

# Manufacturing at Production Scale



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# Production Scale Manufacturing Leverkusen

<b>ZeTO* 1</b> 2,500 to 6,300 l	<b>ZeTO 2</b> 6,300 to 12,000 l	<b>API Unit</b> 2,500 – 8,000 l
SMB Distillation columns Centrifuges Dryer	Distillation columns Filter dryer	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 intern.	GMP and ISO regulated intern.	cGMP API's, regulated intern.

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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 m<sup>2</sup> 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 m<sup>3</sup> 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 m<sup>3</sup>
- Separation from 100 kg
- Annual capacity up to 5 t racemate

# API Unit



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Case Studies | Plant 1 - 4 | Plant 5 - ZeTO | **Plant 5 - API Unit** | Plant 5 - SMB | Redmond | HSE |

# 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 m<sup>3</sup> stainless steel reactor cascade  
– 5 m<sup>3</sup> Hastelloy reactor (cGMP)  
– 5 m<sup>3</sup> 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 m<sup>3</sup>  
(40% glass lined steel);

7 filtration/ drying devices; 9 distillation columns

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