

Manufacturing at Production Scale



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Production Scale Manufacturing Leverkusen

ZeTO* 1 2,500 l reactors SMB Distillation columns Centrifuges Dryer	ZeTO 2 6,300 to 12,000 l Distillation columns Filter dryer	API Unit 2,500 – 8,000 l Centrifuges Filter-paddle - and double cone dryers
-100°C up to 250°C up to 6 bar	-100°C up to 250°C up to 6 bar	-40 °C up to 200°C up to 16 bar
Multipurpose	Multipurpose	Multipurpose
cGMP and ISO API's, regulated interm.	GMP and ISO regulated interm.	cGMP API's, regulated interm.

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* Trademark of Saltigo GmbH

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Production Scale Manufacturing

DHA, Leverkusen

2,000 – 5,000 l

Distillation columns,
Autoclaves
Several filtration and
drying devices

-20°C up to 350°C
up to 200 bar

Multipurpose &
Challenging Chem.

cGMP and ISO
regulated
intermediates

CAE, Dormagen

8,000 – 16,000 l

Distillation columns
Several filtration and
drying devices

-100°C up to 190°C
up to 6 bar

Multipurpose &
Challenging Chem.

ISO
intermediates

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Production Scale Manufacturing - ZeTO 1 and 2

Central Organics Pilot Plants

- 2 main buildings with 14,500 m² production area
- Modular design, multi-purpose
- Around 150 products per year, approx. 60 % new products annually
- Over 40 years experience in almost every area of organic chemistry with more than 6,500 documented operating procedures.



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ZeTO 1 and 2 - Equipment

Agitated reactors

- 130 units, 500 m³ total reactor volume (reactor vol. 100 l – 12.500 l)
- gl, alloy, ss, pressure up to 25 bar
- Autoclaves up to 200 bar
- Separate compartments for handling toxic / sensitizing chemicals

Compound isolation

- Distillation columns up to 68 theoretical plates
- Thin film evaporators
- Agitated nutsche filters - rotary dryers
- Granulators
- Filter dryers - contained packaging systems

Simulated Moving Bed Chromatography – ZeTO



- cGMP standard
- Scale up, optimization, production
- Continuous separation of racemates
- Fast access to pure enantiomers

SMB – Features

- 8 high pressure columns (60 bar)
- Evaporators 2.5 and 6.3 m³
- Separation from 100 kg
- Annual capacity up to 5 t racemate

API Unit



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API Unit

Plant Type	Multi Purpose Plant for production of APIs and Registered Intermediates
Location	Leverkusen
Capacity	> 200 t/a APIs

- Handling of corrosive RSMs and APIs
- Available capacities for reactions, work up, crystallization and re-crystallization under cGMP
- Closed systems for product syntheses and isolations
- Successful FDA-Audits
- Highly skilled personnel
- Good infrastructure with all essential functions nearby, especially the scale-up competence center of ZeTO

DHA Plant in Leverkusen

Core Technology

Hydrogenation (2-200 bar)

Typical Reactions

Catalytic hydrogenation of nitro compounds, ketones etc., incl. enantioselective hydrogenation with homogeneous catalyst; reductive aminations, high-temperature (350 °C, 200 bar) alkylations

Equipment

3 production lines:
1 production line is qualified to cGMP
3 x 2 m³ stainless steel reactor cascade
– 5 m³ Hastelloy reactor (cGMP)
– 5 m³ stainless steel reactor (350 °C)
– 3 distillation columns

Capacity

10,000 mt/a

CAE Plant in Dormagen

Core Technology

Phosgene chemistry / multipurpose plant

Typical Reactions

- continuous and batch phosgenation
- gas- and liquid-phase phosgenation



Formation of aliphatic and aromatic chloroformates, symmetric and mixed carbonates, isocyanates, carboxylic acid chlorides, ureas, urethanes etc.;

Chlorinations; condensations;
up- and down-stream chemistry
to phosgene steps

Equipment

27 reactors; total reactor volume 350 m³
(40% glass lined steel);

7 filtration/ drying devices; 9 distillation columns

Low temperature reactors, -40 °C and -100 °C