



4 PROCESS R&D LABS:

- 4 walk-in hoods; 20 bench top hoods
- 250 ml to 25 Liters
(50 total reactors totaling > 500 L)

4 SCALE-UP GMP KILO LABS

- 30 L glass lined reactor
- 50 L glass lined reactor
- 50 L Hastelloy-C reactor
- 60 L vacuum filter
- 20 L, 30 L, 2 x 50 L separating funnels

DRYING AND STORAGE CAPABILITIES

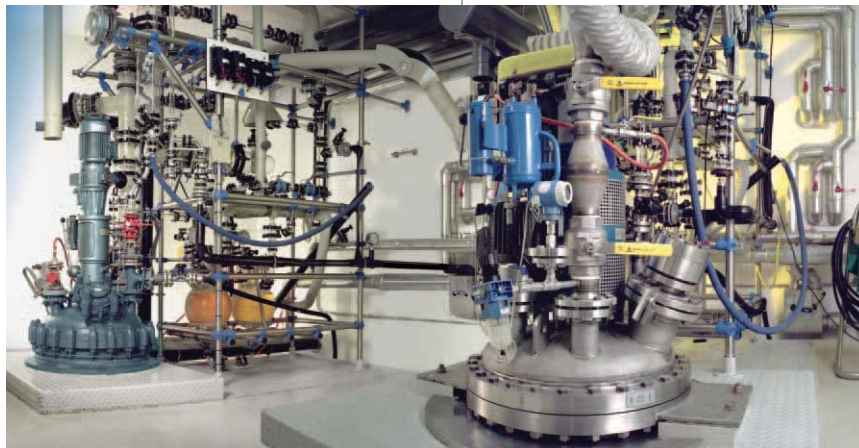
- Drying capabilities up to kg level in vacuum tray dryer
- GMP storage

NEW LABS COMPLETE

- 10 bench top hoods for Process R&D in 2 separate labs
- 2 fully isolated GMP suites
 - Class 100.000 equipped with 1 bench top hood and 2 walk-in hoods
 - 250 ml to 35 Liter scale

The facility houses a complete capability for process research, development, and scale-up with a variety of benchtop and walk-in hoods to accommodate projects from gram scale up to multi-kilo production in a GMP environment. Labs are outfitted with glassware up to 80 liters, rotary evaporators, and drying capabilities up to kilogram scale.

The laboratories contain equipment capable of -100°C up to 250°C, as well as high pressure equipment and capabilities for high vacuum distillations. The design and layout of the laboratories ensures that projects will flow smoothly in a controlled environment from lab scale up to pilot plant. Several jacketed reactor systems mimic the plant environment, thus making process scale-up into the plant as predictable as possible.

**HEATING:**

- Steam; up to 9 bar (170°C)
- Oil heating up to 300 °C

CHILLERS:

- Chillers 5°C and -25°C
- Cryogenic cooling on Hastelloy C22 350 L Reactor (-100°C)

PRESSURE:

- -1 up to 8 bar at pilot plant scale
- Pressure reactors:
2 and 4 L; 40 bar, 10 L; 10 bar,
350 L; 8 bar

Our facility houses reactors in separate suites to accommodate the most challenging projects at the multi-kilogram scale. The facility is designed with isolation and containment in mind, and we routinely provide rapid scale up from early development batches in the lab, to plant scale under GMP conditions. Our plant has been designed to maximize flexibility, not only in reactor parameters (temperature, pressure, materials of construction), but flexibility to rapidly move from project to project, thus speeding overall development time.

GMP:

- 1 x 250 L GL
- 2 X 450 L GL
- 1 x 300 L Hastelloy C22
- 1 x 1,000L GL
- All multi-purpose reactors
- Minimum stirring volume: 10 L
- Receiver vessels: 4 x 200 L glass, 250 L GL, 100 and 200 L stainless steel

ISOLATION EQUIPMENT:

- Pressure filters; 2 x 30 L Seitz (stainless steel), 60 L (stainless steel) Seitz 100L (stainless steel) and 2 x 200 L (stainless steel and GL)
- Vacuum filters; 4 x 200 L
- Centrifuge; 5 kg and 90 kg
- Hast-C Filter/dryer; 380 liter
- Separating funnels; 4 x 200 L glass
- Rotavapors; 1 x 10 L, 3 x 20 L
1 x 50 L
- Freeze dryer; 12 L
- Wiped film evaporator (WFE)

**DRYING EQUIPMENT
(GMP ROOM):**

- Vacuum drying chambers (kilogram quantities)
- Pharma vacuum dryer (tens of kilograms)
- Atmospheric tray dryer (50 kg)



The Weert facility houses fully equipped analytical laboratories to support in-process controls, QC release testing, reference standard qualifications, and method development/validation in compliance with GMP requirements and ICH guidelines.

METHOD DEVELOPMENT AND VALIDATION SERVICES INCLUDE:

- **Stability indicating methods**
- **Residual solvents**
- **Cleaning validation**
- **In-process controls**
- **Forced degradation and impurity identification**

Comprehensive stability storage and testing services are also offered under ICH guidelines. This includes the following stability conditions $25^{\circ}\text{C} \pm 2^{\circ}\text{C}/60\% \text{ RH} \pm 5\% \text{ RH}$, $30^{\circ}\text{C} \pm 2^{\circ}\text{C}/65\% \text{ RH} \pm 5\% \text{ RH}$ and $40^{\circ}\text{C} \pm 2^{\circ}\text{C}/75\% \text{ RH} \pm 5\% \text{ RH}$.

Also, custom stability conditions are available.



ANALYTICAL EQUIPMENT

- **14 x HPLC systems equipped with UV, DAD, RID, ELSD & MS detection**
- **2 x LC-MSD (single quadrupoles)**
- **3 x gas chromatographs with FID detectors**
- **1 x GC-headspace**
- **1 x GC-MS (EI/CI)**
- **UV/VIS spectrometer**
- **Titration equipment**
- **Halogen moisture analyser**
- **Differential Scanning Calorimeter**
- **Ash oven + incubator oven**
- **FT-IR**
- **Polarimeter**
- **Particle size counter**
- **Air monitoring equipment (microbial)**
- **4 x Climatic testing chambers**
- **Ion chromatography**
- **Karl Fischer equipment**
- **Stability storage: $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$, $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$**