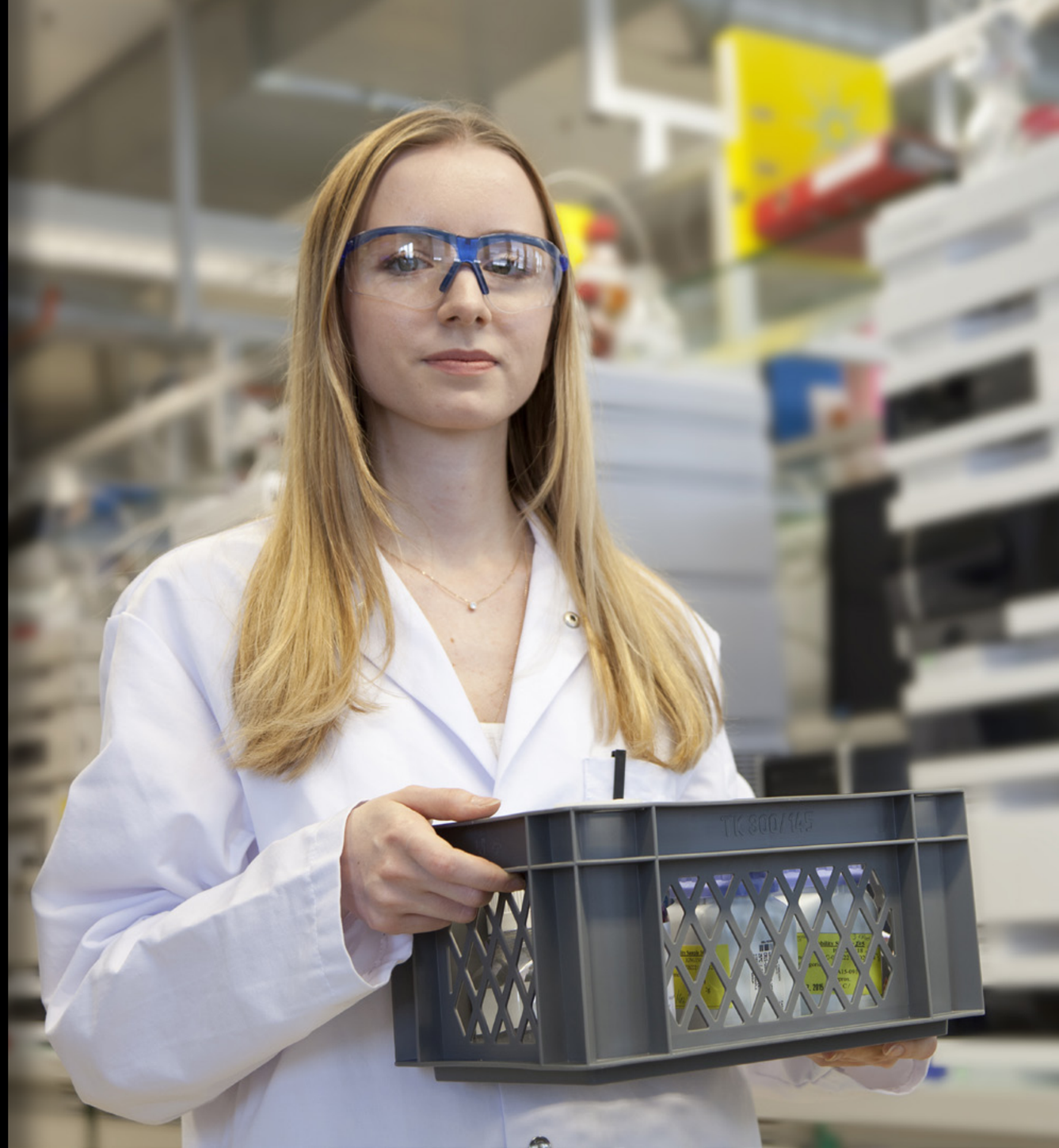
CARBOGEN AMCIS

A Dishman Group Company

BRINGING YOUR SCIENCE TO LIFE

ICH Stability Studies and Integrated Analytical Services



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Stability studies and forced degradation tests are a critical component of drug development for the assessment of drug storage or shipment conditions, expiration date, and packaging. In fact, they provide a thorough understanding of the chemical behavior, degradation pathways and the intrinsic stability of a new molecule. To accelerate the registration process of a new drug product or substance, stability and forced degradation studies should be performed as early as possible in the drug development process.

At CARBOGEN AMCIS AG, we can perform stress and stability studies according to the International Conference on Harmonization (ICH) guidelines. As knowledgeable consultants with over 25 years of expertise in contract chemical process, R&D, and analytical chemistry for active pharmaceutical ingredients (APIs) including highly potent molecules (HPAPIs), we work in close collaboration with our customers to fully understand their new chemical entities (NCEs) and help them to reduce the time, costs and risks associated with their development.

Integrated Analytical Services

APIs • Highly Potent APIs • Drug Products • Drug Substances

Our stability studies are performed in fully cGMP validated and mapped stability chambers, which operate at ICH conditions (25°C/60% RH, 30°C/65% RH, 30°C/75% RH and 40°C/75% RH) and at low temperatures (5°C, -20°C and -80°C). Our forced degradation studies encompass stress testing under acid or alkaline conditions, oxidative stress testing, and photostability studies. Based on the innovator's specific needs, we can develop and tailor stability studies as well as forced degradation tests at any stage of the drug development.

