



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:  $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ ,  $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$**