes

* Occupational Exposure Limit

Handled in High Containment area

Note: Cytotoxic and alkylating agents excluded

Production

Site: Malta

Scale: Up to 120 kg

Products: granules, tablets, film-coated tablets, blister

Equipment: Isolator, V-processor (one pot granulator), sieve (rotating), tablet press, coater, blister machine

Service: Scale-up and commercial manufacturing

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