ICH Conditions

- 25°C / 60% r. H.
- 30°C / 65% r. H.
- 30°C / 75% r. H.
- 40°C / 75% r. H.
- 5°C
- - 20°C
- - 80°C

ICH Stability Studies

- Long-term
- Short-term
- Intermediate
- Accelerated
- Follow-up
- Customized studies

Forced Degradation Studies and Stress Tests

- Acid
- Base
- Oxidation
- Heat
- Photostability
- Heat and humidity
- Customized studies
- Stability indicating method

To ensure sample and data integrity, the chamber conditions are monitored 24 hours a day, seven days a week. Stability data acquisition, evaluation and monitoring are tracked via computer-based systems compliant with the latest FDA standards (21CFR Part 11). Additionally, our Laboratory Information Management System (LIMS) ensures all requested tests are performed on time and allow our customers direct, real-time access to important samples' and analytical information with the highest level of access security.

The degradation products deriving from stress studies can be isolated and fully characterized by means of our extensive in-house analytical tools. Our integrated analytical services for drug substances and products are designed to flexibly support our customers' requirements. We offer support in method development and validation, solid state characterization, crystallization development, and pre-formulation studies with the aim to accelerate registrations for new drug products and substances and to enhance time to market.

Integrated Services from a Single Source

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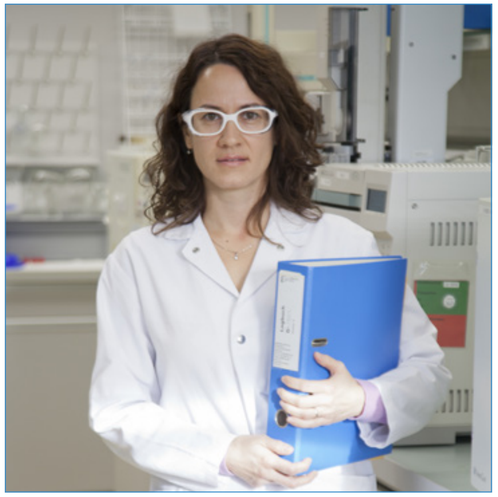


"Stability studies are part of a large number of different projects; the possibility of performing analytical work with different molecules and the discovery of their features is a very interesting part of my work."

Katja - Chemist QC&A

Pre-Formulation Services

- Physical-chemical characterization of APIs
  - H, PB and MP
  - Density and tapped density
  - Appearance and color
  - determination
- Feasibility and pilot studies
  - Dispensing
  - Microdosing
  - Particle size distribution
- Model system for bioavailability studies
  - Dissolution testing
  - Disintegration testing
  - Solubility testing
- Moisture analysis
  - Karl Fischer titration
  - Moisture sorption (DVS)
  - Water activity

Characterization Services

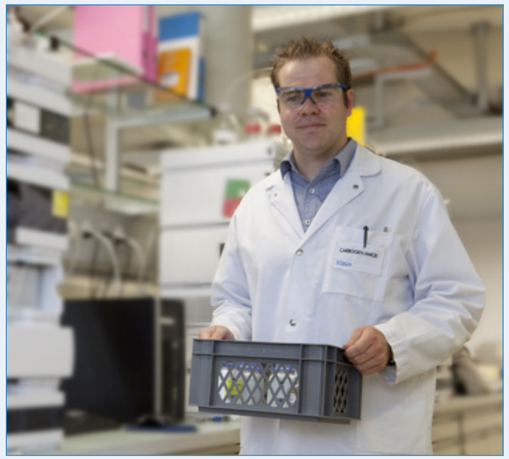
- Complete characterization
  - NMR and X-Ray analysis
  - FTIR, UV, GC/MS analysis
  - Elemental analysis
  - Loss on drying
- Impurity profiling and tracking
  - Heavy metals analysis
  - Residual solvent
  - Limit tests for genotoxic impurities
- Determination of degradation pathways
  - Mechanism
  - Order of reaction
  - Kinetic of formation
  - TGA and DSC analysis

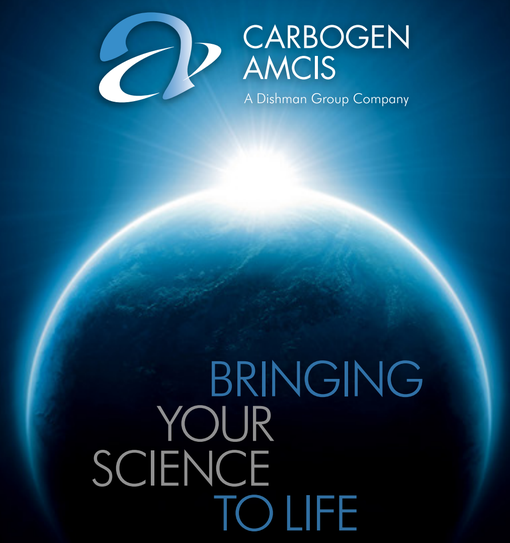
cGMP & Analytical Services

- Specification development
- Method development and validation
  - TLC-UV and FTIR
  - TUPLC and HPLC
  - TGC, GC-MS and CE
  - TKarl Fisher titration
  - TTGA and DSC
- Protocol and report writing
- Packing investigations
  - TContainer closure integrity
- High quality documentation

Solid State & Crystallization Services

- Determination of stereochemical stability
- Polymorphism
  - XPRD analysis
- Crystal forms
- Salt screening
- Structure elucidation
  - TNMR, X-Ray analysis





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